FEMALE-SPECIFIC EDUCATION, MANAGEMENT, AND LIFESTYLE ENHANCEMENT FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PATIENTS: THE FEMALE-ICD STUDY

By

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FEMALE-SPECIFIC EDUCATION, MANAGEMENT, AND LIFESTYLE ENHANCEMENT FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PATIENTS: THE FEMALE-ICD STUDY

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Significant rates of psychological distress occur in implantable cardioverter defibrillator (ICD) patients. Research has demonstrated that women are a particularly at-risk group for developing psychological distress secondary to cardiac disease. The major objectives of the current study were to implement and test the effectiveness of a psychosocial group intervention in outpatient female ICD recipients vs. a wait list control group.

Twenty-nine female ICD patients were recruited from Shands Hospital at the University of Florida. Fourteen women were randomized to the intervention group and 15 the wait list control group. All women completed individual psychological batteries at baseline and at one-month follow-up measuring shock anxiety, death anxiety, body image concerns, and sexual dysfunction.

Pre-post measures of shock anxiety demonstrated a significant time by group interaction effect with the intervention group having a significantly greater decrease in anxiety ($Pillai’s trace = 5.58, p = .03$) than the control participants. A significant interaction effect ($Pillai’s trace = 5.05, p = .046$) was found, such that women under the age of 50 experienced greater reduction in shock anxiety, than their middle-aged cohorts. Pre-post measures of device acceptance revealed a significant time by group interaction effect with the intervention group having
significantly greater increases in reported device acceptance \((Pillai's \ trace = 5.80, p = .02)\) than the control participants. Young women reported greater increased in device acceptance than both the middle- and older-aged groups, and women between the ages of 51 and 64 reported higher rates of device acceptance increase than women over 65.

This study indicates that structured interventions for female ICD patients involving ICD-specific education, CBT strategies, and group social support can provide improvements in shock anxiety and device acceptance. Young women appear to be an at-risk subgroup of this population and would benefit from psychosocial treatment targeting device-specific concerns.
CHAPTER 1
INTRODUCTION

Sudden cardiac death (SCD) is the leading cause of mortality in adults. The implantable cardioverter defibrillator (ICD) has emerged as the treatment modality of choice and has proved superior to medication alone in large scale trials in at risk patients.1-6 The ICD attempts to detect and correct potentially lethal arrhythmias through delivery of an automatic cardioverting shock to the heart.

Despite the success of the ICD in preventing premature mortality in patients at risk for SCD, the psychological effects of living with an ICD can be considerable, with estimates of clinical levels of anxiety and depression at 13-38% and 9-15%, respectively.7 Recent studies reported relatively higher rates of depression among ICD patients in the United States (38%) and in Turkey (41%), that appear to be related to measurement differences.8,9 Quality of life (QOL) research has revealed that ICD recipients report as good or better levels of QOL, compared to patients treated with anti-arrhythmics alone.10,11 However, ICD patients also experience concerns with the potential for shock,12 their potential mortality,13 how the device interferes with socialization,11 and concerns with sexual functioning.11

Specific at-risk groups of ICD recipients have been identified and include patients who are female, under the age of 50, and those with a history of shock.14 While the unequivocal impact of ICD implantation on these groups has not been defined, women with cardiovascular disease are thought to be more susceptible to psychosocial distress due to a variety of biopsychosocial factors.15-21 Shock anxiety, death anxiety, and the ostensible change in physiognomy subsequent to implantation are thought to influence the development of distress in female device recipients. The physiological stress reaction in females may also contribute to the psychosocial adjustment of living with an ICD. Initial intervention studies show that the use of
cognitive behavioral therapy (CBT) with ICD patients can result in decreases in depression\textsuperscript{22,23} and anxiety,\textsuperscript{22,23} and increases in perceived adjustment\textsuperscript{22} and QOL.\textsuperscript{23} Sears and colleagues compared a CBT stress and shock management program for ICD patients delivered in either a one-day workshop or six-weekly group sessions. Results revealed a reduction of anxiety ($p < .05$) and cortisol concentration ($p < .05$) in both the one-day workshop format and the six-week format, suggesting that interventions involving ICD education and CBT strategies can reduce psychological distress, even in a one-day format.\textsuperscript{24}

