FEASIBILITY OF AN INTERVENTION FOR DEFIBRILLATOR CANDIDATES

A FEASIBILITY STUDY OF A PRE-IMPLANTATION NURSE-LED EDUCATIONAL INTERVENTION FOR PRIMARY PREVENTION IMPLANTABLE CARDIOVERTER DEFIBRILLATOR CANDIDATES

By:

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TITLE: A Feasibility Study of a Pre-implantation Nurse-Led Educational Intervention for Primary Prevention Implantable Cardioverter Defibrillator Candidates

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Lay Abstract

An ICD is a medical device placed under the skin that can fix a dangerous heart rhythm. It can do so by shocking the patient's heart if the ICD senses a dangerous heart rhythm. This study was done to determine if it is practical to deliver education to patients before they receive their ICD. Some patients feel they do not receive enough information before getting an ICD. No studies have tested how education before receiving an ICD can impact a patient's quality of life. In this study, ten people received usual care while ten people received usual care and ICD education from a nurse before ICD implantation. The results of this study determined that it was practical for nurses to deliver ICD teaching before the ICD was implanted. A future study testing the impact of education on the quality of life of ICD patients can and should be completed.

Abstract

Background: Implantable cardioverter defibrillators (ICDs) deliver therapy in the form of an internal shock should a life-threatening arrhythmia occur. Literature suggests that patients have misconceptions regarding ICD therapy and unmet information needs.

Purpose: This study assessed the feasibility of delivering a pre-implantation nurse-led educational intervention to ICD candidates.

Methods: ICD candidates attending an outpatient preoperative clinic were invited to participate. Consented participants were randomized to standard care or standard care plus an educational intervention. The educational intervention addressing information gaps identified in the ICD literature was delivered during the preoperative visit. The primary outcome was feasibility with the following targeted rates, (1) 80% recruitment; (2) ≥ 95% consent; (3) 90% randomization; (4) ≥ 90% completion of questionnaires; (5) 80% of intervention sessions delivered less than 45 minutes; and (6) 90% of intervention content delivered. At baseline, demographic data and Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety scores were collected. Four weeks post-ICD implantation, participants completed the PROMIS anxiety measure, Florida Patient Acceptance Survey (FPAS), and Florida Shock Anxiety Scale (FSAS).

Results: Twenty patients consented to the study (10 standard care/10 standard care plus the educational intervention). Feasibility outcomes achieved were, (1) recruitment rate of 80%; (2) consent rate of 87%; (3) 100% randomization; (4) 80% completion of questionnaires; (5) 100% of intervention sessions completed in less than 45 minutes; and (6) intervention checklist completion rate of 100%. The four-week mean (SD) FPAS scores were 80.0 (13.4) in the intervention group compared to 77.0 (16.5) in standard care. Mean (SE) four-week PROMIS

scores were 45.4 (6.4) in the intervention group and 43.7 (8.6) in standard care. Mean FSAS (SD) scores were 14.7 (4.6) in the intervention group and 13.3 (3.9) in standard care.

Conclusion: The results demonstrated feasibility of delivering a pre-implantation nurse-led educational intervention in an outpatient clinic setting to ICD candidates. Further studies to evaluate the effectiveness of the intervention on patient-reported outcomes are warranted.

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Table of Contents

List of Tables and Figures

Acronyms

AHA	American Heart Association
CCS	Canadian Cardiovascular Society
CONSORT	Consolidated Standard of Reporting Trials
D-HRQL	device-specific health-related quality of life
ESC	European Society of Cardiology
FPAS	Florida Patient Acceptance Survey
FSAS	Florida Shock Anxiety Scale
HiREB	Hamilton Integrated Research Ethics Board
HRQL	health-related quality of life
ICD	implantable cardioverter defibrillator
PROMIS	Patient-Reported Outcomes Measurement Information System
SCD	sudden cardiac death
SD	standard deviation
SE	standard error
SF-36	36-Item Short Form Survey

Chapter I: Introduction and Background

Sudden Cardiac Death

Sudden cardiac death (SCD) is defined as a sudden and unexpected death related to cardiac causes. SCD may occur when there is underlying cardiovascular disease that is ischemic or non-ischemic in nature, with causes ranging from inherited genetic conditions to arrhythmias, heart failure, and valve disease (Camm, Gersh, & Katritsis, 2016). The most common causes of SCD are life-threatening ventricular arrhythmias, such as ventricular fibrillation and ventricular tachycardia (Camm et al., 2016). Ventricular arrhythmias may occur when coronary arterial blockages disrupt blood flow to the heart, thus damaging the myocardium and disturbing electrical conductivity within the heart. Reportedly, 10% or less of individuals experiencing a cardiac arrest occurring outside a hospital setting survive as an individual can die within minutes without treatment (Heart & Stroke, 2018). SCD is an ongoing concern as it is associated with 40,000 annual deaths in Canada (Cardiac Arrhythmia Network of Canada, n.d.).

Treatment options are available to reduce the risk of SCD; one such treatment is medical therapy. Medical therapy involves treating patients with medications in an effort to manage risk factors that predispose patients to SCD (Russo et al., 2013). Where medical therapy may be inadequate, another treatment option to reduce the risk of SCD is an implantable cardioverter defibrillator (ICD).

ICD Functionality and Trajectory

An ICD is a battery-operated medical device surgically implanted into the chest wall that is offered to suitable patients to reduce the risk of SCD. ICDs may be offered for two clinical indications: primary prevention, for individuals who are determined to be at high risk for developing a life-threatening arrhythmia but have not yet experienced an episode, and secondary

prevention, for individuals who have already experienced an episode of a sustained, life-threatening arrhythmia (Bennett et al., 2017). ICDs have been shown to significantly decrease mortality for primary and secondary indications in adults with chronic ischemic cardiomyopathy (myocardial infarction), as demonstrated in large-scale randomized controlled trials (Bardy et al., 2005; Bennett et al., 2017; Buxton et al., 1999; Moss et al., 2002).

In 1980, the first ICD was implanted at John Hopkins Hospital in Baltimore, Maryland (Rajabali & Heist, 2014). Since then, the implantation of ICDs has steadily increased worldwide. In 2005/2006, a total of 1,805 ICDs were implanted in Ontario, Canada, across eight specialized cardiac centres. This number grew to 2,203 across 12 centres by 2015/2016. A continued upward trend in ICD implantation is expected in light of the projected increase in the incidence of arrhythmia in Canada (Cardiac Arrhythmia Network of Canada, n.d.).

An ICD is composed of a pulse generator and one to three electrical lead(s). The pulse generator is implanted inferior to the clavicle, subcutaneously, and the electrical leads are placed transvenously into the right atrium, right ventricle, and/or left ventricle (Braunschweig et al., 2010; Rajabali & Heist, 2014; Whited, Sears, Cahill, & Chelu, 2016). The ICD is designed to sense an abnormal heart rhythm through the leads and is capable of terminating such rhythm through either anti-tachycardia pacing or delivery of a shock. Both anti-tachycardia pacing and shock therapy functions are programmed by specialized arrhythmia health professionals (nurses, physicians) using specific rate, detection, and treatment parameters (Braunschweig et al., 2010; Rajabali & Heist, 2014). Anti-tachycardia pacing consists of pacing the heart at a rate higher than detected in an attempt to revert the heart back to normal sinus rhythm, whereas shock therapy involves delivering an internal shock to the heart to correct the life-threatening arrhythmia.

The classification of ICD shock therapy falls into four classes: appropriate shocks, unnecessary shocks, inappropriate shocks, and phantom shocks (Braunschweig et al., 2010). Appropriate shocks are delivered when the ICD senses a life-threatening arrhythmia, whereas unnecessary and inappropriate shocks are classified as shocks delivered during non–life-threatening arrhythmias. Phantom shocks occur when patients report experiencing a shock that cannot be confirmed during device interrogation (Braunschweig et al., 2010). Shocks can be a distressing and upsetting experience for patients and may cause anxiety and subsequently impact quality of life (Ford, Cutitta, Woodrow, Kirian, & Sears, 2011; Ford et al., 2012). As such, supporting patients' mental well-being by preparing them for the potential of shocks and how to respond after experiencing a shock is a priority.

Clinical Practice Guidelines for ICD Implantation

Clinical practice guidelines developed by the Canadian Cardiovascular Society (CCS), American Heart Association (AHA), and the European Society of Cardiology (ESC) guide health professionals in ICD care delivery (Bennett et al., 2017; Priori et al., 2015; Russo et al., 2013). All three practice guidelines evaluate and synthesize evidence to develop recommendations for determining appropriate ICD candidacy. For example, all three guidelines recommend an ICD for primary prevention in those with persistent left ventricular dysfunction due to ischemic or non-ischemic disease. An individual with this underlying disease would be considered for an ICD after three months of optimal medical therapy and at least 40 days following a myocardial infarction (Bennett et al., 2017; Priori et al., 2015; Russo et al., 2013).

Among all the guidelines, there is a consensus on clinical indications to determine eligibility for an ICD, with detailed information outlining specific criteria but paying no attention to psychosocial outcomes, with the exception of the ESC guidelines (Bennett et al., 2017; Priori

et al., 2015; Russo et al., 2013). The ESC guidelines acknowledge the potential for negative psychosocial impact of ICD therapy on a patient's health-related quality of life (HRQL) (Priori et al., 2015). The guidelines recommend that health professionals discuss HRQL issues pre-implantation and throughout the ICD care trajectory (Priori et al., 2015). The need for an assessment of mental well-being and treatment of psychological distress in patients who have experienced repeated inappropriate shocks is also discussed (Priori et al., 2015). These recommendations are supported by evidence suggesting that a portion of ICD recipients experience psychological distress in the form of anxiety, post-traumatic stress disorder, and depression, which can impact quality of life (Dunbar et al., 2012; Manzoni et al., 2015; Ooi, He, Dong, & Wang, 2016; Rahmawati et al., 2016).

The absence of evidence addressing psychosocial outcomes post-ICD implantation in the AHA and CCS guidelines suggests a gap in recommendations for ICD clinical care (Dunbar et al., 2012). Health professionals in Canada and the United States may turn to ESC guidelines to access evidence regarding psychosocial recommendations; however, some health professionals may have difficulty accessing ICD practice guidelines (Al-Khatib, 2011; Rajabali & Heist, 2014). This absence of evidence related to the psychosocial impact/outcomes of ICDs in patients in the CCS and AHA guidelines may present as a barrier for health professionals seeking to access up-to-date recommendations to guide psychosocial care of ICD patients.

Problem Statement

Living with an ICD can be challenging for some patients. Some may struggle with the lifestyle changes associated with living with the ICD, psychological distress, loss of independence, and misunderstanding about the functionality and purpose of the ICD (Burns, Serber, Keim, & Sears, 2005; Ford et al., 2011; Groarke et al., 2012; Ooi et al., 2016). Although

the majority of patients adjust to living with the ICD, patients experiencing difficulty coping following ICD implantation may experience worsening HRQL and feelings of anxiety (Carroll, McGillion, & Arthur, 2014; Dunbar et al., 2012; Ford et al., 2011; Kamphuis et al., 2004; Ooi et al., 2016). Adjustment to living with an ICD may be lifelong; as such, further work examining ways to minimize psychosocial distress is warranted (Sears, Matchett, & Conti, 2009; Udlis, 2013).

ICD candidates must be well informed of ICD therapy, the purpose of the ICD, lifestyle changes, and relevant limitations. Conversations between health professionals and ICD candidates should involve provision of adequate education regarding ICD therapy, and there is evidence to suggest that these discussions may be inadequate, inconsistent, and incomplete, ultimately leading to patient dissatisfaction and misunderstanding of important information (Groarke et al., 2012; Hoogwegt, Widdershoven, Theuns, & Pedersen, 2014; Kuhl, Sears, Vazquez, & Conti, 2009; Ooi et al., 2016; Pedersen, Knudsen, Dilling, Sandgaard, & Johansen, 2017). These information disparities may be a result of time constraints during follow-up appointments, the limited capacity of health professionals to individualize ICD patient care, and health professionals' focus on the technical aspects of ICD therapy (Bolse, Johansson, & Stromberg, 2011; Hauptman, Chibnall, Guild, & Armbrecht, 2013; Hoogwegt et al., 2014; Ooi et al., 2016; Sears et al., 2009). Specific educational disparities experienced by the patient are reported to include (1) lack of awareness of the clinical indication for the ICD; (2) poor knowledge of the functions of the ICD; and (3) misunderstandings about and unrealistic expectations of ICD therapy (Groarke et al., 2012; Ooi et al., 2016).

It is imperative for health professionals to address these educational gaps and clarify false beliefs or misinterpretation of ICD therapy information and the associated limitations imposed

by the ICD (Humphreys, Lowe, Rance, & Bennett, 2016). Evidence suggests that incomplete device information regarding ICD function, shock expectations, and related psychological consequences impacts device-specific health-related quality of life (D-HRQL) and anxiety (Hoogwegt et al., 2014; Kuhl et al., 2009; Ooi et al., 2016). Routine pre-implantation discussions between ICD candidates and health professionals are pivotal in guiding a patient's ability to adjust to living with an ICD and should address the potential for negative psychosocial experiences, but this has often been overlooked, perhaps because of health professionals' lack of comfort with discussing such concerns with patients (Bolse et al., 2011; Hauptman et al., 2013; Ooi et al., 2016; Pedersen et al., 2017; Sears et al., 2000, 2009). To address the inadequate information relayed during conversations with health professionals, there may be an opportunity pre-implantation for nurses to deliver education to ICD candidates.

This opportunity to support ICD patients pre-implantation is through prevention or mitigation of negative psychosocial responses, such as anxiety, and the negative impact on HRQL. This may be accomplished with the provision of comprehensive education on addressing information needs and patient concerns identified in the literature (Dougherty, Benoliel, & Bellin, 2000; Morken et al., 2012; Ooi et al., 2016). The scope of practice of nurses in Ontario creates an opportunity for registered nurses to provide comprehensive education to ICD patients (Registered Nurses' Association of Ontario, 2012). Registered nurses are competent in supporting diverse patient learning needs through building a therapeutic relationship with their patients that respects patient knowledge and experience (College of Nurses of Ontario, 2006; Registered Nurses' Association of Ontario, 2012). Nurses are attentive to psychosocial concerns and the emotional well-being of ICD patients (Sears et al., 2000) and are considered to be a valued resource for ICD education and psychosocial support (Bolse et al., 2011). As such, the

focus on meeting the unique needs of ICD patients makes nurses the prime health professionals to deliver education (Wong, 2017).

By delivering a pre-implantation education intervention designed to enhance patients' knowledge of ICD therapy and minimize misinterpretation of information, a sense of control and confidence about the ICD is reinforced within patients as they prepare for adjustments required post-implantation (Braunschweig et al., 2010). Where there is research focusing on the potential benefits of post-implantation education, there is a lack of research focusing on exploring the benefits of pre-implantation education of ICD patients. Multiple psychosocial interventions have been tested among ICD patients; however, the majority of psychosocial interventions studied were delivered post-implantation (Dunbar et al., 2012) and only two studies examining education-only interventions exist (Cinar, Tosun, & Kose, 2013; Edelman, Lemon, & Kirkness, 2007). As such, little is known about the potential benefits of an education-only intervention delivered to ICD patients and whether delivering this pre-implantation would be feasible. This study explored the feasibility of a nurse-led educational intervention delivered pre-implantation in an outpatient arrhythmia clinic setting.

Need for a Feasibility Study

The purpose of conducting a feasibility study is to identify potential issues for a larger-scale study and to maximize the success of completing the larger study (Thabane et al., 2016). The rationale for conducting the present feasibility study is to determine whether it can work, which, in the context of this study, meant focusing on whether delivering the educational intervention is feasible in an outpatient clinic setting and determining if and how to proceed with a larger-scale study (Orsmond & Cohn, 2015; Thabane et al., 2016). This feasibility study was conducted to assess the outcomes of the process of recruitment, consent rate, randomization,

completion of questionnaires, and delivery of intervention to ultimately determine if the ICD education can be delivered pre-implantation in the outpatient arrhythmia clinic setting (Orsmond & Cohn, 2015; Thabane et al., 2010). Considering the current lack of studies evaluating pre-implantation nurse-led educational interventions, it would be reasonable to conduct a preliminary study to assess potential study process issues that should be corrected if a large-scale study is recommended.

Chapter II: Review of the ICD Literature

This chapter provides a review of the selected literature, including an overview of the search method as well as the definitions and instrumentations to measure selected outcomes, including D-HRQL, anxiety, and shock anxiety. In addition, content related to the role of health professionals within ICD education provision and the rationale for the educational intervention designed for this feasibility study is discussed.

Search Method

To glean an understanding of D-HRQL, anxiety, and shock anxiety within the context of ICD patients, the provision of ICD patient education, and interventions studied to support ICD patients, a search across the ICD literature was undertaken, using the databases OVID Medline Epub Ahead of Print (1946 to 2017), Embase (1974 to 2017), PsycINFO (1806 to 2017), and CINAHL (1981 to 2017). A health sciences librarian was consulted to refine the search process and ensure that relevant evidence was obtained. Reference lists of articles were hand-searched to retrieve additional studies. Variations of the following search terms were included: “implantable cardioverter defibrillator,” “quality of life,” “attitude to health,” “attitude to illness,” “attitude to life,” “social support,” “health behavior,” “health belief,” “health status,” “stress,” “mental stress,” “florida patient acceptance survey,” “florida anxiety scale,” “device,” “education,” “health education,” “cope, “belief,” “activities of daily living,” “psychosocial factors,” “learning needs,” “computer assisted instruction,” “patient perspective,” “online teaching,” “therapy/treatment/intervention,” “personal experience,” “ health knowledge,” “medical information,” “support,” “patient preference,” “psychological adjustment,” “adaptive behavior,” “patient acceptance,” “information literacy,” “information seeking,” “patient satisfaction,”

"patient preference," "patient reported outcome," and "disease specific quality of life." Searches were limited to being published in English and adult (18 years of age and older).

Using EndNote© software, all abstracts and titles were reviewed, and studies not examining ICD patients were discarded. Then the full text of studies was reviewed to determine their relevance. Studies were deemed relevant for inclusion in the following limited review of the literature if (a) the population included adult ICD patients (over 18 years of age) and (b) the study was published in English. Additionally studies were included if any of the following criteria was reported upon: (i) outcomes of anxiety, shock anxiety, and/or D-HRQL; (ii) health professional or patient experiences; (iii) patient education; and/or (iv) intervention.

Psychosocial Factors Affecting ICD Patients

Concept of D-HRQL in ICD Patients

Generic HRQL and D-HRQL outcomes have been explored in the ICD literature. Generic HRQL is a multidimensional concept that spans the domains of physical, mental, and emotional health and social functioning (Centers for Disease Control and Prevention, 2016). A device-specific construct of HRQL in ICD patients exists where patient acceptance or device acceptance is measured as D-HRQL (Burns et al., 2005). The term *patient acceptance* is defined as "the psychological accommodation and understanding of the advantages and disadvantages of the device, the recommendation of the device to others, and the derivation of the benefit in terms of biomedical, psychological, and social functioning" (Burns et al., 2005, p. 385). The ideal instrument to measure D-HRQL must be sensitive in capturing device-specific concerns not explained by underlying cardiovascular disease (Burns et al., 2005).

D-HRQL evidence. Measuring D-HRQL is valuable as it contributes to our understanding of the experience of living with an ICD. For instance, a cross-sectional study

explored D-HRQL in ICD recipients (N = 101) and its association with their attitude toward technology dependence (Udlis, 2013). The study suggested that a patient's attitude toward ICD technology dependence is a significant predictor of D-HRQL. A positive attitude predicted higher D-HRQL, translating to better device acceptance when compared to ICD recipients with a negative or neutral attitude (Udlis, 2013). It is also important to comprehend how ICD patients develop attitudes toward their ICD as these attitudes impact D-HRQL. Humphreys et al. (2016) interviewed 18 ICD patients and their partners in a qualitative study and identified a theme, "coping with the ICD," explaining how patients described device acceptance. One view patients shared was "resigned acceptance": accepting the device due to no other option. The second view was "grateful acceptance": accepting the device as a positive, life-saving therapy. Patients experiencing grateful acceptance held a positive outlook, which may allow for better coping.

Although Humphreys et al. (2016) and Udlis (2013) reported novel findings; there was potential recruitment bias as some patients who may have been overly distressed may not have participated, leading to an underrepresentation of those severely negatively affected by the ICD. Moreover, 37% of the mailed questionnaires in the study by Udlis (2013) were not responded to, and this bias can affect the representativeness of the participants included in the study. In addition, the predominantly older and male sample in Udlis's (2013) study limits its generalizability, whereas the diversity in gender, age, cardiac condition, and ICD indication (primary or secondary) in the Humphreys et al. (2016) study allows for greater generalizability. A limited number of participants who had experienced shock therapy were included meaning their viewpoints were not fully considered (Humphreys et al., 2016). Finally, the cross-sectional design limited the ability to determine a temporal relationship (Udlis, 2013). Nevertheless, the findings are informative in understanding patients' perspectives on their ICDs.