Our recent research with a multi-site, international sample of ICD patients\textsuperscript{25} ($N = 189$) investigated the intersex psychosocial differences between men and women, and the intrasex psychosocial differences among younger, middle-aged, and older-aged females on measures of shock anxiety, death anxiety, and body image concerns. Results showed that young women (under the age of 50) reported significantly higher mean shock anxiety ($p = .018$), death anxiety ($p = .005$), and body image concerns ($p = .018$) than their older-aged cohorts. While no significant differences were found between men and women, both groups reported clinical levels of distress across the domains of shock anxiety and death anxiety. Similarly, women reported clinical levels of body image concerns, while their male counterparts did not. These data represent the first empirical evidence of gender-specific and age-specific concerns among ICD patients. Results suggest that younger female ICD recipients are at risk for the development of distress and may benefit from attention to the unique issues women face after implantation of a cardiac device.\textsuperscript{25}

The main objective of the current study is to examine a one-day CBT intervention specifically tailored to female ICD patients, across a variety of psychosocial markers of distress. The primary endpoints include shock anxiety and death anxiety. Secondary endpoints include
body image concerns and sexual functioning. This study will provide insight into the unique experience of being a woman with an ICD, and will examine the first female-specific psychosocial intervention study of female ICD recipients.
Sudden cardiac death accounts for over 450,000 deaths per year in the United States and is currently the highest ranked cause of mortality, claiming more lives annually than stroke, lung cancer, breast cancer, and AIDS combined. Sudden cardiac death is precipitated by the onset of potentially life-threatening ventricular tachyarrhythmias, resulting in death if not promptly defibrillated (e.g., within 10 minutes). The ICD is a biomedical device designed to contravene potentially lethal arrhythmias by automatic delivery of an electrical cardioverting shock to defibrillate the heart and restore normal sinus rhythm. The ICD had been identified as the treatment modality of choice for patients at risk for arrhythmias. Many large-scale, randomized, controlled trials investigating the efficacy of the ICD compared to traditional pharmacotherapy have shown that the ICD is superior in preventing premature mortality. The ICD is now implanted in approximately 150,000 Americans each year and implant rates are likely to continue rising dramatically, as treatment indications are broadened.

Despite the superiority of the ICD in its ability to prevent premature death, the effects of living with a device can be distressing for patients. Approximately 15% of ICD patients experience clinically significant symptoms of psychological distress related to their device. Sears and colleagues found that ICD patients have similar rates of depression as the general population, with 12-24% reporting depressive symptoms and 9-15% meeting criteria for clinical depression. However, rates of anxiety symptoms in ICD patients exceed those of the general population, with 24-28% reporting symptoms of anxiety, and 13-38% meeting criteria for a diagnosable anxiety disorder.

Quality of life (QOL) has emerged as an endpoint of interest for many researchers investigating the psychological adjustment of ICD patients. Studies show that roughly 91% of
ICD patients return to previous levels of QOL within the first year of implantation.⁷,²⁷ Compared to patients at risk for arrhythmias who are treated pharmacologically, ICD patients report as good or better levels of QOL¹⁰ except across the domains of pain and social functioning.⁵ A study of young adults with ICDs¹¹ found that patients reported improved health since implantation, ability to engage in moderate levels of physical activity, and capability to perform activities of daily living. However, patients also reported concerns with how their clothing fit, how the ICD interfered with their levels of socialization, and concerns with sexual functioning. Schron and colleagues¹² revealed that experiencing more than one shock within the first year after implantation is associated with decreased physical and mental QOL. In summary, while QOL for the majority of ICD patients is desirable, significant concerns may persist, particularly for patients with a history of shock.

Researchers have identified specific groups of ICD patients who may be at an increased risk for psychological maladjustment.¹⁴ These include young patients under the age of 50, females, those with a poor understanding of their device, those with comorbid medical diagnoses, those with a premorbid history of psychological distress, and those who experience shock episodes during which they receive three or more consecutive shocks (also known as ICD ‘storm’). Through identifying risk factors and particularly at-risk groups, we are able to increase our clinical attention to those patients whom may be most likely to develop psychological distress and create more tailored forms of psychological intervention. Implantable cardioverter defibrillator patients are vulnerable to the development of psychological distress due to many factors, including ICD shock, the recognition of their potential mortality by cardiac disease, and the perceived lack of control over their medical condition.⁷ As such, ICD patients have been recognized as an appropriate population for the study of the development of distress.²⁸
Female Cardiovascular Patients: Biopsychosocial Research

Distinct differences are evident in the presentation of CVD between men and women. For example, women suffer from myocardial infarctions (MI) as often as men, but the peak incidence of MI is approximately twenty years later than in men. Similarly, coronary disease in women develops an average of ten years later than in men. While MI and SCD are the more frequent presentations of coronary heart disease (CHD) in males, angina pectoris (chest pain) is the predominant initial presentation of CHD in females. The Women’s Ischemia Syndrome Evaluation (WISE) study produced a large body of evidence that there exist gender differences in the prevalence, presentation, and outcomes of CVD. Despite these gender differences in the presentation of CVD, men and women have the same risk factors, and CVD remains the leading cause of death for both genders. However, while cardiovascular mortality in men decreased between the years of 1997 to 2001, rates among women steadily increased.

Gender differences in general cardiac physiology have also been well established. Differences in electrocardiogram (ECG) readings have revealed that women have a faster resting heart rate, a longer QT interval, and a lower QT dispersion than do men. Women also have a higher incidence of Torsades de Pointes, of mortality after the development of atrial fibrillation, and of supraventricular tachycardia. It has been hypothesized that reproductive hormones play a considerable role in the presentation of arrhythmias, by modulating myocardial repolarization.

In addition to the gender differences in general CVD presentation, there also exist gender specific psychological differences among cardiac populations. Research has recognized females with cardiac illness as a particularly at-risk group for the development of psychological distress secondary to their disease. According to the literature, women experience a higher incidence of depression and anxiety after MI, stent implantation, or CHF, in comparison with males.
This presents a considerable risk of poorer health outcomes for females, as increased anxiety and depression after MI is associated with higher risk of complications and mortality. Among populations of patients with congestive heart failure (CHF), females have consistently exhibited worse QOL than males as well as increased rates of depression. Since CHF patients frequently require ICD implantation congruent with their cardiac disease progression, this population of females is explicitly at risk for adjustment difficulties.

While the development of CVD and subsequent ICD implantation has traditionally been seen as an exclusively male disease, women are now increasingly more likely to receive an ICD as the indications for implantation have grown over recent years. Despite the growing population of women who receive ICDs, gender differences among arrhythmia patients have been traditionally under researched. However, it has been recognized that female ICD patients are more likely to be shocked than their male counterparts, although the etiology of this anomaly is seemingly unknown, since their overall risk of SCD is lower than their male counterparts. Women are highly at risk for the development of distress after ICD implantation, possibly due to body satisfaction issues, sexuality, femininity, and socialization. The development of psychological interventions that are specifically tailored to the unique needs of females may be a step towards providing women with appropriate facilitative care. Interventions could include education about the ICD, coping and relaxation skills training, and supportive therapy focused on specific female needs, including social support, body image concerns, and other age-specific concerns. Women tend to turn to their social support system in times of stress, suggesting that interventions that utilize a group format may be most helpful.