In summary, D-HRQL is an important outcome to examine as it captures how patients' attitudes impact their acceptance of living with an ICD. A patient's attitude may be amenable to a nurse-led educational intervention as providing information could dispel the negative misconceptions of ICD therapy that contribute to a negative attitude. In turn, this could support a positive attitude or grateful acceptance in patients, which may positively impact D-HRQL (Sears, Vazquez, Matchett, & Pitzalis, 2008). The goal of delivering an ICD educational intervention pre-implantation is to impact patient-reported outcomes, including facilitating greater D-HRQL (Ooi et al., 2016).

Rationale for selecting D-HRQL. Measuring D-HRQL is important as ICD patients with higher D-HRQL are more likely to have greater quality of life (Ford et al., 2011) and less anxiety (Bedair et al., 2015) than patients with lower D-HRQL. As such, it is important to focus on improving D-HRQL in ICD patients. The measurement of D-HRQL in the ICD literature is less frequent compared to generic HRQL, as illustrated by two systematic reviews that examined quality of life in ICD patients (Manzoni et al., 2015; Tomzik, Koltermann, Zabel, Willich, & Reinhold, 2015). Across all 67 studies included in both reviews, only four studies measured D-HRQL, whereas the remainder employed generic HRQL tools. Comparatively, generic HRQL instruments cannot capture the device-specific experience of ICD recipients as they neglect to consider the impact of device-specific concerns (Pedersen, Theuns, Muskens-Heemskerk, Erdman, & Jordaens, 2007; Sears & Kirian, 2010; Whited, Sears, Cahill, & Chelu, 2016).

Both reviews concluded that the impact of ICD therapy or shocks on patient-reported outcomes, including HRQL, is inconclusive due to the methodological heterogeneity of the studies (Manzoni et al., 2015; Tomzik et al., 2015). One way to promote consistency within the ICD literature is to use the same instrument to measure the same ICD-specific outcome. For

instance, if D-HRQL is measured, only one validated instrument is available that measures D-HRQL in ICD patients. Using the same instrument to measure D-HRQL across studies could reduce methodological heterogeneity and allow for conclusive meta-analysis. The limited exploration of D-HRQL compared to generic HRQL within the ICD literature suggests that additional studies are needed to explore D-HRQL given the potential impact of D-HRQL on patients' experiences of living with an ICD (Carroll, Markle-Reid, Ciliska, Connolly, & Arthur, 2012; Groeneveld, Matta, Suh, Yang, & Shea, 2007; Hallas, Burke, White, & Connelly, 2010; Kuhl et al., 2009; Morken, Norekval, Bru, Larsen, & Karlsen, 2014; Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Versteeg et al., 2012; Wilson, Engelke, Sears, Swanson, & Neil, 2013).

Measurement of D-HRQL. Currently, four instruments which measure psychological acceptance in patients of their cardiovascular devices have been described in the literature: (1) An unnamed questionnaire designed to measure patient acceptance of the ICD (Lüderitz, Jung, Deister, Marneros, & Manz, 1993); (2) the Aquarel Questionnaire (Stofmeel, Post, Kelder, Grobbee, & van Hemel, 2001); (3) the Implanted Device Adjustment Scale (IDAS) (Beery, Baas, & Henthorn, 2007); and (4) the FPAS (Burns et al., 2005).

The unnamed questionnaire (Lüderitz et al., 1993) was the first to consider the psychological aspects of ICD therapy; however, the questionnaire lacks psychometric validity and reliability testing. The Aquarel Questionnaire was designed to be used in conjunction with the 36-Item Short Form Health Survey (SF-36) specifically for pacemaker patients, and as such is irrelevant to the ICD population under study (Stofmeel et al., 2001). The IDAS has been tested in both pacemaker and ICD patients; however, it measures the concept of adjustment to the implanted device rather than D-HRQL (Beery et al., 2007; Dunbar et al., 2012), as sought in this

study. The measurement of D-HRQL using the Florida Patient Acceptance Survey (FPAS) accounts for the unique psychosocial issues not measured using generic quality of life instruments. The FPAS is psychometrically valid and internally consistent (Versteeg et al., 2012) and has been used in numerous studies within the ICD literature as it is designed to capture cardiac psychology, specifically of ICD patients (Burns et al., 2005; Dornelas, 2012). As such, additional research of D-HRQL is warranted to determine how ICD recipients accommodate their device psychosocially. The FPAS will be used after ICD implantation to measure D-HRQL as its items relate to living with an ICD and can be completed by patients only after implantation.

Concept of Anxiety in ICD Patients

Anxiety is the most prevalent patient-reported outcome studied in the ICD literature (Manzoni et al., 2015; Ooi et al., 2016; Rahmawati et al., 2016) and the most experienced psychological symptom in ICD patients (Dunbar et al., 2012), measured predominantly by using self-report questionnaires (Magyar-Russell et al., 2011; Manzoni et al., 2015). Anxiety can be experienced as symptoms of excessive worrying, irritability, difficulty concentrating, and restlessness (Locke, Kirst, & Shultz, 2015). Patients with chronic cardiovascular disease can experience anxiety, making it difficult to delineate between cardiac and psychological illness (Easton, Coventry, Lovell, Carter, & Deaton, 2016; Magyar-Russell et al., 2011; Olafiranye, Jean-Louis, Zizi, Nunes, & Vincent, 2011; Sears et al., 2008). This means that for patients with an ICD, the potential for exacerbated anxiety is present as they have cardiovascular disease and the additional stress of living with an ICD. Anxiety as a negative emotional response is unfavourable because ICD patients who experience anxiety are proposed to be four times more likely to die (Kikkenborg Berg, Caspar Thygesen, Hastrup Svendsen, Vinggaard Christensen, &

Zwisler, 2014). Examining anxiety in ICD patients is important to understand how the device may impact a patient's well-being.

Evidence of anxiety in ICD patients. Symptoms of anxiety are commonly experienced in ICD patients and are prevalent up to 12 months post-implantation (Dunbar et al., 2012; Magyar-Russell et al., 2011). Anywhere from 27% to 63% of ICD patients experience symptoms of anxiety prior to implantation, and 13% to 59% of ICD patients are reported to experience anxiety symptoms at some point after ICD implantation (Magyar-Russell et al., 2011; Versteeg et al., 2012). Few studies compared anxiety pre-implantation to anxiety post-implantation (Manzoni et al., 2015; Rahmawati et al., 2016; Thylen et al., 2014; Versteeg et al., 2017). This makes it difficult to determine if the ICD caused the development of anxiety or if the anxiety was pre-existing. If relationships between ICD indication and anxiety are being explored, then, once again, establishing the baseline prior to ICD implantation is important (Manzoni et al., 2015).

Moreover, a statistically significantly higher proportion of ICD patients ($p < 0.001$) who reported symptoms of anxiety post-implantation had experienced ICD shock therapy compared to ICD patients with no anxiety symptoms (Thylen, Dekker, Jaarsma, Stromberg, & Moser, 2014) and have high levels of ICD-related concerns when compared to ICD patients with no feelings of anxiety (Thylen et al., 2014). Anxiety has also been demonstrated to be statistically significantly higher in primary prevention ICD patients compared to secondary prevention patients (Rahmawati et al., 2016).

Furthermore, a systematic review of 43 studies examined the prevalence of anxiety pre- and post-implantation in adult ICD patients. However, among the included studies, only seven studies examined anxiety prior to ICD implantation, and of these, only two were conducted in North American populations (Magyar-Russell et al., 2011). The review concluded that the wide

range of anxiety prevalence could be a result of small sample sizes, the use of various instruments, and the study design.

Those who were perhaps more anxious may not have returned mailed questionnaires, resulting in underreporting of anxiety, which is demonstrated by the 50% response rate (Thylen et al., 2014). However, other studies reported a higher response rate of 95% (Versteeg et al., 2017). The participants were male dominated with 79.1% to 81% of the sample being male (Rahmawati et al., 2016; Thylen et al., 2014; Versteeg et al., 2017). One study accessed a national electronic registry for recruitment, increasing its generalizability (Thylen et al., 2014). Patients included in the studies were Swedish, and Japanese, which may reduce generalizability to a North American context (Rahmawati et al., 2016; Thylen et al., 2014). A limitation of the systematic review is the exclusion of a risk of bias assessment that evaluates the quality of the study methodology (Magyar-Russell et al., 2011).

In summary, anxiety has documented prevalence in the adult ICD patient population with a negative impact on patient well-being. This presence, combined with the limited evaluation of anxiety pre-implantation, warrants further data collection on anxiety prior to ICD implantation. These findings may contribute to an understanding of how anxiety is impacted by an ICD and demonstrate that a comparison of pre- and post-implantation anxiety scores after an intervention is merited.

Rationale for selecting anxiety. The importance of measuring anxiety in this study is due to its negative impact on health status and noted prevalence in the ICD population (Hoogwegt et al., 2012; Lang et al., 2014; Magyar-Russell et al., 2011). Despite documented anxiety post-implantation in ICD patients, it remains undertreated (Hoogwegt et al., 2012; Lang et al., 2014). Moreover, anxiety measured post-implantation has also been associated with D-

HRQL, where higher anxiety is statistically significantly associated with poorer D-HRQL post-implantation (Bedair et al., 2015; Burns et al., 2005; Versteeg et al., 2012).

Although studies conclude varying prevalence of anxiety in ICD patients, it exists, and evidence suggests that a proportion of ICD patients experience anxiety to some degree, in a range twice as high compared to patients with general cardiovascular and chronic medical conditions (Dunbar et al., 2012; Magyar-Russell et al., 2011; Qintar et al., 2015; Thylen et al., 2014). As such, designing an intervention to reduce anxiety within the ICD population is important as it can potentially improve D-HRQL, leading to improvements in ICD patients' post-implantation adjustment to living with an ICD.

Measurement of anxiety. Anxiety has been measured using multiple instruments within the ICD literature, including the Hospital Anxiety and Depression Scale, the Depression Anxiety Stress Scales, and the State-Trait Anxiety Inventory (Dunbar et al., 2012; Magyar-Russell et al., 2011). The Hospital Anxiety and Depression Scale and the Depression Anxiety Stress Scales measure depression, which was not an outcome examined in this study. Also, other studies have used varying cut-off criteria in ICD populations for the same instruments to determine if a patient is anxious. This translates to multiple studies using the same instrument to measure anxiety; however, with different cut-off criteria, the studies will have varying prevalence rates, making it difficult to compare and meta-analyze the findings (Magyar-Russell et al., 2011). For example, studies using the Hospital Anxiety and Depression Scale have been documented to use either 11 points (Fitchet et al., 2003; Kim et al., 2009; Lache, Meyer, & Herrmann-Lingen, 2007) or 8 points (Fritzsche et al., 2007; Kapa et al., 2010) as a cut-off for identifying anxiety.

To promote comparability between studies that examine anxiety, this study used the Patient-Reported Outcomes Measurement Information System (PROMIS®) anxiety tool. The

PROMIS tool compares raw scores to a common metric system called the T-score; as a result, there is no cut-off for this instrument in diagnosing anxiety. Rather, the raw score is converted into a standardized T-score with a national average of 50 and standard deviation of 10. This tool has been demonstrated to be able to capture symptoms related to anxiety and was used both pre- and post-implantation (Patient-Reported Outcomes Measurement Information System, 2018).

Concept of Shock Anxiety in ICD Patients

ICD patients experience a unique type of anxiety in the form of shock anxiety (Kuhl, Dixit, Walker, Conti, & Sears, 2006). Shock anxiety is the concern or fear of experiencing a shock from the ICD (Ford et al., 2011; Kuhl et al., 2006). Shocks are unpredictable, and for ICD patients, the mere thought of experiencing a shock can be distressing (Kuhl et al., 2006). Understanding the impact of education on shock anxiety can help specialized arrhythmia nurses plan ICD education accordingly.

Evidence for shock anxiety. A cross-sectional study (N = 167) by Morken et al. (2014) measured shock anxiety and D-HRQL (FPAS) in adult ICD patients attending follow-up visits post-implantation. This study found higher shock anxiety to be statistically significantly ($p < 0.01$) associated with lower D-HRQL, a finding that has been supported by other studies (Udlis, 2013; Wilson et al., 2013). Specifically, higher shock anxiety had a statistically significantly moderate correlation with higher device-related distress ($p < 0.01$) and a statistically significant moderate correlation with lower return to function ($p < 0.01$) on FPAS subscales (Morken et al., 2014). Another cross-sectional study (N = 101) reported that lower shock anxiety (Florida Shock Anxiety Scale [FSAS]) measured post-implantation was a statistically significant predictor of D-HRQL (FPAS) measured post-implantation (Wilson et al., 2013). This suggests that ICD patients

with higher shock anxiety were more distressed about the ICD and had greater difficulty returning to their activities of daily living.

A third retrospective cross-sectional study (N = 167) of adult ICD patients sought to assess the prevalence of shock anxiety in ICD patients post-implantation (Morken et al., 2012). This study reported that 15% of participants had general shock anxiety (defined as those who selected "some of the time" or higher on all FSAS responses), and 44% of participants had a score of 3 out of 5 or higher on at least one of the 10 items on the FSAS (Morken et al., 2012).

Considering a portion of ICD recipients experience shock anxiety, literature has recommended patients should be provided with education on ICD function and a plan of action after receiving shock therapy to reduce shock anxiety in an effort to support them in building a positive attitude toward their ICD (Morken et al., 2012, 2014; Wilson et al., 2013). This recommended information was incorporated within the educational intervention in the present study.

The studies examining shock anxiety within this review have a male predominance in the participants ICD recipients and a single-centre design in the current literature reduces the generalizability of the findings to other genders or care environments (Morken et al., 2014; Wilson et al., 2013). Also, the cross-sectional design of the studies limits the ability to determine causality between shock anxiety and device acceptance (Morken et al., 2014; Wilson et al., 2013). Moreover, a Norwegian ICD patient population in two studies may have different characteristics, impacting the generalizability to a North American context (Morken et al., 2012, 2014). High response rates of 81% (Morken et al., 2012) and 78% (Morken et al., 2014) minimize the non-response bias and translate to greater reliability of the results as representativeness is present. Lastly, self-report measures can introduce recall bias, which can be

difficult to mitigate considering the nature of the instruments available to measure shock anxiety and D-HRQL (Morken et al., 2012, 2014; Wilson et al., 2013). However, these studies reveal an important conclusion: patients with greater shock anxiety are struggling to cope with their device.

In summary, the correlation of D-HRQL and shock anxiety post-implantation reveals that focusing on mitigation of even one of these outcomes could potentially support ICD recipients as they adjust to living with an ICD. For instance, clarifying patient misconceptions regarding shock therapy pre-implantation could prevent manifestation of shock anxiety post-implantation and consequently positively impact D-HRQL. Given that misconceptions can be a result of incomplete patient education, rectifying such inaccuracies is critical in supporting patients' mental well-being (Ooi et al., 2016).

Rationale for selecting shock anxiety. Addressing shock anxiety within ICD patients is important as 38.5% of patients have received at least one shock on average and 19.3% have received five or more shocks at the five-year follow-up (Manzoni et al., 2015). Shock therapy may affect the acute and long-term mental well-being of ICD recipients and their ability to adjust post-implantation (Magyar-Russell et al., 2011). Patients with recent shock experience have also reported statistically significantly higher shock anxiety ($p = 0.002$) than those with no recent arrhythmia (Morken et al., 2012). Even patients who do not experience shock therapy are distressed by the potential of receiving a shock, leading them to engage in behaviours to avoid activities (Lemon, Edelman, & Kirkness, 2004), which reduces their quality of life (Ford et al., 2011). Collectively, the prevalence of shock anxiety and its documented negative impact on D-HRQL and the ability to adjust post-implantation highlight the need to further examine and

determine the potential of providing education on shock therapy management to reduce shock anxiety.

Despite the documented prevalence of shock anxiety in ICD patients, one systematic review and one review of study methods examined anxiety, anxiety related to shock therapy, and the psychological effects of shock therapy. None of the 103 studies collectively reviewed assessed shock anxiety as an outcome (Magyar-Russell et al., 2011; Manzoni et al., 2015). Using generic anxiety instruments may overestimate the anxiety ICD patients experience as they do not account for the impact of the ICD and the severity of their cardiac condition (Sears & Kirian, 2010). Additionally, the measurement of shock anxiety may reveal differences between groups that generic measures lack the sensitivity to expose (Sears & Kirian, 2010).

Shock anxiety is a specific outcome that only ICD patients experience; as such, studying this outcome helps to understand another piece of the complex adjustment ICD patient's experience. However, with limited measurement of shock anxiety within the literature, either alone or in tandem with a generic anxiety instrument, it is difficult to understand the totality of the ICD's impact on a patient's emotional well-being (Sears & Kirian, 2010; Sears et al., 2008). As both anxiety and shock anxiety are prevalent within the ICD patient population and that measurement of both generic and device-specific outcomes is recommended (Sears et al., 2008), the present study measured both general anxiety and shock anxiety

Measurement of shock anxiety in ICD patients. The FSAS measures shock anxiety and an ICD patient's ability to cope and react to a shock (Kuhl et al., 2006). Given that ICD patients are often managing comorbidities, which can contribute to their anxiety, the FSAS differentiates device-specific anxiety from generalized anxiety (Cinar et al., 2013; Dunbar et al., 2012). To our

knowledge, the FSAS is the only validated and reliable tool that measures shock anxiety and was used post-implantation only.

The Role of Health Professionals in Providing ICD-Specific Education

Health professionals, including specialized arrhythmia nurses, are responsible for supporting ICD patients prior to, during, and after ICD implantation. A patient's perception of a health professional's support during these interactions, the content relayed during discussions, and the patient's understanding of the information provided can collectively impact a patient's D-HRQL, anxiety, and shock anxiety. A cross-sectional study by Morken et al. (2014) found that ICD recipients who perceived support from health professionals as non-constructive had a statistically significantly weak correlation with poorer D-HRQL ($p < 0.01$) post-implantation, whereas support perceived by patients as constructive was statistically significantly weakly correlated with better D-HRQL ($p < 0.01$) post-implantation. The study defined perceived constructive support as health professionals explaining a patient's cardiovascular condition and openly listening to the patient's concerns, whereas non-constructive health professional support was the contrary (Morken et al., 2014). Moreover, shock anxiety had a statistically significantly moderate correlation with poorer D-HRQL ($p < 0.01$) (Morken et al., 2014). The study concluded that patients may perceive health professionals' support as non-constructive as a result of a limited provision of ICD patient education (Morken et al., 2014). The above inferences align with those of Hauptman et al. (2013) in a qualitative study that examined the content of physician and ICD patient interactions.

Hauptman et al.'s (2013) study included eight focus groups with ICD patients ($N = 41$) and 12 preoperative standardized patient interviews with cardiologists. Patients with an ICD for primary prevention constituted the focus groups and recalled pre-implantation discussions with

the physician as brief, had a limited focus on the impact of an ICD on HRQL, and had vague acknowledgement of the potential for anxiety or negative emotions. Patients reported pre-implantation conversations were limited in discussing battery/device replacement frequency and procedure, a shock plan, how a shock feels, and the impact of an ICD on extending life. The focus groups findings were supported by the content of 22 videotaped standardized patient interviews with 10 cardiologists. Majority of the interviews revealed discussions containing unexplained medical terminology, minimization of D-HRQL consequences, a lack of discussion of the potential for anxiety, and a lack of a clear explanation of battery/device replacement and inappropriate shock therapy.

The inadequate provision of comprehensive ICD education combined with the minimization of risks associated with an ICD by cardiologists leads to patients misinterpreting information. This misunderstanding may lead to patients avoiding activities they believe affect their ICD functioning. This is referred to as avoidance behaviours, an ICD-specific behaviour explored in a cross-sectional survey of 143 ICD recipients (Lemon et al., 2004). Recipients were mailed a questionnaire requesting responses to specific behaviours or activities they avoided post-implantation. An experienced cardiac nurse indicated whether these avoidance behaviours were medically recommended. The study concluded that the 16 activities avoided by ICD recipients were not medically recommended. This translates to ICD patients needlessly avoiding activities that they previously enjoyed, ultimately negatively impacting their D-HRQL (Lemon et al., 2004; Sears et al., 2008). This patient response could be attributed to anxiety and/or a lack of clear communication by health professionals regarding the limitations following ICD implantation, resulting in a misunderstanding of activity restrictions.

Collectively, all three studies illustrate the gaps in health professional and ICD patient discussions. These discussions are noted to contain inadequate patient education, leading to patients misinterpreting ICD information. Consequently, it is important to address the strengths and limitations of the studies discussed above. First, the cross-sectional design of the studies limits the ability to determine a temporal relationship between outcomes of interest (Lemon et al., 2004; Morken et al., 2014), whereas the qualitative study illuminates detailed content within health professional and patient conversations (Hauptman et al., 2013). Moreover, the potential for biased participant responses exists, where patients are asked to recall content from discussions with health professionals held some time ago (Hauptman et al., 2013; Lemon et al., 2004). Confirmation bias is controlled for with the use of multiple raters and a data abstraction tool when collecting data from the standardized patient interviews (Hauptman et al., 2013).