**Female Stress Response**

Research has shown that there exist pronounced sex differences in stress responsiveness. The physiological response to stress involves the hypothalamic pituitary
adrenal axis (HPA), which can be provoked by a variety of physical, mental, and social situations.\textsuperscript{52} The traditional conception of the biobehavioral stress response has been the “fight-or-flight” response, which suggests that humans respond to threat by becoming aggressive or by avoidant coping.\textsuperscript{53} However, this model is incomplete as it lacks the integration of the concept that as humans experience stress, they have the distinct tendency to affiliate.\textsuperscript{51,54} Taylor has labeled this social response to stress the “tend-and-befriend” response.\textsuperscript{51} She asserts that when oxytocin is released in response to stress, it prompts affiliative behavior, in conjunction with dopaminergic and opioid systems.\textsuperscript{53} Animal studies have established that oxytocin does in fact promote affiliation\textsuperscript{55} and is also thought to underlie affiliative processes in humans.\textsuperscript{53,56}

Gender-specific differences in the stress response of females are thought to be mediated by oxytocin and endogenous opioids.\textsuperscript{57} Women consistently show stronger affiliative processes in response to stress when compared to men.\textsuperscript{53} Estrogen enhances the effects of oxytocin which further supports a greater role of the hormone in females than in males. As a result, the “tend-and-befriend” response is now considered a more appropriate stress response pattern in women than the acknowledged “fight-or-flight” response.\textsuperscript{57} Although the “fight-or-flight” response may characterize the primary physiological stress response for both men and women, biobehaviorally, the “tend-and-befriend” response is the more marked pattern in females.\textsuperscript{51}

The impact of stress associated with medical illness has traditionally overlooked the issues specific to women.\textsuperscript{58} The impact of the development and treatment of CVD in females has been described by women in distinctly feminine constructs.\textsuperscript{58} For example, family role functioning has been shown to be as predictive of the development of CVD as are biomedical risk factors.\textsuperscript{59} Psychosocial factors such as multiple role responsibilities and chronic life stress have been identified as critical to the understanding of the health status of women with CVD.\textsuperscript{60}
Although women on average report more stress than do men\textsuperscript{61} effective coping methods for women have resulted in improvement in QOL and an overall reduction and reported stress symptoms.\textsuperscript{62} Interventions that utilize a group format that offer women essential social support,\textsuperscript{58} that provide an opportunity to discuss the meaning of having a potentially life-threatening condition,\textsuperscript{58} and that instruct women in coping strategies for dealing with emotional stress after a cardiac event\textsuperscript{62} have resulted in significant benefits among females with CVD.\textsuperscript{63}

**Shock Anxiety**

To prevent SCD in the event of an arrhythmia, the ICD attempts to detect and correct the potentially life-threatening arrhythmia by the delivery of a 35-joule shock to the patient’s heart. Shock has been described by patients as similar to a swift kick in the chest and is rated a “6” on a 0 to 10 pain scale.\textsuperscript{64} Within the first year of implantation, the overall rate of prevalence of ICD shocks ranges from 10.3\% to 38.5\%, depending on the use of anti-arrhythmics in conjunction with ICD therapies.\textsuperscript{65} In short, shock may be a common experience for many ICD patients.

Research has suggested that the occurrence of shock can often be a precursor to adjustment difficulties in ICD patients. Godemann and colleagues\textsuperscript{66} found that ICD patients who experienced shock were more likely to meet criteria for this disorder (17\% non-shocked vs. 21\% shocked). Sears and Conti\textsuperscript{10} state that patients who have a history of ICD firings are at particular risk for psychosocial difficulties. Recent research indicates that ICD patients who receive shocks experience more depression and anxiety, and have poorer adjustment to the device than patients who receive no shocks.\textsuperscript{22,67} Shock anxiety, the fear of ICD shock that may result in increased anxiety and avoidance behaviors,\textsuperscript{68} has emerged as a construct of interest, both in research and in clinical settings. Even in the minority of ICD patients who do not experience shocks, shock anxiety may result in increased avoidance behaviors and a perceived limitation in performing everyday activities.\textsuperscript{14}
Sears and colleagues\textsuperscript{7} proposed the Cognitive Appraisal of ICD Activity theory, that explains how shock may lead to the development of avoidance behaviors and hypervigilance, which can greatly impair QOL and daily functioning. Through operant conditioning, avoidance behaviors act as negative reinforcers that maintain feelings of fear or anxiety. Shock can also result in catastrophizing cognitions, which can contribute to the development of fear and anxiety about future shock (shock anxiety). According to the theory, patients use the occurrence of ICD shock as an indicator of cardiac functioning and prognosis. When patients experience shock, they interpret the event as a sign of declining health; conversely, when they do not experience shock, they perceive their health as improving. Unfortunately, while this may provide patients with a false sense of understanding of their health, shock is not an indicator of failing health.