The generalizability of the conclusions to the ICD patient population is limited for multiple reasons. First, the potential for a response bias demonstrated by the low response rate from Morken et al. (2014) of 78% and from Lemon et al. (2004) of 58% could indicate potential underrepresentation of those severely distressed. Second, the majority of participants were male (Morken et al., 2014), with equal representation of both genders only in the Lemon et al. (2004) study. Finally, exclusion of secondary prevention ICD patients (Hauptman et al., 2013) and data collection from single centres (Lemon et al., 2004; Morken et al., 2014) further limited the generalizability. Nevertheless, the studies have a similar line of inquiry, with findings that support each other.

In summary, the evidence reinforces the need to address the content of patient education discussions between health professionals and ICD recipients. Focusing on improving communication to reduce patients' misinterpretation of ICD information could subsequently

mitigate the negative psychosocial impact on ICD patients (Hauptman et al., 2013; Lemon et al., 2004; Morken et al., 2014). One way to improve communication is a brief nurse-led educational session which reinforces the delivery of comprehensive ICD patient education to facilitate patient understanding (Lemon et al., 2004; Morken et al., 2014). Furthermore, a designated time pre-implantation for ICD patient education provides patients with an opportunity to clarify concerns and avoid misinterpretation of ICD knowledge and facilitates a clearer understanding of limitations post-implantation, which could impact D-HRQL and anxiety.

ICD Patient Education

Arrhythmia centres in Ontario that perform ICD implantations provide their own ICD patient education booklets to patients. The majority of print ICD manufacturer patient education documents are biased toward favourable outcomes of the ICD, with little focus on negative ICD complications (Strachan et al., 2012)—similar to hospital educational material that lack information regarding emotional well-being (Bolse et al., 2011). The educational content of manufacturer and hospital print material is persuasive and focused on positive benefits, with minimal attention to negative effects, such as inappropriate shocks (Strachan et al., 2012).

Moreover, although patients receive routine ICD patient information, patients report the information may not be comprehensive in covering all patient concerns. ICD patients have described not receiving information regarding the psychological and social consequences of living with an ICD and the psychological support for themselves as their physicians focused on clinical, device-related issues (Hoogwegt et al., 2014; Johansen et al., 2011; Pedersen et al., 2017). The lack of topic coverage is concerning as patients reporting lower satisfaction with information regarding psychological consequences and physical limitations post-implantation is statistically significantly related to increased anxiety (Hoogwegt et al., 2014).

Face-to-face discussions with ICD candidates prior to implantation give health professionals the opportunity to identify distress and respond to patient concerns (Pedersen et al., 2017). Also, some patients learn about ICD function and its associated risks and benefits only after the implantation as pre-implantation education is limited (Hauptman et al., 2013). Thus, health professional conversations clarifying and reinforcing content within written ICD materials are important, especially considering that several studies reported increased ICD knowledge scores to be an independent, statistically significant predictor of D-HRQL ($p = 0.01$) (Kuhl et al., 2009), ($p = 0.001$) (Wilson et al., 2013).

It would be beneficial for the ICD patient population to explore the feasibility of delivering an educational intervention that includes in-depth coverage of medically necessary information as well as closing knowledge gaps in ICD topics identified by patients. This would in turn support ICD patients by facilitating their adjustment to living with an ICD (Hallas et al., 2010; Hauptman et al., 2013; Morken, Severinsson, & Karlsen, 2010). In what follows, the literature specific to ICD educational interventions is reviewed.

Psychosocial Interventions for Patients with ICDs

A number of ICD interventions have examined the impact on psychological outcomes in ICD patients, including anxiety, shock anxiety and D-HRQL (Dunbar et al., 2012; Edelman, Lemon, & Kidman, 2003; Pedersen, van den Broek, & Sears, 2007; Salmoirago-Blotcher & Ockene, 2009). To date, three conceptual reviews (Dunbar et al., 2012; Edelman et al., 2003; Pedersen, van den Broek, et al., 2007) and one systematic review (Salmoirago-Blotcher & Ockene, 2009) have collectively reported on 17 different studies, that have evaluated psychosocial interventions. Of the 17 studies, 14 included a combination of anxiety, shock anxiety, or D-HRQL as outcomes. As well, seven additional studies were published after these

reviews examining psychosocial interventions and the above outcomes (Cinar et al., 2013; Cossette et al., 2017; Habibovic et al., 2017; Kuhl et al., 2009; Qintar et al., 2015; Salmoirago-Blotcher et al., 2013; Toise et al., 2014). The characteristics for the 21 studies are described in Table 1 in Appendix A.

A psychosocial intervention within this literature review is defined as any intervention that was not solely delivering education, whereas; an educational intervention only involved delivering education. The psychosocial interventions included one or a combination of the following: cognitive-behavioural therapy, support groups, stress management, telephone support, ICD-specific education, counselling, mindfulness training, and relaxation techniques. Two studies reported on the provision of pre-implantation education as a component of the intervention (Kohn, Petrucci, Baessler, Soto, & Movsowitz, 2000; Lewin, Coulton, Frizelle, Kaye, & Cox, 2009), whereas the rest of the studies either tested post-implantation interventions or did not specify the timing of delivery of the intervention.

There was some evidence in the literature that cognitive-behavioural therapy and multifactorial interventions were effective in reducing anxiety (Chevalier et al., 2006; Dougherty, Lewis, Thompson, Baer, & Kim, 2004; Dougherty, Thompson, & Lewis, 2005; Dunbar et al., 2009; Fitchet et al., 2003; Frizelle et al., 2004; Kohn et al., 2000; Sears et al., 2007). However, the findings should be viewed with caution given that most studies had small sample sizes that were not powered, sizable loss to follow-up, high refusal of eligible patients to participate, and incomplete explanation of control group treatment. Also, only five of the 21 studies measured ICD specific outcomes of shock anxiety or D-HRQL using the FSAS or FPAS respectively with the remaining studies using generic quality of life or anxiety measures. The majority of studies were pilot studies with no follow-up larger scale study conducted. As such,

given these limitations in the evidence, it is difficult to determine conclusive results regarding the impact of psychosocial interventions. As well, access to psychosocial interventions (such as cognitive behavioral therapy) delivered by a mental health professional within an outpatient arrhythmia care setting is limited, as mental health professionals are not generally practising within arrhythmia clinics (Sears et al., 2009; Sears, Matchett, Vazquez, & Conti, 2011).

The inconclusive evidence suggests that no single intervention meets the complete psychosocial needs of ICD patients. Finally, it is noteworthy that only two studies examined an education only intervention however, neither was delivered pre-ICD implantation. The present study intended to address these gaps in the ICD literature by assessing the feasibility of a nurse-led educational intervention delivered pre-implantation.

Educational Interventions for Patients with ICDs

To better understand the body of evidence examining educational interventions in the ICD literature, the two studies that provided stand-alone education in their intervention were examined. The first was a pilot study that compared ICD patients receiving usual care (n = 9), which involved verbal information from a cardiologist and an ICD manufacturer booklet, versus the treatment group (n = 13), which received a single educational session (Edelman et al., 2007). This pilot study aimed to evaluate an educational intervention delivered two weeks post-implantation and its effect on anxiety, depression, and hostility. The researchers found no significant differences in depression, anxiety, stress, or hostility at baseline or two, four, and six months between participants who received the intervention and those who did not.

A second mixed methods study, in which the quantitative component used a randomized controlled trial design, evaluated an educational follow-up program comparing participants who received an educational program (n = 27) at 2 weeks and 3 months post-implantation to patients

who received standard care (n = 27) (Cinar et al., 2013). Outcome measures included ICD knowledge, anxiety (State-Trait Anxiety Inventory), depression, and quality of life. The study found that knowledge of ICD therapy statistically significantly increased in the educational program group compared to the standard care group and statistically significantly decreased anxiety in the education group, with no difference in anxiety scores between the groups. Thus, delivering a structured educational program post-implantation can improve patients' knowledge of ICD therapy, which has been suggested to have a positive impact on D-HRQL and to decrease anxiety (Kuhl et al., 2009; Morken et al., 2014; Wilson et al., 2013).

Evaluating the methodology of the education only studies revealed incomplete provision of the methods including, method of randomization, allocation concealment and how outcome assessors were blinded to treatment assignment, inclusion criteria, and recruitment strategy, which collectively bring into question the quality of data collected (Edelman et al., 2007). There was also no mention of who delivered the intervention and whether they were blinded (Cinar et al., 2013). Also, the extremely small sample size in both studies does not ensure adequate power, reducing confidence in the findings (Cinar et al., 2013; Edelman et al., 2007). Finally, neither of the two studies measured ICD-specific outcomes such as shock anxiety or D-HRQL, which would speak more to the ICD patient experience (Cinar et al., 2013; Edelman et al., 2007). The studies were conducted in Turkey and Australia respectively limiting generalizability to Canadian ICD recipients.

Summary of Intervention Literature

A paucity of high-quality studies in adult ICD patients evaluating educational interventions makes it difficult to draw accurate conclusions. In addition, the two educational intervention studies (Cinar et al., 2013; Edelman et al., 2007) were delivered post-implantation,

as well as all other psychosocial interventions across the 21 studies (Cinar et al., 2013; Cossette et al., 2017; Dunbar et al., 2012; Lewin et al., 2009; Qintar et al., 2015; Salmoirago-Blotcher et al., 2013; Toise et al., 2014). Two studies delivered education pre-implantation as a component of a multifactorial intervention (Kohn, Petrucci, Baessler, Soto, & Movsowitz, 2000; Lewin, Coulton, Frizelle, Kaye, & Cox, 2009). Moreover, when considering the readiness of health professionals to deliver the demanding interventions evaluated in the literature, health professionals often lack the required time or skills to deliver the interventions (Sears, Jr. & Conti, 2002). As such, further exploration evaluating the feasibility of a pre-implantation educational intervention is warranted.

Pre-implantation Nurse-Led Educational Intervention

The educational intervention designed for this study included patient education on ICD indication and function, a shock plan, the benefits and limitations of an ICD, battery/device replacement, restrictions post-implantation, an identification card, and support. The purpose of providing this education is to prepare patients for lifestyle adjustments that may be needed and to support patients to maintain confidence in returning to life with the ICD. The content of the educational intervention was drawn from multiple resources, including ICD manufacturer websites (Medtronic and Boston Scientific). However, it focused on addressing the information gaps within the literature that patients and health professionals identified as commonly missed or misinterpreted during conversations (Groarke et al., 2012; Hauptman et al., 2013; Hoogwegt et al., 2014; Lemon et al., 2004; Ooi et al., 2016).

Not only is the content of education for ICD patients important, but the delivery is equally as important. Where the content of the educational intervention in the present study is informed by the literature review, the delivery was informed broadly by the principles of adult

learning (Palis & Quiros, 2014). Adult learning principles involve incorporating multiple learning experiences and encouraging self-directed learning which this study captured through the use of an auxiliary website, a demonstration ICD, verbal information, and images (Palis & Quiros, 2014). In addition, the educational intervention was delivered at a time when adult patients were motivated to learn as the reality of living with their new ICD was present (Palis & Quiros, 2014).

Patient education is routinely delivered and reinforced at multiple time points throughout the ICD care trajectory; however, pre-implantation education is important for several reasons. First, patients deserve to receive education regarding all relevant ICD topics to ensure that informed consent is obtained for the implantation. Second, the initial post-implantation period is challenging as patients can experience anxiety and fear while also attempting to recover physically. Anxiety is prevalent pre-implantation as well; however, initiating education earlier in the trajectory could be beneficial in reducing anxiety. A randomized controlled trial (Harkness, Morrow, Smith, Kiczula, & Arthur, 2016) conducted in Canada reported on an intervention involving a discussion with a cardiovascular nurse specialist while adult patients waited for an elective cardiac catheterization procedure. Anxiety was measured using the State-Trait Anxiety Inventory and found participants who received the intervention reported statistically significantly lower anxiety scores ($p = 0.002$) than participants who did not. Although the patients studied are not ICD patients, they have cardiovascular conditions similar to those of ICD patients. As well, the procedure, being elective, aligns with the decision to receive an ICD which is also elective. The study concluded that intervention, including verbal support from a health professional, may help decrease anxiety in patients waiting for elective cardiac catheterization. In relation to the

ICD patient population and the present study, ICD patient education clarifies patient ICD concerns through face-to-face conversations with a health professional (Sears et al., 2008).

Third, the literature suggests that patients report pre-implantation ICD discussions lack complete topic coverage, with limited patient understanding of the information provided (Groarke et al., 2012; Hauptman et al., 2013; Hoogwegt et al., 2014). Given that patients report a lack of understanding of pre-implantation ICD therapy and the limited literature examining pre-implantation education, further exploration of pre-implantation ICD education is warranted. This study provides information on the feasibility of pre-implantation education and reports on preliminary estimates demonstrating the efficacy of the intervention.

Lastly, evidence suggests that the status of pre-implantation mental well-being impacts post-implantation adjustment. For instance, poor pre-implantation mental health contributes to decreased D-HRQL post-implantation (Carroll et al., 2012), and high levels of pre-implantation ICD concerns are statistically significantly associated with two times higher risk of mortality, which is concerning as ICD concerns are an independent determinant of anxiety (Pedersen, Broek, Berg, & Theuns, 2010; Pedersen, van Domburg, Theuns, Jordaens, & Erdman, 2005; Thylen et al., 2014).

In summary, it is important to focus on pre-implantation education to ensure that patients are educated on ICD therapy including topics commonly missed and to clarify any misconceptions or address concerns in an effort to improve D-HRQL and anxiety post-implantation (Udlis, 2013; Wilson et al., 2013).

Summary of Literature Review

This study sought to address the gap in the literature regarding improving pre-implantation education. A pre-implantation nurse-led educational intervention delivered to ICD

candidates could allow new ICD recipients to live with confidence with their ICD by clarifying misconceptions and preparing patients by addressing overlooked ICD topics identified within the literature. The intervention is intended to mitigate general anxiety and shock anxiety to ultimately promote higher D-HRQL.

Chapter III: Methods

Purpose

The aim of this study was to assess whether a pre-implantation educational intervention in an outpatient arrhythmia clinic setting to primary prevention ICD candidates was feasible in relation to recruitment, consent rates, randomization, and delivery of education and, ultimately, to assess the potential for a larger-scale randomized controlled trial.

Research Questions

This study sought to answer the following question: "What is the feasibility of delivering a pre-implantation nurse-led educational intervention plus standard care to primary prevention ICD candidates compared to standard care in an outpatient arrhythmia setting?" The primary outcome was feasibility. A secondary question was "Does a pre-implantation educational intervention impact pre- and post-implantation general anxiety and post-implantation device-specific health-related quality of life and shock anxiety?"

Study Design

The study design employed was a parallel–arm pilot randomized controlled trial. One arm consisted of standard care pre-implantation plus a nurse-led educational intervention; a second arm delivered standard care pre-implantation only. The educational intervention was designed to be delivered during a routine pre-implantation appointment.

Randomization, Allocation Concealment, and Blinding

Participants were randomized using 1:1 block randomization. The random block size sequence was prepared by a biostatistician, with the allocation sequence stored in a locked research office. The randomization sequence used sequentially numbered, sealed opaque envelopes (to ensure allocation concealment), which the nurse opened immediately after

obtaining consent. Considering the nature of the intervention, participants and the nurse providing the intervention could not be blinded to treatment group allocation. In an effort to reduce the impact of performance bias, the ICD clinic nurse providing standard care was blinded to participant allocation.

Setting

This study took place in the outpatient arrhythmia clinic at Hamilton Health Sciences. This hospital is an academic tertiary care centre in Hamilton, Ontario, Canada, that provides cardiovascular care to over 1.4 million people in the Local Health Integrated Network area of Hamilton, Niagara, Haldimand, and Brant (Hamilton Niagara Haldimand Brant Local Health Integration Network, 2014). HHS was selected due to the high volume of arrhythmia patients.

Inclusion and Exclusion Criteria

Inclusion criteria were (1) candidacy for first primary prevention ICD; (2) age $\geq$ 18 years; (3) ICD implantation date confirmed; and (4) ability to provide informed consent. Exclusion criteria were (1) inability to communicate with research staff to complete questionnaires or a telephone interview (i.e., language barrier, vision, cognitive or hearing impairment); (2) previous ICD or pacemaker; and (3) cardiac resynchronization device indication.

Sample Size

In keeping with the design of a feasibility study and the aim of measuring preliminary estimates only, a powered sample size calculation was not undertaken (Thabane et al., 2010). This study included a convenience sample of 20 patients to assess the feasibility of the study procedures. With approximately 300 new ICDs implanted at HHS annually, recruiting 20 patients was feasible for this study.

Data Collection on Outcomes

Feasibility Outcomes

The primary outcomes in this study focused on feasibility specific to process outcomes. These included assessing recruitment, consent rate, randomization, completion of questionnaires, delivery of the intervention, and percentage of missing data (Thabane et al., 2010). The recruitment rate represents the number of participants in the study divided by the total number of eligible participants. The consent rate refers to the percentage of eligible participants approached by the study nurse who provided written consent. The randomization rate refers to the percentage of consented participants randomly allocated to either intervention or standard care. Completion of data collection measures is defined as the proportion of consented participants who completed the PROMIS questionnaire at baseline and the PROMIS, FPAS, and FSAS at four weeks post-implantation. Delivery of the intervention refers to the proportion of participants in the intervention group who received the intervention in the allotted time of 45 minutes. In addition, the length of time in minutes to complete consent forms was obtained, as well as whether additional information resources were accessed, identification of these resources where applicable, and if they were accessed prior to the ICD surgery.

The following was collected from the intervention group: (1) number of key topics completed during the educational intervention (see Appendix B); (2) length of time in minutes to complete the intervention; and (3) number of times the website (www.asktheicd.com) was accessed post-intervention (Bowen et al., 2009; Thabane et al., 2010).

Preliminary Estimates from PROMIS, FPAS, and FSAS

Data from the PROMIS, FPAS, and FSAS instruments were collected (see Appendix C). The data collected was not a powered data set. As such, they are presented as estimated effect

size with precision (confidence interval) in accordance with the CONSORT reporting guidelines for feasibility studies (Thabane et al., 2010, 2016). All participants completed the PROMIS tool at baseline during the pre-implantation appointment. At four weeks post-implantation, the PROMIS, FPAS, and FSAS measures were completed by all participants (See Table 1 in Appendix D for psychometric properties of instruments).

Instrumentations

PROMIS

This study used PROMIS Short Form v1.0 - Anxiety 8a, a self-report tool designed to measure general anxiety. The tool includes eight items rated using a 5-point Likert scale recalling the last seven days. A score of 1 indicates "never," and a score of 5 indicates "always." Examples of items include "I felt fearful," "I felt tense," and "My worries overwhelmed me." The tool was developed based on item response theory, a model that improves the precision of measurement of anxiety (HealthMeasures, n.d.). A higher T-score indicates greater measurement of anxiety; for instance, a T-score of 70 is two standard deviations worse than the general population average of 50 (Patient-Reported Outcomes Measurement Information System, 2018). The PROMIS tool was selected to promote standardization in measurement of anxiety as proposed by the National Institutes of Health (Schalet, Cook, Choi, & Cella, 2014). Compared to other tools, such as the Beck Anxiety Inventory, the PROMIS tool asks patients to recall from a shorter time period (seven days) versus 30 days. The PROMIS scale has been demonstrated to be sensitive to changes post-intervention across multiple chronic conditions (Schalet et al., 2016).

The PROMIS has shown reliability, precision, and construct validity, with internal consistency alpha coefficients of 0.89 to 0.98 and strong correlations with the Mood and Anxiety Symptom Questionnaire, $r = 0.72$ to $r = 0.80$, for individuals with chronic heart failure, cancer,

arthritis, psychiatric illness, and chronic obstructive pulmonary disease (Cella et al., 2010; Pilkonis et al., 2011; Schalet et al., 2014). The content validity of the short form was confirmed by expert review (Pilkonis et al., 2011). To our knowledge, no psychometric testing has been completed with an ICD population, and this study offers a contribution in this area.

FPAS

The FPAS measures patient acceptance of a cardiac device, as described earlier, which in this study is interchangeable with D-HRQL. The FPAS asks patients to rate 18 items (three are fillers) on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The total highest score possible is 75. The FPAS consists of four subscales: Return to Function, Device-Related Distress, Positive Appraisal, and Body Image Concerns (Burns et al., 2005). Items on the FPAS include the following: "When I think about the device, I avoid doing things I enjoy," "I am safer from harm because of my device," and "I am confident about my ability to return to work if I want to." Subscale and total FPAS scores were calculated using response scores from the 15 items. The FPAS is sensitive in assessing unique device-specific adjustment issues due to the nature of the questions included (Burns et al., 2005). Higher scores on the FPAS indicate greater D-HRQL, which translates to more positive or better acceptance of the device. FPAS been tested in both North American and European populations (Burns et al., 2005; Versteeg et al., 2017).

Convergent validity of the FPAS demonstrated that the FPAS total score and subscales were significantly correlated with eight subscales of the SF-36, indicating that both measure the same construct, which is HRQL (Burns et al., 2005). Discriminant validity is established as the FPAS, unlike the SF-36, can detect differences in HRQL between ICD and pacemaker patients (Burns et al., 2005). The FPAS has demonstrated acceptable to good internal consistency, with a

total scale Cronbach's alpha of 0.83 (Burns et al., 2005). The subscales have Cronbach's alphas ranging from 0.73 to 0.89, indicating an acceptable to good range of reliability (Burns et al., 2005; Pedersen et al., 2008; Versteeg et al., 2017). Reported mean total scores for the FPAS are 76.0 to 73.44 and for the subscales are as follows: Return to Function, 54.80 to 60.46; Device-Related Distress, 18.06 to 20.53; Body Image Concerns, 10.18; and Positive Appraisal, 77.50 (Burns et al., 2005; Morken et al., 2014).

FSAS

The FSAS is designed to measure ICD patients' shock-related anxiety. This instrument was selected as it differentiates anxiety related to the ICD versus generalized anxiety. The FSAS has a demonstrated ability to detect changes in psychosocial interventions (Ford et al., 2012). Also, to our knowledge, the FSAS is the only validated tool able to quantitatively measure ICD patients' shock anxiety. The tool consists of 10 items rated on a 5-point Likert scale ranging from 1 (not at all) to 5 (all of the time). The total highest score possible is 50. Items include the following: "It bothers me that I do not know when the ICD will fire," "I have unwanted thoughts of my ICD firing," and "I worry about the ICD not firing sometime when it should." Higher total mean scores indicate higher shock anxiety, whereas lower total mean scores indicate lower shock anxiety. Convergent validity for the total FSAS scale revealed good internal consistency, with Cronbach's alpha of 0.89 to 0.91 (Ford et al., 2012; Kuhl et al., 2006).

Discriminant validity revealed that the total FSAS score had a weak negative correlation with emotional well-being, sense of security, quality of life, and general health and a moderate negative correlation with the Multidimensional Fear of Death Scale (Ford et al., 2012; Kuhl et al., 2006). This translates to lower FSAS scores associated with higher levels of emotional well-

being, sense of security, quality of life, and general health. Overall, the FSAS has good construct validity.

Moreover, two separate studies found that the second-order factor model was a better fit (Ford et al., 2012; Kuhl et al., 2006). Reported mean (SD) FSAS total scores range from 15.4 (7.6) to 21.2 (9.7) (Ford et al., 2012). Subscale scores were as follows: mean (SD) consequence score of 1.50 (0.89) and mean (SD) triggers score of 1.54 (1.04) (Kuhl et al., 2006).

Standard Care

All participants within the study received standard care from the ICD clinic nurse. Standard care involved the provision of a pre-existing HHS patient education booklet and review of patients medical history, medications, what to expect the day of surgery and answering any questions. This interaction typically lasted between 20 and 30 minutes, and participants were permitted to bring a family member to the appointment.

Pre-implantation Nurse-Led Educational Intervention

The nurse-led ICD educational intervention consisted of standard care plus the educational intervention delivered by the study nurse (see Appendix E for a detailed outline of the intervention). The intervention was a single session delivered immediately after the standard care discussion with the ICD clinic nurse. Delivery of this education is within the scope of practice of registered nurses. Forty-five minutes was allotted for delivery of the intervention.

The proposed educational intervention incorporated a pre-existing educational support website (http://www.asktheicd.com/). This particular website was selected as it was developed and is supported by Medtronic, the ICD brand the patient sample would be receiving. It is recognized as an educational tool by the Heart Rhythm Society, a leading resource on cardiac pacing and electrophysiology. The website is a data bank of information organized in a question-

and-answer format, providing ease of navigation by patients. The purpose of the website as an adjunct allowed participants to openly access accurate ICD information discussed during the intervention and additional information at their convenience.

The content for the educational intervention was informed by multiple sources, including patient ICD knowledge disparities revealed within the literature, standard education according to ICD manufacturer websites, and recommendations of pre-implantation topics from conceptual papers (Boston Scientific, 2017; Dunbar et al., 2012; Ford et al., 2011; Hoogwegt et al., 2014; Johansen et al., 2011; Linder et al., 2013; Medtronic, 2014; Ooi et al., 2016; Pedersen et al., 2017; Sears et al., 2000). Information that was repeated and emphasized across all sources was selected to be included within the intervention. Specific information disparities addressed were clinical indication for an ICD, functionality of an ICD, potential for negative emotions, device replacement, and restrictions. To ensure the information provided to participants was consistent, a checklist was developed for use by the study nurse during the intervention (Hoogwegt et al., 2014) (see Appendix B). Topics included (1) ICD demonstration model and purpose; (2) ICD function; (3) shock therapy and shock plan; (4) benefits and limitations of an ICD; (5) device/battery replacement; (6) physical, driving, and electromagnetic interference and airport restrictions; (7) ICD identification card; and (8) the potential for post-implantation psychological consequences and support resources (Bolse et al., 2011; Cinar et al., 2013; Dunbar et al., 2012; Ford et al., 2011; Groarke et al., 2012; Hoogwegt et al., 2014; Ooi et al., 2016; Pedersen et al., 2017; Zayac & Finch, 2009). The topics of end-of-life care and ICD deactivation were not discussed because of the length of time required.

The study nurse explained the intervention to the participant using a laptop to demonstrate navigation of the www.asktheicd.com website, and accessing information was

discussed throughout the intervention. Participants were given an opportunity to rephrase content in their own words to ensure that comprehension was achieved, discuss the new information learned, and have their questions or concerns addressed (Groarke et al., 2012).

Study Procedures

Patient Recruitment

Patients were introduced to the study by the booking clerk. Those who met the inclusion criteria were asked if they would like to be considered for the study by the booking clerk, who routinely conducts calls to arrange preoperative appointments. Potential participants who agreed were contacted by telephone by the study nurse, and details of the study were provided (see Appendix F). The study nurse answered questions, obtained verbal consent to participate, and arranged to meet participants in the outpatient clinic at the time of their preoperative appointment.

Data Collection

Visit 1: preoperative appointment. Written consent was obtained from all participants. Following consent, baseline anxiety using the paper-based PROMIS tool was collected, along with demographic information (see Appendix G for the demographic form) by the study nurse. The medical history was obtained from the patient's electronic health chart. Following this, the study nurse opened the sealed envelope to determine the participant's allocation. Participants were randomized to receive standard care plus a nurse-led ICD educational intervention or standard care only.

At the end of visit 1 preoperative appointment, participants in both groups were provided with an envelope containing a copy of their written signed consent and three 4-week follow-up questionnaires (PROMIS, FPAS, and FSAS) for visit 2. Applicable feasibility outcome data were

recorded after each visit on the participant demographic forms, and field notes were made, with attention given to questions asked by participants. All participants were asked to provide contact information, including a phone number (if possible, a home number and a cellphone number) as well as an e-mail address (if applicable) to secure communication for visit 2.

Visit 2: telephone call at week 4 post-implantation. At week 4 post-implantation, contact with all study participants via telephone was made to obtain patient responses from the three questionnaires (PROMIS, FPAS, and FSAS) provided in the study envelope at visit 1. The study nurse followed a script (see Appendix H). Up to three attempts were made to contact patients for visit 2. Those patients who were unsuccessfully contacted for visit 2 were mailed questionnaires (PROMIS, FPAS, and FSAS) with a prepaid return envelope. An appreciation letter and a gift card were mailed to all participants after study completion. ICD implant status was obtained from the medical record. Patients in the intervention group were asked if they had revisited the educational website or other sources. Patients receiving only standard care were also asked to indicate if other sources of ICD information were sought and to specify these resources.

Ethical Considerations

This study adhered to the ethical guidelines of the Hamilton Integrated Research Ethics Board (HiREB). HiREB approval was obtained prior to study commencement (HiREB # 3679). All data collected remained confidential. No patient identifiers were recorded on the data collection forms used to collect patient information, and participants were assigned a study identification number, which was placed on each form. All paper data were kept in a locked room at McMaster University, and electronic data were encrypted and password protected. Informed written consent was obtained face to face at the initial preoperative appointment, with each participant receiving a signed copy of the consent form (see Appendix I for the consent

form). Participants were reminded that their involvement was voluntary and were provided with the opportunity to ask questions at any time. The study process ensured respect for persons in accordance with the Tri-Council Policy Statement for ethical conduct for research involving humans. Participants received a gift card ($10) from a local coffee shop as a token of appreciation.

Data Analysis

Descriptive Data

Demographic variables were summarized using descriptive statistics. Age is presented as a mean and a median (with standard deviation), whereas the nominal variables of treatment group, gender, medical history, education, living status, employment status, and health information access using the Internet are presented as frequencies. A CONSORT flow diagram was completed to indicate the participant flow process (see Figure 1) and the length of time in minutes required to complete consent forms.

Feasibility Outcomes

Feasibility was the primary outcome for the study. Success criteria for feasibility were based on the primary objectives of this study. The following success criteria were outlined a priori: (1) recruitment rate of at least 80% of eligible patients; (2) consent rate $\geq$ 95%; (3) completion rate $\geq$ 90%; (4) randomization rate of at least 90% of recruited participants; (5) delivery of intervention to 80% of participants assigned to receive it; and (6) at least 90% of participants completing at least 80% of the topics on the checklist. The reasons for missing data were noted (see Figure 1). Data were analyzed using proportions, with the target and observed percentages presented.

PROMIS, FPAS, and FSAS

The point estimates from the PROMIS tool in the form of T-scores (with standard error) from the intervention and standard care groups at baseline and 4 weeks post-implantation were calculated. The mean consequence, triggers, and total scores from the FPAS were calculated for the intervention and standard care. The mean total score and mean score across the four subscales from the FPAS are presented for both groups. Finally, the mean difference between the intervention and standard care groups was calculated; with corresponding confidence intervals for the total mean scores for PROMIS at the two time points, FPAS, and FSAS. All data was analyzed using PASW version 18 (formerly SPSS).

Chapter IV: Results

This chapter includes the results of sample characteristics, feasibility outcomes, participants' self-report of accessing of resources, and preliminary estimates from the PROMIS, FPAS, and FSAS. Corresponding tables and figures are presented at the end of this chapter.

Characteristics of the Sample

Over a three-month period (November 2017–January 2018), a total of 28 patients were assessed for eligibility, with 20 recruited and consented. The 20 patients who consented were randomized to standard care (n = 10) or an educational intervention (n = 10).

The majority of participants across groups were male (90.0%) and between the ages of 62 and 70 years, with a mean age of 66 years. Majority of participants had either a high school or no education (60.0%), did not live alone (70.0%), and were retired (35.0%) (see Table 1). Review of the past medical history found that the majority of participants had a history of congestive heart failure (90.0%), hypertension (70.0%), or diabetes (55.0%). Both groups were balanced in terms of characteristics, with the exception of the intervention group containing a higher proportion of patients with atrial fibrillation, diabetes and the mean age was higher in the intervention group, 69.9 (11.3) years compared to 61.8 (9.4) years in the standard care group. A lower proportion of participants in the intervention group reported having Internet access at home (70% versus 100% standard care), and only 30% reported accessing health information using the Internet, compared to 50% of standard care participants (see Table 2).

Figure 1 provides the CONSORT flow diagram (Eldridge et al., 2016; Thabane et al., 2016) for the study. Although the standard care and intervention groups were balanced in terms of allocation of participants, the number of participants analyzed was higher in the educational intervention group due to loss to follow-up in the standard care group.

Primary Outcome–Feasibility

Four of the six a priori criteria for feasibility success were met: recruitment rate, randomization rate, time of intervention delivery, and intervention checklist completion (see Table 3). The time of intervention delivery target was met, with a mean (SD) completion time of 26.0 (4.1) minutes, which is under the allotted 45 minutes. All participants who received the educational intervention completed over 18 topics, with more than half completing all 22 (60.0%). Table 3 summarizes the feasibility outcomes and a priori criteria for success. The mean (SD) number of minutes within which written consent was completed was 5.2 (2.3) for the standard care group and 4.8 (1.7) for the intervention group.

The consent rate target was not met as three eligible participants were not consented for the following reasons: one patient declined to participate due to an appointment elsewhere immediately after the routine preoperative appointment; a second patient was missed because the study nurse was unable to attend the appointment because of a snowstorm; and the third patient left the clinic prior to seeing the study nurse. The completion of data collection measures was below the a priori target as two participants were lost to follow-up (did not return calls or mailed requests), and a third did not receive the ICD during the study period and thus was not eligible to complete the designated four-week post-implantation questionnaires.

Additional feasibility outcomes were collected regarding additional resources patients accessed. One participant in the intervention group reported accessing the www.asktheicd.com site introduced during the intervention, once after implantation. A second participant within the intervention group reported accessing additional resources to the booklet or website by speaking to a health professional during post-implantation care. The majority of participants in the intervention group reported not accessing health information using the Internet (70%) versus

50% in the standard care group (see Table 3). The lack of information-seeking behaviour in the intervention group participants could explain the lack of accessing of the website provided.

Three participants in the standard care group reported accessing the internet (Google) for information and images of the ICD in addition to receiving the booklet from the clinic nurse. Two of the three participants indicated that they accessed the additional information prior to surgery, and the third participant reported accessing after surgery. Overall, few participants in both groups accessed additional information beyond what was discussed with them in person by either the study nurse or the clinic nurse.

Preliminary Estimates

PROMIS

The mean PROMIS T-scores (SE) in the standard care group at pre-implantation was 44.0 (2.4), and at 4 weeks was 43.7 (8.6). These scores are lower compared to the intervention group which had mean PROMIS T-scores of 50.0 (2.7) and 45.5 (6.4), respectively (see Table 4). A higher T-score translates to greater anxiety experienced by the participant. Both groups reported lower PROMIS anxiety scores post-implantation, as demonstrated by the mean difference [CI] in T-scores at baseline and four weeks. The mean difference [CI] in PROMIS scores between groups was greater at baseline, 6.4 [−1.1, 14.0], compared to at 4 weeks, 1.7 [−6.3, 9.7].

FPAS

Participants in the intervention group reported higher mean (SD) total FPAS scores compared to the standard care group, although the number of participants analyzed between groups was unbalanced due to loss to follow-up (see Table 4). The intervention group reported lower FPAS scores on the Device-Related Distress and Body Image Concerns subscales, but

higher scores on the Return to Function and Positive Appraisal subscale compared to the standard care group. Higher scores on the Device-Related Distress and Body Image Concerns subscales indicated lower D-HRQL as patients reported being more distressed about the ICD and greater body image concerns than those who scored lower on the subscales. Higher scores on the Positive Appraisal and Return to Function subscales indicate higher D-HRQL as patients reported a greater return to pre-ICD functioning and positive attitude compared to those who scored lower on these subscales.

FSAS

The intervention group reported higher mean (SD) total FSAS scores and mean FSAS consequence scores compared to the standard care group but equal scores on the mean triggers FSAS subscale. The mean difference [CI] between the intervention and standard care groups is 1.4 [−3.3, 6.1]. Higher FSAS scores on either the total scale or subscales indicate greater shock anxiety experienced by participants.

Table 1: Baseline Patient Characteristics and History

Characteristic	**Standard Care** ***n*** **= 10 (%)**	**Educational Intervention** ***n*** **= 10 (%)**
Age: mean (SD)	61.80 (9.4)	69.90 (11.3)
Gender		
Male	10 (100.0)	8 (80.0)
Female	0 (0)	2 (20.0)
Education		
No degree	3 (30.0)	3 (30.0)
High school	2 (20.0)	4 (40.0)
College	2 (20.0)	1 (10.0)
Trade	1 (10.0)	0 (0)
University	1 (10.0)	1 (10.0)
Graduate/professional	1 (10.0)	1 (10.0)
Current employment status		
Full-time/part-time	3 (30.0)	3 (30.0)
Retired	4 (40.0)	3 (30.0)
Disability	3 (30.0)	3 (30.0)
Living status		

Alone	3 (30.0)	3 (30.0)
With someone	7 (70.0)	7 (70.0)
Past medical history*		
Previous MI	4 (40.0)	3 (30.0)
Hypertension	8 (80.0)	6 (60.0)
Atrial fibrillation	2 (20.0)	5 (50.0)
CHF	9 (90.0)	9 (90.0)
Diabetes	4 (40.0)	7 (70.0)

Note. CHF = congestive heart failure; MI = myocardial infarction.

*Participants can have multiple comorbidities.

Table 2: Internet and Health Information Access

Characteristic	**Standard Care *n* = 10 (%)**	**Educational Intervention *n* = 10 (%)**
Do you access health information using the Internet?		
Yes	5 (50.0)	3 (30.0)
No	5 (50.0)	7 (70.0)
Do you have Internet access at home?		
Yes	10 (100.0)	7 (70.0)
No	0 (0)	3 (30.0)

Table 3: Feasibility Outcomes

Measure	**Observed**	**Target: A Priori Criteria for Success**	**Description of Outcome**
Recruitment rate	$\frac{20}{25}$ (80%)	80%	Proportion of eligible participants who participated in the study
Consent rate	$\frac{20}{23}$ (87%)	≥ 95%	Proportion of eligible participants approached by study nurse who provided written consent
Randomization rate	$\frac{20}{20}$ (100%)	90%	Proportion of consented participants randomly allocated to either standard care or educational intervention
Completion of data collection measures	$\frac{17}{20}$ (85%)	≥ 90%	Proportion of consented participants who completed all questionnaires at baseline and 4 weeks post-implantation

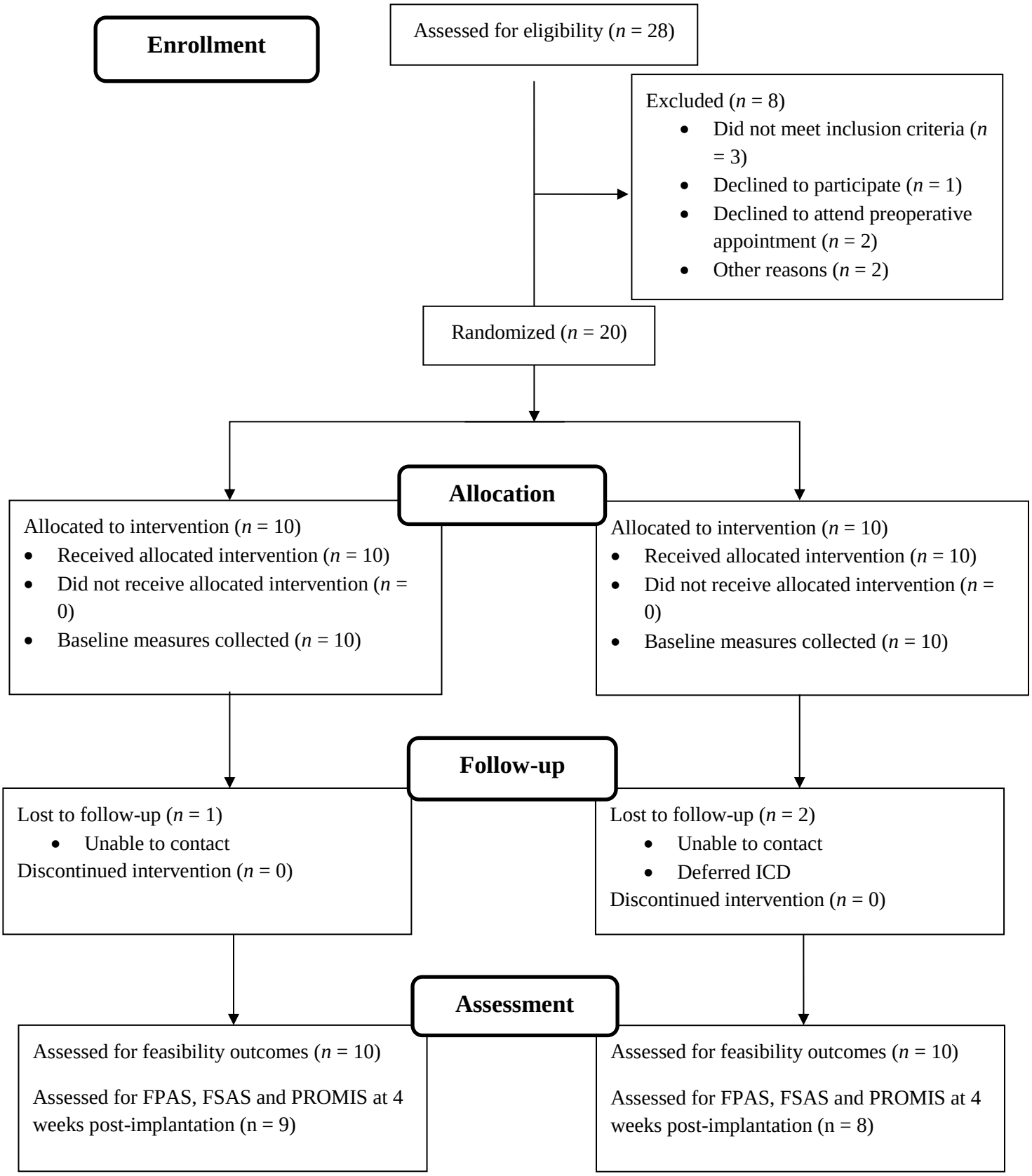
Time of intervention delivery	$\frac{10}{10}$ (100%)	80%	Proportion of participants who completed the educational intervention in less than the allotted 45 minutes
Intervention checklist completion	$\frac{10}{10}$ (100%)	90%	Percentage of participants who completed 80% of topics (18 topics out of 22)

Table 4: Patient-Reported Outcome Measures

Measure	Standard Care (SC)	Educational Intervention (EI)	Difference in Group Means EI − SC [95% CI]
PROMIS[a]: mean T-score[b] (SE)			
Pre-implantation (*n* = 10)	44.0 (2.4)	50.4 (2.7)	6.4 [−1.1, 14.0]
4 weeks	43.7 (8.6) *n* = 7	45.5 (6.4) *n* = 9	1.7 [−6.3, 9.7]
FPAS[c]: mean total score (SD)	76.9 (16.5) *n* = 7	80.0 (13.4) *n* = 9	3.1 [−12.9, 19.1]
FPAS[d] subscales			
Return to function	68.0 (30.8)	68.1 (21.5)	
Device-related distress	22.9 (19.8)	18.9 (14.1)	
Positive appraisal	77.7 (12.9)	86.1 (14.9)	
Body image concerns	8.9 (9.4)	6.9 (14.1)	
FSAS: mean total score (SD)	13.3 (3.9) *n* = 7	14.7 (4.6) *n* = 9	1.4 [−3.3, 6.1]
FSAS subscales			
Mean consequence score	1.3 (0.3)	1.5 (0.5)	
Mean triggers score	1.5 (0.5)	1.5 (0.5)	

[a]PROMIS = Patient-Reported Outcomes Measure Information System. [b]T-score is measured in comparison with the general population average of 50, with a T-score of 30 indicating two standard deviations better than the average as a higher score indicates that more anxiety is measured. [c]FPAS = Florida Patient Acceptance Survey. [d]FSAS = Florida Shock Anxiety Scale.

Figure 1: CONSORT Extension for Pilot and Feasibility Trials Participant Flow Diagram



Chapter V: Discussion

This chapter is organized into four sections. First, the feasibility outcomes and the importance of measuring device-specific patient-reported outcomes are discussed. Second, the strengths and limitations of the present study are examined. Third, a discussion of the implications for nursing practice is included, followed by a brief examination of the contributions of the findings to research.

The primary purpose of this study was to assess the feasibility of delivering a pre-implantation educational intervention in an outpatient arrhythmia clinic setting to primary prevention ICD candidates. Feasibility study design is important to determine whether a new intervention can be delivered and to address uncertainty in preparation for a future large-scale trial (Arain, Campbell, Cooper, & Lancaster, 2010; Lancaster, 2015; Orsmond & Cohn, 2015; Thabane et al., 2010, 2016). Although multiple studies may identify as a feasibility design, they often do not contain the methodological features or objectives that are considered a true feasibility study (Abbade, Abbade, & Thabane, 2018; Arain et al., 2010; Thabane et al., 2016). This is apparent when studies fail to outline clear feasibility outcomes and place the primary focus on effect size and hypothesis testing (Abbade et al., 2018). As such, the CONSORT extension established guidelines for reporting pilot and feasibility studies (Arain et al., 2010). The present study adhered to the CONSORT extension and, as a result, offers an important contribution to a growing body of feasibility research and addresses the gap in educational research on the growing population of ICD recipients.

The six feasibility outcomes in the present study comprised the main objectives. The majority of targets for these outcomes were met (four of six), suggesting that delivery of a nurse-led educational intervention is feasible within an outpatient clinic setting. The two feasibility

outcomes that were not met (consent rate and full completion of data collection) may reflect ambitious a priori targets of 90% and 95%. In a similar feasibility study that included primary prevention ICD patients, testing the feasibility of delivering a patient decision aid included an a priori target of 80% (Carroll et al., 2017), whereas other feasibility studies did not set targets (Cossette et al., 2017; Edelman et al., 2007; Smeulders et al., 2007).

What follows is an in-depth discussion of the feasibility outcomes and recommendations to improve these aspects when planning a future definitive trial to test the efficacy or effectiveness of an educational intervention. First, accessing eligible participants for study recruitment was feasible in an outpatient clinic setting as all patients scheduled for ICD implantation were due to attend a preoperative appointment in the clinic. Although other research has included telephone support as a component of the intervention (Cossette et al., 2017), a move away from face-to-face discussions with nurses would remove the ability to assess uncomfortable or distressed body language that cannot be observed over the telephone. Overall, although verbal consent from patients was obtained, it was evident that they did not hesitate to participate in the present study as participants met the study nurse immediately after their preoperative clinic appointment, with no secondary visit required.

The consent rate of 95% was not achieved; however, in our sample of 20, a small number of only three eligible participants declined. To improve consent rates in a larger trial, it may be worthwhile to be flexible with the timing of both consent and the educational intervention. One eligible patient declined to participate because of an appointment immediately after the preoperative ICD appointment, whereas another two eligible non-consenting participants would have agreed if provided with another time pre-implantation to consent. Offering alternate options pre-implantation for consent and the delivery of the educational intervention could improve the

consent rate in a future trial. Once participants consented to the study, there was minimal loss to follow-up, with only two participants unable to be contacted by telephone.

No issues were observed with the procedure of using opaque envelopes for randomization of consenting participants. All participants were randomized after completing the PROMIS tool to ensure that knowledge of group allocation did not affect their scores. Blinding of participants was not possible due to the nature of the intervention; however, since the outcome measures were completed by patients, this avoided assessor bias.

Selecting appropriate outcome measures and corresponding instruments is equally important as ensuring complete data collection of the outcome measures. To our knowledge, this is the first study using the PROMIS anxiety scale in an adult ICD population. During the administration of the PROMIS tool pre-implantation, it was evident that some participants experienced difficulty interpreting how to respond to some of the questions. Participants said that they were unsure whether the questions related to how they felt about the ICD or how they felt generally. This could potentially affect the validity of the results if participants did not respond to the items as the tool intended. Given that the PROMIS instrument has been tested in patients with chronic conditions, it may be worthwhile to conduct psychometric testing of the instrument in an adult ICD population prior to using it in a large-scale study. Pending the reliability and validity testing of the PROMIS tool in ICD patients, future studies should consider using device-specific instruments, such as the FPAS and FSAS, which have been validated within ICD populations. None of the generic anxiety tools used in the current ICD literature (Hospital Anxiety and Depression Scale and State-Trait Anxiety Inventory) have been validated for use with ICD patients despite their prominent use in ICD patients (Conelius, 2017; Magyar-Russell et al., 2011). For example, recently, a new ICD-specific instrument, the Emotional Responses

Post Implantable Cardioverter Defibrillator Scale (Conelius, 2017), which measures depression, general anxiety, and fear of the ICD, was developed. Future studies should consider using an instrument developed for the ICD population, such as this tool, to measure general anxiety in ICD patients.

Moreover, the post-implantation administration time points of the instruments (PROMIS, FPAS, and FSAS) should be reconsidered for future studies. In the current study, administering the PROMIS, FPAS, and FSAS tools at 4 weeks post-implantation was too early in a patient's post-implantation trajectory as patients are focused on physical healing and managing new limitations imposed by the ICD (Ooi et al., 2016). This was supported by participant comments that asking questions addressing "return to life" included in the FPAS at 4 weeks post-implantation was premature as patients were still recovering physically. As such, future studies should consider collecting data using the FPAS, FSAS, and PROMIS beyond the acute four- to six-week healing time as this may provide a better representation of patient adjustment. Also, repeating measurement of patient-reported outcomes at multiple time points rather than at a single time point may reveal whether the intervention can lead to sustained effects.

Furthermore, the ability to contact patients for completion of follow-up measures is critical for complete data collection. Securing alternative methods to contact patients four weeks post-implantation would have improved the rate of data completion. Although the protocol was amended to include a patient mail response option for those who did not respond to three telephone contacts, only one out of three returned the questionnaire. Unfortunately, this was beyond the four-week post-implantation time frame of the study, and the data could not be used.

The feasibility of the delivery of the educational intervention was successful as all participants completed the intervention and at least 80% of the outlined topics in the allotted

time. These findings suggest that in this population, the intervention is suitable for delivery by nurses in a reasonable time frame of 26 minutes in an outpatient clinic. These findings are in line with findings from a feasibility study by Cossette et al. (2017), which reported that a nurse-led intervention addressing specific patient ICD concerns was delivered in an average of 20 minutes. In the present study, the nurse was able to discuss 20 out of 22 topics on the intervention checklist. Given that non-physician health professionals, including nurses and medical device technicians, report spending an average of 28.6 minutes with ICD patients pre-implantation (Johansen et al., 2011), the findings from this study support the realistic potential to deliver education pre-implantation to patients in an outpatient clinic setting.

The present study used three instruments: PROMIS, FPAS, and FSAS. Considering this is the first study with ICD patients to use the PROMIS tool there is no previous literature reporting PROMIS scores in ICD patients to compare the PROMIS results of this study to. The intervention aimed to decrease anxiety however, the mean PROMIS T-scores were higher in the intervention group compared to the standard care group at both baseline and 4-weeks post-implantation. As discussed above these results could be contributed to patient's misunderstanding the items and context of the PROMIS tool which ultimately could have affected the validity of the scores.

Mean FPAS scores in the present study in the intervention group (80.0) were higher compared to scores in the standard care group (76.9) but in a range similar to that of other ICD studies. Cossette et al. (2017) reported higher total mean FPAS scores (SD) in the intervention group of 64.77 (6.31) compared to 61.99 (10.70) for controls. Moreover, Udlis (2013) and Wilson et al. (2013) reported mean FPAS scores (SD) of 74.9 (17.0) and 80.9 (16.5), respectively. Higher FPAS scores indicate greater D-HRQL, which translates to patients

experiencing less distress related to the ICD, greater return to function, and viewing the device with a positive attitude. The educational intervention in the present study was designed to promote higher D-HRQL as it is related to increased ICD knowledge (Kuhl et al., 2009; Morken et al., 2014; Wilson et al., 2013). Closing this knowledge gap can improve D-HRQL and support ICD patients in living confidently with their ICD.

In the present study, higher total mean FSAS scores were reported in the educational intervention group (14.7) compared to the standard care group (13.3); however, the range was similar to that of other ICD studies using the FSAS. Other ICD studies reported mean total FSAS scores ranging from 14.5 to 16.5 (Cossette et al., 2017; Morken et al., 2014; Udlis, 2013; Wilson et al., 2013). Higher FSAS scores indicate greater shock anxiety, which can impede a patient's adjustment to living with the ICD. Patients with greater shock anxiety are known to be distressed about future shocks and, if this is uncorrected, can develop clinical anxiety and/or avoidance behaviours, leading to a negative impact on quality of life (Ford et al., 2012). When considering the delivery of education regarding shock therapy to patients, some studies recommend including a shock plan (Alba et al., 2013; Kuhl et al., 2006; Morken et al., 2012, 2014), whereas other studies report that patients may not be able to cope with certain topics (Humphreys et al., 2016). It is important to consider that perhaps for some patients, receiving information regarding the delivery of shocks as part of ICD therapy could contribute to greater shock-related anxiety (high FSAS scores), whereas for others, providing shock therapy information can ameliorate shock anxiety (Alba et al., 2013; Kuhl et al., 2006; Morken et al., 2012, 2014).

Although the present study incorporates ICD education within the intervention, future studies may want to consider tailoring the educational intervention checklist to allow patients to identify topics they prefer to learn more about. A large-scale randomized controlled trial could

explore the delivery of the educational intervention at multiple time points, including pre and post-implantation with the same checklist carried forward throughout a patient's care trajectory. This design feature could mitigate anxiety and shock anxiety and promote D-HRQL by tailoring information to patient preferences.

Study Strengths and Limitations

The present study has several methodological strengths and limitations. A leading strength is the adherence to the CONSORT extension for randomised pilot and feasibility studies. The main purpose of conducting this study aligns with feasibility study objectives as it assessed the feasibility of delivering an intervention pre-implantation that it was uncertain would be achievable in an outpatient clinic setting. The success of the primary objectives was determined by a priori criteria, which are recommended to be included (Lancaster, 2015).

Specific study design features are important to recognize despite the sample size not being powered to detect differences between the intervention and control groups. The randomized controlled trial design reduced bias. Allocation concealment and randomization of participants minimized selection bias as the study nurse was unaware of and had no control over allocation. These design features increased the internal validity of the findings. Moreover, the present study contributes to the understanding of the adult ICD patient population in a Canadian context as most studies either examining the perceptions of ICD patients or examining interventions in ICD populations, have been conducted in the United States and European countries (Magyar-Russell et al., 2011; Ooi et al., 2016).

The limitations of the study include its single-centre design from an urban specialized cardiovascular centre, which decreases the generalizability of the findings to other clinics that may be rural. Moreover, with the sample size being 90% male, future consideration should

involve a recruitment process to incorporate more female participants to mitigate any gender differences regarding the intervention's efficacy. Additionally, focusing on primary prevention ICD candidates limits external validity to those offered a cardiac resynchronization therapy device and secondary prevention indication candidates. Finally, although the intervention in the present study incorporated a comprehensive list of topics, end-of-life deactivation and ICD recall were not included due to the limited time frame allotted in the preoperative clinic. Although these topics are widely highlighted in the literature, the breadth and complexity of both topics exceed what is possible in a single face-to-face encounter with a health professional, particularly pre-implantation (Dunbar et al., 2012; Ooi et al., 2016; Pedersen et al., 2017; Steinke, Gill-Hopple, Valdez, & Wooster, 2005).

Implications for Nursing Practice

The present study has important implications for nursing practice. This study demonstrated that it was feasible for a registered nurse to deliver pre-implantation education to patients in a reasonable time frame, reinforcing appropriateness and fit within practice. The delivery of ICD education to patients is within registered nurses' scope of practice, and as suggested by Bolse et al. (2011), nurses, as front-line health professionals, should be leading the education of ICD patients in arrhythmia clinics. Nurses are highly competent at recognizing the emotional well-being of ICD patients (Sears et al., 2000) and also spend more time with ICD patients discussing their therapy (Johansen et al., 2011). Furthermore, many outpatient clinics do not have access to a mental health professional to offer psychosocial support to ICD patients; thus, registered nurses are well positioned to take on the role of supporting and counselling patients pre-implantation.

Face-to-face preoperative discussions, which patients identified as the preferred method of acquiring information, give patients an opportunity to pose questions and have their concerns addressed (Braunschweig et al., 2010; Serber et al., 2009). This is especially important as printed ICD patient educational material has been shown to be persuasive in language, have high readability, and focus on the benefits of an ICD, with limited or no mention of negative aspects, including device manufacturer recalls and inappropriate shocks (Strachan et al., 2012). Furthermore, some studies have documented inadequate preoperative discussions between ICD patients and physicians (Hauptman et al., 2013; Yuhas et al., 2012). Patients have noted a lack of information provided (Hauptman et al., 2013; Hoogwegt et al., 2014) and limited discussion of the impact of an ICD on quality of life and potential psychosocial issues, including anxiety (Hauptman et al., 2013; Hoogwegt et al., 2014). This study highlights how registered nurses can competently provide support in the form of education to patients pre-implantation in a timely and efficient manner.

Contribution to Research

The present study addresses a gap identified in the adult ICD literature. The findings shed light on the feasibility of a pre-implantation educational nurse-led intervention, a topic not previously explored in the ICD literature. Although multiple studies have incorporated ICD education within psychosocial interventions, only two used education-only interventions, although neither was delivered pre-implantation (Cinar et al., 2013; Edelman et al., 2007).

As well, this study measured shock anxiety and D-HRQL, which are ICD-specific concepts that allow for a broad understanding of an ICD patient's experience. In the ICD literature, generic patient-reported outcomes are common despite the existence of validated and reliable ICD-specific instruments. It is important to use device-specific instruments such as the

FPAS and FSAS, which measure concepts experienced only by those with an ICD, which generic tools cannot capture. Keeping current with new device-specific instruments is critical to ensure that outcomes related to ICD patients are measured and reported appropriately. The present study highlights the suitability of the device-specific measurement of outcomes and potential challenges with using PROMIS in an ICD population within this study design.

Finally, this study is the first to assess the feasibility of delivering a nurse-led educational intervention pre-implantation to ICD candidates. A large-scale randomized controlled trial evaluating the efficacy of this intervention in relation to D-HRQL, anxiety, and shock anxiety is warranted to determine if education delivered pre-implantation can positively impact post-implantation adjustment.

Conclusion

Patients living with ICDs report unmet educational needs regarding ICD therapy. This study employed an educational intervention that aimed to close these information gaps. Multiple interventions designed to support the psychosocial well-being of ICD patients have been documented; however, a pre-implantation educational intervention has not been assessed until now. This study determined that it was feasible to deliver a novel nurse-led educational intervention to primary prevention ICD candidates pre-implantation in an outpatient clinic setting. Future research should focus on evaluating the effectiveness of this educational intervention and on pre-implantation interventions in a powered trial.

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Appendix A: Literature Review Table

Table 1: Summary Table of Literature Review—Intervention Studies

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
Authors: Molchany & Peterson **Year:** 1994 **Country:** Not Reported	**Question:** How does a support group intervention impact psychosocial well-being of ICD recipients **Design:** Comparative exploratory pilot study with two-group pre- and post-test	**Outcome(s) and Tools**: Anxiety (State Anxiety Inventory) Quality of Life (Medical Outcomes Study) **Timing of outcome:** Baseline and at nine months	**Sample size**: Intervention:11 Control: 5 **Mean Age (SD):** Not reported. But an age range is provided **Gender:** [Male %]: Intervention: 90.9%; Control: 80%	**Intervention:** Support groups led by a psychiatric and a cardiac nurse **Intervention delivered when:** Post-implantation **Frequency and session duration:** 1.5 hour monthly sessions **Control group:** Not reported	No statistically significant changes in anxiety scores	No details regarding the care the control group received Limited demographic information provided for study participants Did not specify the number of sessions completed for the intervention group
Authors: Kohn et al. **Year:** 2000 **Country:** USA	**Question:** To examine the impact of a cognitive behavioral therapy intervention in reducing psychological	**Outcome(s) and Tools**: Anxiety (State-Trait Anxiety Inventory) Depression (Beck Depression	**Sample size** Intervention: 25 Control: 24 **Mean Age (SD):** 66 (10)	**Intervention:** One on one cognitive behavioral therapy delivered by a doctoral psychology student (over the phone if in-person	At nine months the intervention group had lower mean trait anxiety scores compared to the control	High loss to follow up at nine months Did not report what "no therapy" for the control group included

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
	distress **Design:** Randomized controlled trial	Inventory) **Timing of outcome:** Baseline and nine months	**Gender:** [Male %]: 65	not possible) **Intervention delivered when:** Pre-implantation, pre-discharge from hospital, weekly for four weeks and then at routine one, three, and five months follow-up in the clinic **Frequency and session duration:** 30 to 60 minutes pre-implantation and pre-discharge, and 15 min to 30 min post-implantation (9 sessions total) **Control group:** No therapy	group ($p = 0.013$) 	Small sample with no sample calculation for adequate power
Authors: Fitchet et al.	**Question:** To investigate the effects of a	**Outcome(s) and Tools**: Anxiety and	**Sample size**: Group A: 8	**Intervention:** Comprehensive	Decrease in mean anxiety and depression	Small sample with no sample calculation for

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
Year: 2003 **Country:** UK	comprehensive cardiac rehabilitation program on ICD patients **Design:** Randomized controlled trial (Cross over design)	Depression (Hospital Anxiety and Depression Scale) **Timing of outcome:** Baseline, before the intervention, at the end of the intervention and 12 weeks after	Group B: 8 **Mean Age (SD):** Group A: 56.8; Group B: 59.7 **Gender:** [Male %]: 88	cardiac rehabilitation program with exercise, educational seminars and cognitive behavioral therapy. Access to a 24 hour ICD help line monitored by a nurse as well as a patient support group. **Intervention delivered when:** Post-implantation to Group A and then after 12 weeks the groups cross-over and Group B received the intervention **Frequency and session duration:** Two hour sessions,	scores from pre to post intervention in the intervention group for the 11 patients from both group A and B who completed the entire intervention ($p < 0.001$)	adequate power No intention to treat analysis completed Patients volunteered for the study lending to selection bias

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
				twice a week for 12 weeks **Control group:** Access to a 24 hour ICD help line monitored by a nurse as well as a patient support group.		
Authors: Dougherty et al. **Year:** 2004, 2005 **Country:** USA	**Question:** To determine the benefits of a telephone intervention **Design:** Randomized controlled trial	**Outcome(s) and Tools**: Anxiety (State-Trait Anxiety Inventory) Depression (Centers for Epidemiologic Studies-Depression) General Health (Short Form Health Survey-12) **Timing of outcome:** Baseline (first	**Sample size**: Intervention: 85 Control: 83 **Mean Age (SD):** Intervention: 63.02 (12.31); Control: 65.06 (12.24) **Gender:** [Male %]: Intervention: 67; Control: 62	**Intervention:** Booklet with information regarding sudden cardiac death, telephone support, and access to a 24/7 nurse pager. Content based on Bandura's Social Cognitive Theory. Telephone support delivered by a cardiac nurse focused on behavioral skills and promoting self-efficacy	No statistically significant difference in depression or general health scores between treatment groups at three, six or 12 months Mean anxiety scores at 12 months were lower in the intervention group	Lengthy questionnaire packet could mean participants more highly motivated completed it thus, limiting generalizability Excluded primary prevention ICD candidates thus, limiting generalizability to this indication

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		week post hospital discharge), three, six and 12 months post hospitalization		**Intervention delivered when:** Post-implantation immediately following hospital discharge for 8 weeks **Frequency and session duration:** Weekly sessions lasting between 15 to 20 minutes **Control group:** Usual care involving standardized education in booklet, video and health professional discussion formats	compared to the control group (p = 0.04)	No ICD specific outcomes measured Small sample with no sample calculation for adequate power
Authors: Frizelle et al. **Year:** 2004	**Question:** To evaluate the effect of a cognitive behavioral cardiac rehabilitation	**Outcome(s) and Tools**: Anxiety and depression (Hospital	**Sample size**: Intervention: 12 Control: 10	**Intervention:** Group rehabilitation program, education session based on	The change in depression scores (p = 0.001) and anxiety scores	No demographic characteristics table outlined for study

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
Country: UK	program **Design:** Pilot randomized controlled trial	Anxiety and Depression Scale Quality of life (The MacNew Quality of Life after Myocardial Infarction Questionnaire and EuroQual) **Timing of outcome:** Baseline, end of intervention or waiting period, at the end of the second treatment group and at three months for both groups.	**Mean Age (SD):** Intervention: 60.4 (10.13); Control: 62.8 (4.66) **Gender:** [Male %]: Not reported	cognitive behavioral therapy, relaxation tapes, home-based exercises and a follow-up phone call **Intervention delivered when:** Post-implantation **Frequency and session duration:** Weekly for six weeks with a follow-up phone call at nine weeks to reinforce the intervention. Each session was two hours. **Control group:** Waiting treatment group which received routine care including ICD	($p = 0.012$) were greater in the intervention group compared to the control group pre- and post-treatment	participants Pilot study with small sample size Lack of an attention control group Only 26% of patients invited to the study consented to participate

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
				clinic appointments or own physician appointments		
Authors: Chevalier et al. **Year:** 2006 **Country:** France	**Question:** To determine whether cognitive behavioral therapy affects arrhythmia events requiring ICD intervention **Design:** Pilot randomized controlled trial	**Outcome(s) and Tools**: Anxiety (Hamilton Anxiety Rating Scale) Depression (Beck Depression Inventory) Quality of life (Tool not reported) **Timing of outcome:** Baseline, three months, and 12 months	**Sample size**: Intervention: 35 Control: 35 **Mean Age (SD):** Intervention: 58.5 (10); Control: 57.9 (11) **Gender:** [Male %]: Intervention: 85.7; Control: 97.1	**Intervention:** Group cognitive behavior therapy delivered by a psychologist and psychiatrist which involved stress management **Intervention delivered when:** Post-implantation **Frequency of intervention:** Six bi-weekly, two hour sessions **Control group:** Treatment as usual	At three months, anxiety scores were lower in the intervention group than the control ($p = 0.04$) and at 12 months ($p = 0.03$) Both depression and quality of life scores not statistically significantly different between treatment groups	Refusal from eligible patients to participate high (72%) Did not specify the care the control group received Small sample with no sample calculation for adequate power
Authors: Edelman, Lemon, & Kirkness** **Year:** 2007	**Question:** To evaluate the feasibility of an educational intervention on hostility, anxiety,	**Outcome(s) and Tools**: Anxiety, depression, stress and hostility (DASS)	**Sample size**: Intervention: 13 Control: 9 **Mean Age (SD):**	**Intervention:** Group format educational session delivered by nurse and psychologist	No association between the intervention and any of the outcomes	No mention of how patients were randomized into the treatment

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
Country: Australia	depression and stress **Design:** Pilot randomized controlled trial	**Timing of outcome:** Prior to ICD implantation, two, four, and six months post implantation	Not reported **Gender:** [Male %]: 86	**Intervention delivered when:** Two weeks post-implantation **Frequency and session duration:** One session lasting 1 to 1.5 hours **Control group:** Discussion with cardiologist and a device manufacturer booklet		groups Demographic information not separated between the two treatment groups Small sample size with no adequate power as it is a pilot study No ICD specific outcomes measured
Authors: Sears et al. **Year:** 2007 **Country:** USA	**Question:** To evaluate the effects of an ICD stress and shock management program **Design:** Randomized controlled trial	**Outcome(s) and Tools**: Anxiety (State-Trait Anxiety Inventory) Depression (Centers for Epidemiologic Studies-Depression)	**Sample size**: 30 **Mean Age (SD):** Weekly intervention: 60.27 (4.56); Workshop: 59.35 (2.62) **Gender:** [Male %]: 70	**Intervention:** ICD education, stress management and relaxation training, cognitive behavioral techniques, group discussion, and social support. **Intervention delivered when:**	**Follow-up:** No statistically significant changes at four months for anxiety, quality of life or device acceptance Increase in depression	Small sample with no sample calculation for adequate power Workshop was four hours, and weekly groups were nine hours meaning unequal

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		Device acceptance (Florida Patient Acceptance Survey) Quality of life (Short Form Survey-12) **Timing of outcome:** Baseline, after treatment, two and four months post treatment (workshop or intervention)		Post-implantation **Frequency and session duration:** Six weekly, 90 minute group sessions **Workshop group:** One day, four hour psychoeducational workshop	within workshop participants from baseline to four months ($p = 0.02$) Intervention group had a greater decrease in anxiety ($p = 0.03$) compared to the workshop group	researcher time spent between groups. Attention control group not used Did not detail how participants were randomized into the two treatment groups
Authors: Smeulders et al. **Year:** 2007 **Country:** Netherlands	**Question:** To explore the feasibility and benefits of a nurse and peer led version of the structured Chronic Disease Self-Management Program (CDSMP).	**Outcome(s) and Tools**: Feasibility Outcomes 1.Performance of the intervention according to protocol 2.Attendance of patients 3.Adherence of patients	**Sample size**: 10 **Mean Age (SD):** 65.5 (7.9) **Gender:** [Male %]: 100	**Intervention:** CDSMP delivered by a cardiac nurse and a patient with cardiovascular disease (peer). Program emphasized patient's role in self-managing their illness to regain	The CDSMP was feasible according to the participants and leaders Participants reported a score of 8.4 out of 10 for the overall	Low consenting rate with only ten out of 26 eligible patients consenting No a priori targets set to determine feasibility success

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
	Design: Non-randomized quasi experimental	4.Patients and leaders opinions about the program Anxiety and depression (Hospital Anxiety and Depression Scale Quality of Life (RAND-36) **Timing of outcome:** Baseline and six weeks		control. Received booklet regarding chronic conditions **Intervention delivered when:** Post-implantation **Frequency of intervention:** Six weekly sessions, each session was 2.5 hours	program Participants preferred activities involving making an action plan and managing emotions 8/10 participants attended at least four of the six sessions Leaders reported difficulty delivering program as per protocol	No ICD specific outcomes measured
Authors: Dunbar et al. **Year:** 2009 **Country:** USA	**Question:** To examine the effects of a psychoeducational intervention during the first year post-implant	**Outcome(s) and Tools**: Anxiety (State-Trait Anxiety Inventory) Depression	**Sample size**: Group: 85 Telephone:83 Control: 78 **Mean Age (SD):**	**Intervention:** Education involving ICD therapy, symptom management training, and cognitive behavioral	At three months, anxiety scores were lower in both the telephone and group	High proportion of eligible participants declined (49%) No ICD

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
	Design: Randomized controlled trial	(Beck Depression Inventory) **Timing of outcome:** Baseline, one, three, six and 12 months	Intervention: Group: 59.0 (10.6); Telephone: 58.0 (10.9); Control: 58.4 (12.0) **Gender:** [Male %]: Intervention: Group: 82.9; Telephone: 71.6; Control: 70.1	therapy techniques to improve coping Two intervention groups with identical content but different delivery 1)Telephone: cardiovascular research nurse delivered 2)Group: led by mental health nurse **Intervention delivered when:** Pre-hospital discharge, two to three months post-implantation and a booster session at four to five months post-implantation **Frequency and session duration:** Nurse delivered both telephone and group in a 20 to 30	treatments compared to usual care (p = 0.03) No significant difference in anxiety scores at six and 12 months Telephone may be a cost effective follow up method to bridge gap between acute and outpatient care	specific outcomes measured Difficult to implement intervention with an unwell patient Randomization methods not explained clearly

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
				minute session. Telephone call delivered one week post discharge for reinforcement, and booster sessions at four to five months **Control group:** Standard discharge teaching with audiotape containing same information. ICD device manufacturer booklets provided		
Authors: Kuhl et al. **Year:** 2009 **Country:** USA	**Question:** To examine a computer assisted education for ICD patients **Design:** Pilot randomized controlled trial	**Outcome(s) and Tools**: ICD Knowledge (Florida ICD Knowledge Acquisition Survey) Device acceptance (Florida Patient Acceptance Survey)	**Sample size**: Intervention:15 Control: 15 **Mean Age (SD):** Intervention: 54.00 (14.99); Control: 60.88 (13.08) **Gender:** [Male	**Intervention:** CD-ROM with the PACER program which included psychoeducational cognitive behavioral therapy with coping techniques **Intervention delivered when:** Post-implantation	New recipients (less than 3 months) demonstrated lower device acceptance scores ($p = 0.01$) and greater shock anxiety scores ($p = 0.04$) compared to those with an	Small sample Sample included patients with an ICD for variable amount of time – unclear if this affected results Use of PACER not monitored

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		Shock anxiety (Florida Shock Anxiety Scale) Anxiety (State-Trait Anxiety Inventory) Quality of Life (Short Form-12) Cardiac-specific Quality of Life (Left Ventricular Dysfunction Questionnaire) **Timing of outcome:** Baseline (post-implantation) and repeated at one month	%]: Intervention:56.2; Control: 53.8	**Frequency and session duration:** CD-ROM so participants can access at their own convenience **Control group:** Basic information related to ICD, in the form of one-on-one Q and A with a physician and educational brochures	ICD for greater than three months Age (β = 0.49,p = 0.04) and knowledge (β=0.64, p = 0.01) are independent predictors of device acceptance	including time spent using the program and patients comfort with technology
Authors: Lewin et al. **Year:** 2009 **Country:** UK	**Question:** Evaluate clinical and cost effectiveness of a home based rehabilitation plan for ICD patients	**Outcome(s) and Tools**: Anxiety and depression (Hospital Anxiety and Depression Scale	**Sample size**: Intervention: 93 Control: 175 **Mean Age (SD):** Intervention: 58.7	**Intervention:** Cognitive behavioral rehabilitation programme including booklets	No statistically significant results in anxiety	Unbalanced group sizes (intervention and control) Unclear which health

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
	Design: Prospective cluster-randomized controlled trial	**Timing of outcome:** Pre-implantation, pre-intervention, and six months post-implantation	(13.3); Control: 63.4 (12.1) **Gender:** [Male %]: Intervention: 74; Control: 83	regarding common pre-ICD fears, relaxation tape, second booklet about post-implantation coping **Intervention delivered when:** First booklet given pre-ICD but programme delivered post-implantation **Frequency and session duration:** Facilitator made contact one, three, and six weeks post discharge for reinforcement **Control group:** Seen by an arrhythmia nurse or physician for usual		professional delivered the intervention

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
				care. Educated on procedure and coping after discharge. To control for attention provided with booklet and telephone contact by facilitator		
Authors: Crossmann et al. **Year:** 2010 **Country:** Germany	**Question:** To evaluate an intervention targeting anxiety and reduced quality of life in ICD patients **Design:** Randomized controlled trial	**Outcome(s) and Tools**: Anxiety and depression (Hospital Anxiety and Depression Scale) Psychological distress (Symptom Checklist-Short form) Quality of life (Short Form-36) Fear, and attention, avoidance	**Sample size**: Intervention: 63 Control: 63 **Mean Age (SD):** Intervention: 60.6 (12.55); Control: 61.1 (11.97) **Gender:** [Male %]: Intervention: 91; Control: 92	**Intervention:** Booklet and support phone calls by study therapist focusing on reinforcing physical activity and discussing stages of adjustment post-implantation **Intervention delivered when:** Booklet given and phone calls initiated 10 days after booklet mailed **Frequency and**	No statistically significant difference in any outcome measure After treatment, patients (under 65years) had reduced anxiety and less psychological distress, improved somatic QOL and decreased heart focused attention when compared to	Absence of comparable control treatment Did not meet the powered sample size calculation of N=138 No ICD specific outcome measured

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		(Cardiac Anxiety Questionnaire) **Timing of outcome:** Questionnaires mailed 14 days post-implantation and six months after intervention		**session duration:** Six monthly phone calls **Control group:** Routine checkup at one, three, and six months post implant with an ICD manufacturer booklet provided	age matched control group	
Authors: Irvine et al. **Year:** 2011 **Country:** Canada	**Question:** To evaluate the effectiveness of a cognitive behavioral therapy intervention **Design:** Randomized controlled trial	**Outcome(s) and Tools**: Anxiety (Hospital Anxiety and Depression Scale Phobic anxiety (Crown-Crisp experiential index) Post-traumatic stress disorder (Impact of Events Scale revised) Quality of life (Short Form-36)	**Sample size**: Intervention: 96 Control: 97 **Mean Age (SD):** Intervention: 65.6 (14.3); Control: 63.2 (14.2) **Gender:** [Male %]: Intervention 83.3; Control: 81.4	**Intervention:** Cognitive behavioral therapy based intervention which included a therapist manual, telephone counseling sessions, psychoeducational booklet, CD with mindfulness-based exercises and muscle relaxation exercises. Counseling offered to those who experienced shock therapy.	Statistically significantly lower depression scores in the intervention group compared to the control group for woman ($p = 0.01$) but not men ($p > 0.05$) Within the intervention and control group there was no significant	Exclusion of patients with ischemic heart disease with primary prevention ICD Majority of the participants are male Did not complete statistical analysis comparing the treatment and control group. Only within group analysis

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		Timing of outcome: Baseline, six and 12 months		**Intervention delivered when:** Post-implantation **Frequency and session duration:** Eight counselling sessions. Duration not reported. **Control group:** Routine ICD treatment at the site. Standard educational material regarding heart disease ad ICD	decrease in anxiety from baseline to 12 months but there was a significant decrease in depression scores in the intervention ($p = 0.003$) but not within the control group ($p = 0.500$)	completed No ICD specific outcomes measured
Authors: Cinar, Tosun, & Kose** **Year:** 2012 **Country:** Turkey	**Question:** To determine the experience and need for education of ICD patients and assess effects of an education intervention **Design:** Mixed methods: randomized	**Outcome(s) and Tools**: ICD knowledge (Form for Assessment of Patients' Knowledge Level about ICD) Anxiety (State-Trait Anxiety Inventory)	**Sample size**: Intervention: 27; Control: 27 **Mean Age (SD):** Intervention: 63.41 (11.37); Control: 63.74 (11.00)	**Intervention:** One-on-one education session, questions answered, and educational brochure provided **Intervention delivered when:** Post-implantation (baseline), 15 days	Intervention group had higher knowledge scores than the control group ($p < 0.001$) State anxiety decreased within the intervention	One site limiting generalizability Small sample with no sample calculation for adequate power Measured outcomes at different time

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
	controlled trial and qualitative	Depression (Beck Depression Inventory) Quality of Life (Short Form-36) Semi-structured interviews to determine educational content of intervention **Timing of outcome:** Intervention group: baseline post-implantation knowledge collected, 15 days later the STAI, BDI II and SF-36 collected, 6 months later all outcomes collected again Control group:	**Gender:** [Male %]: Intervention: 77.7; Control: 81.4 **Qualitative:** Individual interviews with only intervention participants which were analyzed using Colaizzi method of analysis.	after baseline and again three months after **Frequency and session duration of intervention:** Two sessions but duration not reported **Control group:** Standard care including routine follow-up every six months	group ($p < 0.001$) but control group had no significant change ($p = 0.245$)	points for the intervention and control group Did not report who delivered the intervention

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		all outcome measures at baseline and again 6 months after				
Authors: Salmoirago-Blotcher et al. **Year:** 2013 **Country:** USA	**Question:** To determine the feasibility, acceptability, sand safety of a phone-delivered mindfulness intervention in ICD patients **Design:** Pilot randomized controlled trial	**Outcome(s) and Tools**: Primary outcomes: recruitment, retention, adherence and treatment fidelity. Secondary outcomes: Mindfulness (Five Facets of Mindfulness) Anxiety (Hospital Anxiety and Depression Scale) **Timing of outcome:** Baseline is post-implantation and	**Sample size**: Intervention: 23 Control: 22 **Mean Age (SD):** Intervention: 66.3 (10.4); Control: 62.9 (10.2) **Gender:** [Male %]: Intervention: 56.5; Control: 81.8%	**Intervention:** Mindfulness-Based intervention delivered by phone with an audio CD containing instructions **When intervention delivered:** Post-implantation **Frequency and session duration:** Eight weekly sessions that lasted 30 minutes **Control group:** To equalize study contact, control group received a ten minute scripted weekly phone call	Intervention is feasible and acceptable to outpatients with ICDs Patients in the intervention group had higher mindfulness scores than the control group ($\beta = 3.31$, $p = 0.04$)	Phone call to control group may have minimized difference between the intervention and control group. Only 13% of eligible patients enrolled Not an ethnically diverse group No a priori targets for success of feasibility outcomes set No ICD

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		again between nine and ten weeks after enrollment		addressing possible concerns for ICD		specific outcomes measured
Authors: Toise et al. **Year:** 2014 **Country:** USA	**Question:** To examine the effects of yoga on decreasing various stress and anxiety related measures **Design:** Pilot randomized controlled trial	**Outcome(s) and Tools**: Device acceptance (Florida Patient Acceptance Survey) Shock Anxiety (Florida Shock Anxiety Scale) Depression (Center for epidemiologic Studies Depression Scale) Anxiety (State-Trait Anxiety Inventory) **Timing of outcome:** Baseline (post-implant) and	**Sample size**: Intervention: 31 Control: 24 **Mean Age (SD):** Intervention: 63.3 (12.0); Control: 69.8 (14.9) **Gender:** [Male %]: Intervention:69; Control: 90	**Intervention:** Yoga with breathing techniques, physical postures, and meditation techniques specific to ICD patients. Monthly call from a cardiac nurse (5 calls total) **Intervention delivered when:** Post-implantation **Frequency and session duration:** Weekly, 80 minute group sessions **Control group:** Regular follow-up at six to nine months at device clinic. Monthly call from a cardiac nurse	Shock anxiety decreased for the intervention group and increased for the control group ($p < 0.0001$). Total device acceptance score not statistically significantly different between the control group and the intervention group	Pilot study reporting on p-values and completed a powered sample calculation is not appropriate for the study design Small sample size

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		eight weeks		(5 calls total)		
Authors: Qintar et al. **Year:** 2015 **Country:** USA	**Question:** To examine the effectiveness of cognitive behavioral therapy **Design:** Pilot randomized controlled trial	**Outcome(s) and Tools**: Anxiety (Generalized Anxiety Disorder-7 and Beck Anxiety Inventory) **Timing of outcome:** Baseline and three, six, 12 months post	**Sample size**: Intervention: 14 Control: 15 **Mean Age (SD):** Intervention: 53.3 (13.3); Control: 54.4 (14.1) **Gender:** [Male %]: Intervention:71.4; Control: 46.7	**Intervention:** Cognitive behavioral therapy sessions with a treatment manual (readings, and relaxation CD) **Intervention delivered when:** Post-implantation by two psychologists **Frequency of intervention:** Three sessions each 45 minutes **Control group:** Verbal reassurances, educational pamphlets on anxiety and contact numbers for additional assistance	No statistically significant difference in anxiety due to the small sample size	Sample size calculation required 50 participants in each group to be powered but did not achieve. High loss to follow-up (>50%)

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
Authors: Cossette et al. **Year:** 2017 **Country:** Canada	**Question:** To assess the feasibility, acceptability, and preliminary efficacy of the PRO-CARE intervention post implantation **Design:** Feasibility randomized controlled trial	**Outcome(s) and Tools**: Feasibility and acceptability of the intervention Shock anxiety (Florida Shock Anxiety Scale) Device acceptance (Florida Patient Acceptance Survey) Anxiety (Hospital Anxiety and Depression Scale) **Timing of outcome:** Baseline (post-implantation) and one month after	**Sample size**: Intervention:15 Control: 15 **Mean Age (SD):** Intervention: 60.17 (11.88); Control: 60.42 (15.36) **Gender:** [Male %]: Intervention:100; Control: 73	**Intervention:** PRO-CARE intervention delivered by nurse based on cognitive behavioral therapy. **Intervention delivered when:** Post-implantation **Frequency and session duration:** Three encounters with the first in hospital prior to discharge and two by telephone after discharge (at one and two weeks) **Control group:** Routine educational and discharge planning and usual follow up	More than 50% of intervention participants received all three encounters 12 out of the 15 intervention patients stated the intervention was acceptable and appropriate and 13 said they would get the intervention again. All 15 were extremely (n=13) or very satisfied (n=2) with intervention Preliminary efficacy in	Not a powered sample size as per feasibility study

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
					favor of the intervention with higher device acceptance scores and lower anxiety and shock anxiety scores compared to the control group but none statistically significant	
Authors: Habibovic et al. **Year:** 2017 **Country:** Netherlands	**Question:** To investigate the effectiveness of the WEBCARE intervention **Design:** Randomized controlled trial	**Outcome(s) and Tools**: Anxiety (Generalized Anxiety Disorder -7, State-Trait Anxiety Inventory, and Hospital Anxiety and Depression Scale) Depression (Patient Health Questionnaire, and Hospital Anxiety and	**Sample size**: Intervention: 146 Control: 143 **Mean Age (SD):** Intervention: 58.2 (9.9); Control: 58.6 (10.2) **Gender:** [Male %]: Intervention: 82.2; Control: 80.4	**Intervention:** Online course based on problem solving and cognitive behavioral therapy **Intervention delivered when:** Post-implantation **Frequency and session duration:** Participants had six sessions to complete on their own time over 12 weeks	No statistically significant differences between intervention and control group at three months on anxiety, depression, health related quality of life, shock anxiety, ICD concerns, and device acceptance.	**Limitations:** Sample size short of the powered sample size calculation of N = 175 in each condition Intervention was specifically modified for Dutch ICD patients reducing its generalizability

Study	Question and Design	Psychological Outcome(s)*	Participants	Treatment Groups	Results	Limitations
		Depression Scale) Health related Quality of Life (Short-Form-12) Device acceptance (Florida Patient Acceptance Survey) Shock Anxiety (Florida Shock Anxiety Scale) **Timing of outcome:** Baseline (one day post-implantation) and again at three, six and 12 months post-implantation		**Control group:** Standard care from hospital	Prevalence rates of anxiety and depression varied within the study depending on the instrument used so the choice of instrument has implications	to Canadian patients Only 23% of the intervention group completed all six intervention lessons Participants were majority wise highly educated men

***Only psychological outcomes were mentioned within this table for each study where some studies may have collected on other outcomes, these were not reported. **Education only intervention examined**

Appendix B: Educational Intervention Checklist

Please check off topics once intervention is completed to indicate the topic has been covered.

Key Topics

ICD indication

- ☐ ICD model
- ☐ Primary and secondary prevention
- ☐ Life-threatening arrhythmia

ICD function

- ☐ Anti-tachycardia pacing (ATP)
- ☐ Shock therapy: appropriate versus inappropriate shocks

Shock plan

- ☐ What a shock may feel like
- ☐ When and where to seek medical attention

Benefits and limitations of an ICD

- ☐ Life-saving against SCD
- ☐ No effect on underlying cardiovascular condition, including CHF

Battery/device replacement

- ☐ How a device/battery is replaced
- ☐ Frequency of replacement
- ☐ Factors influencing battery longevity

Restrictions

- ☐ Physical restrictions
- ☐ Driving restrictions

- ☐ Electromagnetic interference (EMI)
- ☐ Airport security limitations

Identification card

- ☐ Carry your ICD identification card at all times
- ☐ Consider creating a MedicAlert bracelet

Support

- ☐ May experience negative psychosocial response (anxiety, depression)
- ☐ Cardiac rehabilitation
- ☐ Online discussion boards and family/friends
- ☐ Openly access patient education (online and HHS booklet)

Total: 22 topics

Appendix C: Instrumentations

☐ Baseline ☐ 4 Weeks

Patient-Reported Outcomes Measurement Information System Short Form v1.0 – Anxiety 8a [1]

Please respond to each question or statement by checking one box per row.

In the past 7 days…

Statement	Never [1]	Rarely [2]	Sometimes [3]	Often [4]	Always [5]
1. I felt fearful…….	☐	☐	☐	☐	☐
2. I found it hard to focus on anything other than my anxiety…….	☐	☐	☐	☐	☐
3. My worries overwhelmed me……	☐	☐	☐	☐	☐
4. I felt uneasy……	☐	☐	☐	☐	☐
5. I felt nervous……	☐	☐	☐	☐	☐
6. I felt like I needed help for my anxiety…….	☐	☐	☐	☐	☐
7. I felt anxious……	☐	☐	☐	☐	☐
8. I felt tense……	☐	☐	☐	☐	☐

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Florida Patient Acceptance Survey[2]

We want to understand what it is like for you to live with a medical device. Below are some statements that describe living with a medical device. Please rate the extent to which you agree or disagree with each of the following statements by checking the most appropriate box for each question.

Statement	Strongly Disagree [1]	Mostly Disagree [2]	Neither Agree or Disagree [3]	Mostly Agree [4]	Strongly Agree [5]
1. Thinking about the device makes me depressed	☐	☐	☐	☐	☐
2. When I think about the device I avoid doing things I enjoy	☐	☐	☐	☐	☐
3. I avoid my usual activities because I feel disfigured by my device	☐	☐	☐	☐	☐
4. It is hard for me to function without thinking about my device	☐	☐	☐	☐	☐
5. My device was my best treatment option	☐	☐	☐	☐	☐
6. I am confident about my ability to return to work if I want to	☐	☐	☐	☐	☐
7. I am safer from harm because of my device	☐	☐	☐	☐	☐
8. The positive benefits of this device outweigh the negatives	☐	☐	☐	☐	☐
9. I have continued my normal sex life	☐	☐	☐	☐	☐
10. I would receive this device again	☐	☐	☐	☐	☐
11. I know enough about my device	☐	☐	☐	☐	☐
12. I am careful when hugging or kissing my loved ones	☐	☐	☐	☐	☐
13. I have returned to a full life	☐	☐	☐	☐	☐

[2] Burns et al., 2005; Versteeg et al., 2012

Statement	Strongly Disagree [1]	Mostly Disagree [2]	Neither Agree or Disagree [3]	Mostly Agree [4]	Strongly Agree [5]
14. I feel that others see me as disfigured by my device	☐	☐	☐	☐	☐
15. I feel less attractive because of my device	☐	☐	☐	☐	☐
16. I am knowledgeable about how the device works and what it does for me	☐	☐	☐	☐	☐
17. I am not able to do things for my family the way I used to	☐	☐	☐	☐	☐
18. I am concerned about resuming my daily physical activities	☐	☐	☐	☐	☐

Florida Shock Anxiety Scale[3]

We want to understand what it is like for you to live with an ICD. Below are some statements that describe living with an ICD. Please rate the extent to which you agree or disagree with each of the following statements by checking the most appropriate box.

Statement	Not at all [1]	Rarely [2]	Some of the time [3]	Most of the time [4]	All of the time [5]
1. I am scared to exercise because it may increase my heart rate and cause my device to fire	☐	☐	☐	☐	☐
2. I am afraid of being alone when the ICD fires and I need help	☐	☐	☐	☐	☐
3. I do not get angry or upset because it may cause my ICD to fire	☐	☐	☐	☐	☐
4. It bothers me that I do not know when the ICD will fire	☐	☐	☐	☐	☐
5. I worry about the ICD not firing sometime when it should	☐	☐	☐	☐	☐
6. I am afraid to touch others for fear I'll shock them if the ICD fires	☐	☐	☐	☐	☐
7. I worry about the ICD firing and creating a scene	☐	☐	☐	☐	☐
8. When I notice my heart beating rapidly, I worry that the ICD will fire	☐	☐	☐	☐	☐
9. I have unwanted thoughts of my ICD firing	☐	☐	☐	☐	☐
10. I do not engage in sexual activities because it may cause my ICD to fire	☐	☐	☐	☐	☐

[3]Ford et al., 2012

Appendix D: Psychometric Properties of Instruments

Table 1: Psychometric Properties of Instruments

STUDY	**SUBSCALES/DOMAINS**	**NUMBER OF ITEMS**	**RELIABILITY**	**VALDITY**
Florida Patient Acceptance Survey (FPAS)				
Study: Burns et al. (2004)	4 Subscales: Return to Function Device-Related Distress Positive Appraisal Body Image Concerns	15 items with 3 fillers items (9, 11, 16) for a total of 18 items	***Internal Consistency*** Total FPAS: $\alpha = 0.83$	***Convergent validity*** Pearson product-moment correlation coefficients for Short Form-36 Health Survey (SF-36). Total FPAS scores significantly correlated with the eight SF-36 subscales: Physical Functioning ($r = 0.260$, $p < 0.0001$) Physical Role ($r = 0.356$, $p < 0.0001$) Body Pain ($r = 0.206$, $p = 0.004$) General Health ($r=0.470$, $p < 0.0001$) Vitality ($r = 0.359$, $p < 0.0001$) Social ($r = 0.290$, $p < 0.0001$) Emotional Role ($r = 0.321$, $p < 0.0001$) Mental Health ($r = 0.351$, $p < 0.0001$) Atrial Fibrillation Symptoms Severity Scale

STUDY	SUBSCALES/DOMAINS	NUMBER OF ITEMS	RELIABILITY	VALDITY
				(r = -0.241, p = 0.001) Center for Epidemiological Studies-Depression Scale (CES-D) (r = -0.513, p < 0.001) State-Trait Anxiety Inventory (r = -0.425, p < 0.001)
Study: Versteeg et al. (2012)	15 items has 4 Sub-scales: Return to Function Device-Related Distress Positive Appraisal Body Image Concerns 12 items has 3 sub-scales: 4 Subscales: Return to Function Device-Related Distress Positive Appraisal	15 items (used for factor analysis, excluding filler items 9, 11, and 16) 12 items (excluding items 12, 14, and 15) used for validity testing	***Internal Consistency*** Factor 1: Return to Function (α = 0.80) Factor 2: Device-Related Distress (α = 0.75) Factor 3: Positive Appraisal (α = 0.76) Factor 4: Body Image Concerns (α = 0.82) Total FPAS: α = 0.82	***Correlation Matrix*** FPAS is correlated with the Hospital Anxiety and Depression Scale -0.53 and -0.50 (p ≤ 0.001)

STUDY	**SUBSCALES/DOMAINS**	**NUMBER OF ITEMS**	**RELIABILITY**	**VALDITY**
Florida Shock Anxiety Scale (FSAS)				
Study: Kuhl et al. (2006)	2 Subscales Consequence Factor Trigger Factor	10 items	***Test-retest*** Score = 0.79, $p < 0.01$ **Internal consistency** Consequence factor ($\alpha = 0.88$) Triggers factor ($\alpha = 0.74$)	***Discriminant validity*** Multidimensional Fear of Death Scale ($r = -0.65$, $p < 0.01$)
Study: Ford et al. (2012)	2 Subscales Consequences of shock Factor Triggering devices of shock Factor	10 items	**Internal consistency** Total FSAS ($\alpha = 0.89$)	***Convergent validity*** Number of shocks received $r = 0.464$, $p < 0.01$) ICD-shock life disruption ($r = 0.482$, $p < 0.01$) ***Divergent validity*** Pearson Product-Moment Correlations with Quality of Life Measures (single-item indices) Emotional well-being ($r = -0.378$, $p < 0.01$)

STUDY	SUBSCALES/DOMAINS	NUMBER OF ITEMS	RELIABILITY	VALDITY
				Sense of security (r = -0.365, p < 0.01) Quality of life (r = -0.216, p < 0.01) General Health (r = -0.185, p < 0.01)
Patient Reported-Outcomes Measurement Information Systems (PROMIS) - Anxiety				
Study: Schalet et al. (2014)	No subscales	15 items	**Internal consistency** α = 0.98 for total PROMIS scale 15 items correlation (disattenuated correlation) with PROMIS 0.85 (0.91) for Mood and Anxiety Symptom Questionnaire (MASQ) 0.86 (0.91) for Generalised Anxiety Disorder Scale (GAD-7)	IRT cross-walk scoring between PROMIS: correlation between actual and linked PROMIS T-scores MASQ-GA 0.82 GAD-7 0.82 PANAS 0.89

STUDY	SUBSCALES/DOMAINS	NUMBER OF ITEMS	RELIABILITY	VALDITY
			0.89 (0.93) for Positive and Negative Affect Schedule (PANAS)	
Study: Pilkonis et al. (2011)	No subscales	Item bank (29 items)	**Internal consistency** α = 0.79 of total PROMIS short form	***Content validity*** ● Expert consensus ● Comprehensive literature reviews ● Patient feedback ***Convergent validity*** MASQ (r = 0.80) ***Divergent validity*** CES-D (r = 0.75)

Appendix E: Nurse-Led Educational Intervention Guide

(Only for participants randomized to receive educational intervention)

We will review information about your ICD together now. Feel free to stop me and ask questions at any time. I will be writing things down to make sure we are on track, so do not feel that I am ignoring you.

We will be reviewing a lot of information, which you may find overwhelming. Be advised that the information we discuss is available either in the patient education booklet provided to you by the preoperative nurse you just met with and on a website that I will introduce you to.

ICD Model

Let's begin by showing you what an actual ICD looks like (*present mock ICD to patient and show different key features of device, including leads and pulse generator*).

This is where the leads and pulse generator will be placed (*an illustration depicting where the pulse generator and leads are placed will be used to support understanding of ICD placement*).

Let us now log onto a website that is created by an ICD manufacturer, Medtronic (*log onto asktheicd.com and show participant how to use interface*).

ICD Indication

What is a *life-threatening arrhythmia*? It is when your ventricles beat so fast and out of control that the heart is no longer able to pump blood effectively. If this rhythm continues, it can cause you to pass out because your heart is unable to supply oxygen to your brain and body. Without oxygen, your brain and body cannot survive, so this can lead to sudden cardiac death.

There are two circumstances that may result in someone receiving an ICD:

1) Primary prevention: you have never experienced a life-threatening arrhythmia but are at high risk for experiencing one.
2) Secondary prevention: you have previously experienced a life-threatening arrhythmia or sudden cardiac arrest due to a life-threatening arrhythmia.

ICD Function

Now let us review the function of an ICD. There are two main functions of an ICD: one is anti-tachycardia pacing (ATP), and the other is shock therapy.

Anti-tachycardia pacing: The leads sense that your heart is beating fast, so the ICD then delivers short, rapid, controlled bursts of pacing pulses to make the heart beat faster to try and interrupt

the fast heart rate. ATP is generally the first line of treatment to reduce the need for delivering shock therapy. If the ICD delivers ATP, it is usually painless.

Shock therapy: If ATP is unsuccessful in terminating the life-threatening arrhythmia, then the ICD will deliver a shock through the leads to the heart.

- An **appropriate** shock is when the leads correctly sense and shock a life-threatening arrhythmia.
- An **inappropriate** or "unnecessary" shock is when the leads oversense and deliver a shock for a non–life-threatening arrhythmia that would have spontaneously terminated on its own or with ATP.

The ICD stores all this information when a shock is provided or when ATP pacing was initiated. This information is reviewed by the device technician when you come in for your follow-up appointment. This is known as device interrogation.

asktheicd: Let's type in "*how does an ICD work*" and see what you can review at home.

ICD Shocks

Patients experience shocks differently, but some have described a shock feeling like:

- "explosion," "blow," "lightning," "sledgehammer hitting the chest," or "electric shock"

During an active shock, if someone is touching you, they should not feel the shock.

asktheicd: Let's type in *"what should I do if I get shocked."*

ICD Shock Plan

If you were to receive a shock, you should know how to react and when to seek medical attention. There are two potential plans that you can follow.

PLAN A: If you experience one shock but you feel okay and have no symptoms, such as no chest pain or shortness of breath, then it is okay to call the arrhythmia clinic during regular hours.

PLAN B: If you get shocked but do not feel okay and are experiencing symptoms of chest pain, dizziness, light-headedness, or nausea **OR** if you receive multiple shocks in a 24-hour period, you must seek immediate medical attention. You can have someone drive you to the closest emergency room or call 911 if you are alone. You should not be driving if you are following plan B.

Benefits and Limitations of ICD

There are common misconceptions about an ICD that patients may have. Let's go through these so we can clarify the purpose of an ICD.

- An ICD will save you from sudden cardiac death but has no effect on your current underlying cardiovascular condition.
- If you have congestive heart failure, atrial fibrillation, or aortic stenosis, the ICD will not affect or correct these. An ICD will not result in symptom relief or delay your heart failure progression.
- The ICD is proven to lower death rates associated with sudden cardiac death.

Battery/Device Replacement

When it is time to replace the battery, the entire pulse generator needs to be replaced. This means a new incision is made and the generator (*show the ICD model at this point*) is replaced because the battery is inside the generator and cannot be swapped out. If the leads are still in the correct position, they may be used with the new device or your doctor may also replace the leads at this time.

Battery replacement depends on the settings, number of shocks discharged, and how often ATP pacing is used. An ICD can last approximately 4–7 years. The battery will not run out without warning; this is why it is important you attend all of your follow-up appointments routinely because the device technician will be able to tell you when your battery is low.

asktheicd: Let's search "*device replacement.*".

Restrictions

Driving: You are advised to not drive for one month after receiving your implant.

Physical restrictions:

Timeline	**Avoid these activities**	**You can do these activities**
First 24 hours: your arm will be in a sling to restrict your arm movement	Avoid moving your shoulder on the insertion side	You can bend your elbow
First 2 weeks	Do not lift your affected arm over your head	After the first 24 hours, you can move your arm freely below your shoulder. Within 1–2 days after your surgery, you should begin to use your arm; otherwise, you may end up with frozen shoulder. Perform gentle exercises in the form of 8–10 circles in the air 3 times a day by lifting your arm no higher than your shoulder. Do

		shoulder rolls daily on the side of the ICD by slowly rotating shoulders backwards and forwards.
First 6 weeks	Avoid any kind of push or pull over 5 pounds or repetitive movement such as vacuuming, golfing, swimming, bowling, raking, or shoveling.	You may resume most of the same activities you were doing prior to receiving the ICD. You may resume sex when you feel comfortable unless otherwise indicated by your physician.

Do not lift your left arm as you may pull out the leads before they have a chance to attach within the heart. Do not perform any heavy lifting for 4–6 weeks to allow the incision to heal and the leads to settle into place within the heart.

Electromagnetic interference (EMI): EMI is invisible electromagnetic fields around objects that use electricity or transmit wireless signals.

Safe to use:

- ICDs have built-in features to protect them from EMI from most household items, such as
    - Microwaves, hair dryers, electric blankets, computers, TV, vacuum cleaner, CD/DVD player, and radios
- Mammogram, dental equipment, x-ray, ultrasound procedure, EKG machine, or CT scan

Safe to use with precautions: Keep the following at least 6 inches away from your ICD:

- Anything with a magnet
- Cellphones, tablets, computer or other mobile devices. Use your cellphone on the opposite ear to the side where your ICD is implanted. Do not place the cellphone in the breast pocket of your shirt/jacket on the same side as your ICD.
- You also don’t want to keep anything like a tablet or computer on your chest, for example, while you are lying down.
- If you are using headphones, avoid keeping them around your neck while not in use.

Safe to use with extra precautions: Keep the following at least 12 inches (30 cm away) from your ICD:

- Battery-powered cordless AND corded power tools
- Chainsaw
- Lawn mower, leaf blower, slot machines, snow blowers, and stereo speakers

Safe to use with extra precautions: Keep the following at least 24 inches (60 cm away):

- Arc welders
- Running motors and alternators (avoid leaning over running motors)

Not safe to use:

- Body-fat measuring scales
- Jackhammers
- Magnetic mattresses and chairs
- Stun guns
- Magnetic resonance imaging (MRI) – unless physician confirms your ICD is eligible

Airport security: The full-body scanner will not harm your ICD; however, the metal detector will set off the alarm. Thus, do not go through a metal detector. Security may use a hand-held security wand; make sure to notify the guard that you have an implanted device and the wand should not be held over your device for too long as it will affect its functionality. You may ask for a hand-pat search instead in private.

ICD Identification Card

Carry this card with you at all times and notify all of your health care providers that you have the device. Sometimes your ICD may cause security alarms to go off, so you may show your identification card to authorities.

A temporary ICD identification card is provided prior to discharge, and a permanent one is mailed to you by the manufacturer 6–8 weeks after the device is implanted. You may also wear a MedicAlert bracelet or necklace indicating that you have an ICD. The local pharmacy can assist with this.

Where to Seek Help/Support

Due to the feeling of depending on the device for survival, unpredictability of shock therapy, and significant lifestyle changes to be made, some ICD patients report feeling anxious, depressed, or other negative feelings after the ICD is implanted. It is normal to experience these feelings and there are multiple supportive resources that you can use to help you adjust to living with an ICD and help you if you are feeling anxious.

- Your cardiologist can refer you to the cardiac rehabilitation program at Hamilton General Hospital. This will provide you with access to cardiac therapists for physical activity and a social worker for emotional support.
- You can also try searching online for blogs and discussion boards to connect with ICD patients from around the world. This may help you cope as you can relate with others experiencing the same changes you are.

- Don't forget your family and friends are there to help you heal as you go through this life-changing event. They know you best and will be able to provide you with the support you need. You should be able to openly discuss your feelings, thoughts, and concerns with them.
- You have open access to the website (www.asktheicd.com) and the patient education booklet if you need to reference something we discussed. Increasing your knowledge and awareness of what to expect and how to care for your device may help to alleviate the stress of lifestyle changes associated with the device.

Follow-up Visits

You will visit the device clinic 1 week after the implantation, 3 months after, and then every 6 months. These follow-up visits are important in ensuring your ICD is working appropriately and checking the battery life of your device.

Teach Back!

We covered quite a bit of information together; what are some new things you learned today? What are some things you already knew?

Conclusion

Do you have any questions or concerns? (*Refer back to initial preoperative interview guide for concluding remarks*.)

Table A1: Content Included and Related Supporting Literature

Table A1 outlines the rationale and content for each topic in the educational intervention. The *rationale* is evidence based, dictating the intention for including the specific topic. The *content* outlines the source of the specific information related to that topic discussed in the educational intervention.

Intervention Guide	Supporting Literature
ICD model: Patients will be presented with an actual ICD and shown where it will be implanted (in particular where the leads will be placed).	***Rationale:*** Patients are surprised at the size of the device and location of implantation. Patients also report that the site is painful and restricts arm movement (Angelidou, 2009; Humphreys et al., 2016). ***Content:*** Patients will have the opportunity to hold an ICD model. An illustration depicting an ICD and where leads are placed within the heart will be shown to patients to support their understanding of device placement (Medtronic, 2014).
ICD indication: Both indications for an ICD,	***Rationale:*** Patients lack an understanding of

primary and secondary, will be discussed as well as an explanation of a life-threatening arrhythmia.	the reason they have received or are receiving an ICD; as such, it is important to provide them with information pertaining to the indication (Ooi et al., 2016; Zayac & Finch, 2009). ***Content:*** The definitions of both primary and secondary prevention will be discussed, as well as life-threatening arrhythmia (Bennett et al., 2017; Boston Scientific, 2017; Medtronic, 2014).
ICD function: There are two main functions of an ICD: one is anti-tachycardia pacing (ATP), and the other is shock therapy. • Anti-tachycardia pacing • Shock therapy (appropriate versus inappropriate shock)	***Rationale:*** Educating patients on the function of the ICD is a critical component to include during teaching, ensuring that patients are fully aware of how the device works (Angelidou, 2009; Clark et al., 2011; Ford et al., 2011; Ooi et al., 2016; Sears et al., 2009). Knowing how the device works may also be reassuring for patients (Ford et al., 2011) ***Content:*** Explanation of both anti-tachycardia pacing and shock therapy will be included ((Boston Scientific, 2017; Hamilton Health Sciences, 2016; Medtronic, 2014).
ICD shocks: • Describe how a shock feels using terms from ICD patients in the literature. **ICD shock plan:** • Outline the two-pronged plan on what to do if you get shocked. • Clearly delineate the steps for patients on when to seek medical attention after receiving a shock.	***Rationale:*** All participants in this study are first-time ICD recipients and have never experienced an ICD shock before. Providing participants with an idea of what to expect in terms of physical sensation during shock discharge is often included in patient educational material and may prepare participants for the experience (Angelidou, 2009; Dunbar et al., 2012; Strachan et al., 2012). Moreover, a "shock plan," delineating that a participant's actions during a shock discharge may increase a patient's confidence in coping with a shock (Clark et al., 2011; Ford et al., 2011; Kuhl et al., 2006). ***Content:*** The terms patients have used in qualitative studies to describe the feeling of a shock will be discussed (Cinar et al., 2013; Clark et al., 2011; Humphreys et al., 2016; Ooi et al., 2016). Additionally, a plan A and a plan B are outlined so that patients are clear on where and when to seek medical attention after

	experiencing a shock (Hamilton Health Sciences, 2016; Medtronic, 2014).
Benefits and limitations of an ICD: • Life-saving against sudden cardiac arrest but no effect on underlying cardiovascular condition • Lack of effect of ICD on all-cause mortality, delay of heart failure progression, symptom relief (breathing, exercise) • The device is associated with lower mortality	***Rationale:*** Clarification of misconceptions identified in the literature is necessary by reviewing the function and purpose of an ICD (Boston Scientific, 2017; Cinar et al., 2013; Clark et al., 2011; Dunbar et al., 2012; Groarke et al., 2012; Medtronic, 2014). ***Content:*** Explicitly informing patients what the ICD cannot do for their heart condition will clarify their understanding of the limitations of the device (Clark et al., 2011; Dunbar et al., 2012).
Battery/device replacement: • Device replacement – how often, how it works • Battery longevity – will not deplete without warning	***Rationale:*** ICD patients should know how long the battery life of the device is as well as how battery replacement works (Clark et al., 2011; Dunbar et al., 2012). Patients worry that the battery may deplete without warning; thus, clarifying this misconception is important (Dunbar et al., 2012). ***Content:*** Clarifying how battery replacement is completed as well as the frequency of replacement is important. Moreover, patients should also be specifically educated on the factors affecting longevity of the battery (Boston Scientific, 2017; Medtronic, 2014).
Restrictions: • Driving (licence in Ontario) • Physical restrictions • Electromagnetic interference: what to avoid and how much distance to maintain from certain objects • Airport security: how to safely pass through airport security	***Rationale:*** The literature suggests that patients do not receive all necessary information regarding restrictions post-ICD implantation (Clark et al., 2011; Ooi et al., 2016). ICD patients are reported to engage in avoidance behaviours involving avoiding specific places, objects, and activities in fear of eliciting a shock from the ICD (Lemon et al., 2004). These avoidance behaviours subsequently affect the quality of life of ICD patients; thus, ensuring that patients understand the extent of the restrictions post-implantation may facilitate appropriate adjustment (Lemon et al., 2004; Ooi et al., 2016). The literature reveals that the learning needs of ICD patients specifically include driving restrictions, resuming sexual and physical activities, and appropriate use of electrical appliances (Angelidou, 2009; Clark

	et al., 2011; Dunbar et al., 2012; Ford et al., 2011; Ooi et al., 2016). ***Content:*** Driving restrictions are retrieved from Hamilton Health Sciences (2016). Physical restrictions, electromagnetic interference, and airport security restrictions are included (Angelidou, 2009; Boston Scientific, 2017; Hamilton Health Sciences, 2016; Medtronic, 2014).
ICD identification card: • Carry the ICD identification card at all times and notify all health care providers of your ICD. • Consider wearing a MedicAlert bracelet or necklace.	***Rationale:*** All ICD patients should carry their ICD identification card and consider making a MedicAlert bracelet to alert medical and security personnel that they have an ICD (Boston Scientific, 2017; Clark et al., 2011; Hamilton Health Sciences, 2016). ***Content:*** Patients are given a temporary identification card upon discharge, and a permanent one is mailed out within 8 weeks of implantation (Boston Scientific, 2017; Hamilton Health Sciences, 2016; Medtronic, 2014).
Where to seek help/support: • Raise patients' awareness of the potential for negative psychosocial feelings, such as anxiety and depression • Provide resources for support, including online support groups, their family and friends, ICD health team, cardiac rehabilitation (at HHS), and online resource (asktheicd.com).	***Rationale:*** Patients should be encouraged to seek support from multiple resources and be aware of the support network available to them (Ford et al., 2011; Hoogwegt et al., 2014; Zayac & Finch, 2009). Patients report dissatisfaction with information provision regarding psychological and social consequences; thus, an explicit discussion on the potential for experiencing psychosocial consequences should take place (Hoogwegt et al., 2014; Pedersen et al., 2017). Normalizing these potential psychosocial concerns may allow patients to feel a greater sense of control over their situation and device (Angelidou, 2009; Braunschweig et al., 2010). ***Content:*** Prompting of various support resources, such as the cardiac rehabilitation program at Hamilton General Hospital, online discussion boards, friends and family, as well as the ICD health team, will be provided. Patients will be encouraged to routinely access the Medtronic website and Hamilton Health

	Sciences patient education booklet as needed when questions or concerns arise.
Follow-up visits: • Patients should be notified of the importance of attending routine follow-up visits (every 6 months). • The goal of follow-up appointments should also be discussed.	***Rationale:*** Patients must be prepared to commit to attending routine follow-up appointments (Clark et al., 2011; Zayac & Finch, 2009). Some patients may need to make arrangements for transportation in advance; as such, notifying them of the frequency of appointments can be helpful. ***Content:*** Post-ICD implantation follow-up appointments will be arranged at 1 week, 3 months, and then every 6 months thereafter in the arrhythmia clinic (Hamilton Health Sciences, 2016).
Teach back: • Providing patients with an opportunity to explain what they have learned in their own words is one way to ensure that comprehension of education is achieved.	***Rationale:*** The overwhelming amount of information, compounded by anxiety, can affect the comprehension of information (Groarke et al., 2012). Despite the provision of patient education, there are existing gaps in learning. Thus, asking patients to "teach back" salient information to the nurse researcher may help clarify their understanding. ***Content:*** Patients will be provided with an opportunity to openly discuss what they have learned to demonstrate their understanding.
Conclusion: • Patients are given an opportunity to clarify any content discussed, ask questions about the asktheicd.com site, and have any other concerns addressed.	***Rationale:*** Providing patients with an open opportunity to address any concerns pre-implantation may help reduce their negative psychosocial adjustment post-implantation (Dunbar et al., 2012; Ford et al., 2011; Pedersen et al., 2017). ***Content:*** To conclude the educational intervention session, patients will be given an open opportunity to address any outstanding concerns or questions they may still have.

Appendix F: Initial Telephone Contact Guide

All potential participants to receive this phone call for initial contact once patient has agreed with booking clerk to be contacted by nurse researcher.

Introduction

Hello (patient name). I'm Jasprit, a nurse who is working with Dr. Carroll at McMaster University and the cardiac specialists in the arrhythmia clinic at Hamilton General Hospital. We are conducting a study as a part of my master's program. I am calling you because the booking clerk indicated you would be interested in hearing about the study. Is this correct?

First, let's go over some of the key details of the study so that you can decide if you are interested in participating. This will take about 10 minutes. I will review the participant information sheet with you and answer any questions you have (*review participant information sheet and obtain verbal consent to meet with nurse researcher during preoperative appointment*).

End of Conversation

Thank you for taking the time to listen to the study details. Are there any other questions you have at this time? My contact information is pannagj@mcmaster.ca or 905-525-9140 extension 21431. If you have any questions or concerns after this phone call, please feel free to contact me. I look forward to meeting you on [*enter date of preoperative appointment*]. Have a great day!

Appendix G: Participant Demographic Form

Feasibility of Educational Intervention Study – Baseline Visit (page 1 of 6)
All participants to complete

Study ID # | | | |

Inclusion criteria: ◯ First primary prevention ICD ◯ ≥ 18 years of age
◯ ICD implantation date booked ◯ Ability to consent autonomously

Randomization date (also the preoperative appt. date): _____

Treatment group: ◯ Standard care ◯ Intervention

Date of birth: _____ (MM/DD/YYYY)

Sex: ◯ Male ◯ Female

ICD surgery date: _____

Actual implant date: _____

1. Background medical history: *Fill in ALL the options that apply.*

◯ Previous MI ◯ Atrial fibrillation ◯ Diabetes

◯ Hypertension ◯ CHF

2. Highest level of education: *Select only ONE option.*

◯ No degree, certificate, or diploma
◯ High school graduation certificate
◯ College certificate or diploma
◯ Trade certificate or diploma
◯ Bachelor's degree from university
◯ Graduate/professional (master's degree or PhD)

Feasibility of Educational Intervention Study – Baseline Visit (page 2 of 6)

All participants to complete

Study ID # | | | |

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3. Living status: *Select only ONE option.*

○ Live alone ○ Do not live alone

4. Employment status: *Select only ONE option.*

○ Working full-time ○ Working part-time ○ Retired ○ Disability

5. Do you access health information using the Internet? *Select only ONE option.*

○ Yes ○ No

6. Do you have Internet access at home? *Select only ONE option.*

○ Yes ○ No

7. Contact information:

Email address: | | | | | | | | | | | | | | | |

Work/home phone: | | | | | | | | | | |

Cellphone: | | | | | | | | | | |

8. Best time of day to reach by telephone:

○ 8:00 a.m–11:00 am ○ 12:00 pm to 3:00 pm ○ 4:00 pm to 6:00 pm ○ 7:00 pm to 9:00 pm

Feasibility of Educational Intervention Study – Baseline Visit (page 3 of 6)
All participants to complete

Study ID # | | | |

Date to initiate contact (4 weeks from surgery date): _____

Date attempts made to contact: **(MM/DD/YYYY)**

1: _____

2:_____

3:_____

9. Outcome measures completion (checkmark if completed in full):

☐ PROMIS at baseline

10. Was gift card mailed out to patient? ◯ Yes ◯ No

Mailing address for patient: _____

_____

11. Length of time in minutes to complete consent forms | | | |

Feasibility of Educational Intervention Study – Baseline Visit (page 4 of 6)

Intervention group to complete

Study ID # | | | |

---

1. Did patient receive the intervention? ○ Yes ○ No

If patient allocated to receive intervention and did not, then please provide a reason why:

_____

_____

2. Number of key topics completed from checklist: | | |

3. Number of minutes intervention completed within: | | |

Feasibility of Educational Intervention Study – Visit 2: 4-Week Telephone Follow-up
(page 5 of 6)
Standard care participants to complete

Study ID # | | | |

---

1. Did you access any additional resources other than the booklet?

◯ Yes ◯ No

2. What other resources did you access?

_____
_____
_____

3. If answered "yes" to question 2: Did you access these before the ICD surgery?

◯ Yes ◯ No

4. Outcome measures completion: *(checkmark if completed in full)*

☐ PROMIS at 4 weeks ☐ FPAS at 4 weeks ☐ FSAS at 4 weeks

Feasibility of Educational Intervention Study – Visit 2: 4-Week Telephone Follow-up
(page 6 of 6)
Intervention group to complete

Study ID # | | | |

---

1. What is the number of times you would say you accessed the website after our last meeting?

2. Did you access any additional resources other than the website or booklet?

◯ Yes ◯ No

3. What other resources did you access?

_____

_____

_____

4. If answered "yes" to question 2: Did you access these before the ICD surgery?

◯ Yes ◯ No

5. Outcome measures completion: *(checkmark if completed in full)*

☐ PROMIS at 4 weeks ☐ FPAS at 4 weeks ☐ FSAS at 4 weeks

Appendix H: Interview Guide for Telephone Follow-up Call at 4 Weeks Post-implantation

All participants to receive this phone call to complete the 3 questionnaires

Introduction

Hello, this is Jasprit speaking. We met at your preoperative ICD appointment on [*insert date*] at the Hamilton General Hospital. I am calling to follow up on our meeting and to review the forms in the envelope I gave you at our meeting. Did you have a chance to look them over? Do you have 10–15 minutes at this time to review the forms? (*If patient prefers another time/date, please confirm when*.)

Okay, let us first review the form entitled "PROMIS Tool" (*review each question and mark down participant's response*). Now we will review the form titled "The Florida Patient Acceptance Scale" (*review each question and mark down participant's response*). Finally, we will review the last form titled "Florida State Anxiety Scale" (*review each question and mark down participant's response*).

Questions specifically for participants in the intervention group only:

1) Did you revisit the website (www.asktheicd.com) we accessed together? If so, how many times?
2) Did you access any other additional resources other than the website or the booklet the clinic nurse provided to you? What resources did you access? Did you access these before the ICD surgery?

Questions specifically for participants in the standard care group only:

1) Did you access any other additional resources other than the booklet the clinic nurse provided to you? Did you do so before? If so, please specify which resources were accessed.

End of Conversation

I would like to thank you for your time. Do you have any questions? Once again, you have my contact information if you have any questions or concerns after this phone call. I will be mailing out your gift card to the address you noted on the form filled out at your last visit. Thank you for your time. Enjoy the rest of your day!

Appendix I: HiREB Consent Form

PARTICIPANT INFORMATION/CONSENT

Feasibility Study of a Nurse-Led Educational Intervention for Primary Prevention Implantable Cardioverter Defibrillator (ICD) Candidates

Local Principal Investigator:
Dr. Sandra Carroll
Department of Nursing
McMaster University
Hamilton, ON, Canada
(905) 525-9140 ext. 22400
carroll@mcmaster.ca

Student Investigator:
Jasprit Pannag RN
Department of Nursing
McMaster University
Hamilton, ON, Canada
(905) 525-9140 ext. 21431
pannagj@mcmaster.ca

Sponsor: No sponsor

Invitation to participate in research:

You are being invited to participate in this research study because you are scheduled to receive an implantable cardioverter defibrillator (ICD). This study is part of a student master's project conducted under the supervision of Dr. Sandra Carroll at McMaster University.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and any potential risks and benefits. This form gives you detailed information about the study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family. Choosing not to participate will in no way affect your care.

Why is this study being done?

Many patients receive ICDs at Hamilton Health Sciences. Some patients need support to adjust to living with their new medical device. We would like to deliver the best care to our ICD patients, and part of what we would like to explore is how feasible it is to add an additional educational support during the preoperative appointment. In order to do this, we are conducting this research to determine the practicality of this educational support and how it will affect adjustment to the device in the early post-implantation period.

How many participants will be in this study?

We are inviting approximately 30 patients to participate in this study.

What will happen during the study?

If you choose to participate, you will meet with the nurse researcher directly after your preoperative appointment with the arrhythmia nurse specialist. At this time, you will be asked to complete one questionnaire with 8 questions about anxiety (5 minutes), demographic questions such as age, and your heart history (5 minutes). If required, the nurse researcher will collect demographic and heart history information from your medical record. You will then be assigned to receive the educational session (maximum of 45 minutes) or carry on with the usual appointment process. We assign you by "randomizing" you to one of the two groups. This is like flipping a coin. At the end of this meeting, you will be asked to provide contact information (email and/or telephone) so that we may contact you 4 weeks after your ICD is implanted to complete three brief patient-centred questionnaires over the telephone.

Are there any risks to doing the study?

The risks involved in this study are minimal. It is not likely that any physical discomfort will occur to you in this study. You may worry about how others will react to what you say. It is possible that you may find it overwhelming to receive the ICD education if you are assigned to the educational support group. You may also find it stressful or uneasy to answer some of the questions on the questionnaires. You do not need to answer questions you do not want to answer. You can stop to take a break or stop taking part in the study at any time. We describe below the steps we are taking to protect your privacy.

Are there any benefits to doing this study?

We cannot guarantee any personal benefits to you from your participation in this study. It is possible that if you receive the educational session you may have more information available to you, which may help you have a better understanding of adjustment to the ICD. This additional information may also result in you having more concerns you want to discuss with your doctor or nurse. This study may not benefit you directly, but we hope to learn more about the possibility of introducing an educational session into the preoperative setting for ICD candidates.

Payment or Reimbursement

To show our appreciation for your participation in this study, we will be providing you with a $10 gift card to a local coffee shop.

How will we keep your information private?

Your participation in this study will be kept confidential. We will not use your name or any information that would allow you to be identified. Your name will be replaced with a study number. No one but the research team (such as the research assistant) will know that you participated unless you choose to tell them. The information/data you provide is kept in a locked desk/cabinet where only research team members have access. Information kept on the computer is password protected. Once the study is complete, the data will be destroyed.

What if I change my mind about being in the study?

Your participation in this study is voluntary. If you decide to be a part of the study, you may stop (withdraw), at any time, even after signing the consent form or partway through the study. If you decide to withdraw, there will be no consequences to you. If you do not want to answer some of the questions you do not have to, but you can still be a part of the study. Your decision whether or not to be part of the study will not affect your care at Hamilton Health Sciences.

How do I find out what was learned in this study?

If you would like a brief summary of the study results, please let us know how you would like it sent to you.

Questions about the Study

If you have questions or need more information about the study itself, please contact the nurse researcher at pannagj@mcmaster.ca or 905-525-9140, extension 21431.

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, HiREB, at 905.521.2100 x 42013.

CONSENT

I have read the information presented in the information letter about a study being conducted by Dr. Carroll and Jasprit Pannag of McMaster University. I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.

I understand that if I agree to participate in this study, I may withdraw from the study at any time. I have been given a signed copy of this form. I agree to participate in the study.

1. I would like to receive a summary of the study's results. *Yes* *No*

If yes, where would you like the results sent:

Email: _____

Mailing address: _____

_____

_____

2. I agree to be contacted about future research and
I understand that I can always decline the request. *Yes* *No*

Please contact me at _____

_____ _____ _____
Name of Participant (Printed) Signature Date

Consent form explained in person by:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in the study.

_____ _____ _____
Name and Role (Printed) Signature Date