**Death Anxiety**

Death anxiety is a multidimensional construct characterized by cognitive and affective changes, physical alterations, stress, and even pain.\textsuperscript{69} Death anxiety has been described as a dynamic factor that changes with an individual’s age, experiences, and health. Tomer and Eliason\textsuperscript{70} define death anxiety as the anticipation of a state in which the self does not exist, which is variable in intensity over time. For many people, death anxiety may not be a part of their everyday thoughts, although it is considered fundamental to human existence.\textsuperscript{71} Part of being human involves knowing that death is inevitable. Feelings of death anxiety may become a larger part of consciousness with increasing age, after loss of a spouse or loved one, or congruent with disease progression.

The experience of death anxiety can be particularly salient in the presence of a life threatening illness. However, high levels of death anxiety may lead to avoidance of behaviors that are necessary for the maintenance of a person’s health.\textsuperscript{69} For example, people with chronic health conditions, such as cardiovascular disease, may avoid attending medical appointments
because they fear what their physicians may tell them about their prognosis. Similarly, they may struggle with medication adherence or lifestyle modification because by adhering to medical prescriptions they would be acknowledging the fact that they have a serious medical condition. These behaviors can be described as “microsuicidal” in that they slowly lead to death by reducing healthy behaviors and increasing unhealthy behaviors in their daily lives.72

In the existing literature, gender is considered a moderating factor in the occurrence of death anxiety. Research has established that women report higher levels of death anxiety, on average.73-75 Death anxiety research has revealed that female participants display higher levels of death anxiety than do males, regardless of the sample population. However, more recently Neimeyer76 found that even when controlling for emotional expressiveness among gender, female participants endorsed greater death anxiety compared to their male counterparts.

As an individual is faced with a life-changing event such as diagnosis of cardiac disease, survival from cardiac arrest, and subsequent ICD implantation, the frequency and intensity of death anxiety is likely to increase. This life-threatening experience is likely to increase levels of death anxiety in ICD patients, by forcing them to face their mortality in a way that they may not have previously. Despite the heuristic value of this phenomenon, there is a notable absence of research devoted to examining death anxiety among cardiac populations.

**Body Image and Sexual Health**

Body image is a prevalent issue in women’s health research and is particularly relevant for females who undergo ICD implantation.49 Socially visible scars, similar to those created by implantation of an ICD, have been associated with poor self-ratings of appearance, appearance satisfaction, and appearance-related anxiety.11,77 Traditional ICD placement involves creating a 3-4 inch incision for a subpectoral or subfascial pocket in the left chest wall wherein the device
is implanted. This procedure produces both visible scarring and bulging around the implant site due to the placement of a 78 gram/40 cm³ device underneath the skin.

This protocol presents a particularly sensitive problem for women, whose clothing often leaves this part of the upper body exposed. Device placement can be challenging for women due to their physiognomy; the weight of the breast itself may pull and tear on incisions making the scar larger still. The practical limitations of bra straps, purse straps, and seat belts⁷⁸ are consequences of device placement that have been acknowledged. Davis and colleagues⁷⁹ examined the body satisfaction of women implanted with cardiac pacemakers. They reported that the visibility of their scar, how their clothing fit with the device, and the impact their device had on wearing swimsuits, were significant concerns of women, compared to their male cohorts. Although scar management techniques, including silicone gel sheeting and corticosteroid injections, have been outlined as appropriate treatments for a variety of abnormal scars⁸⁰ little research is available in the efficacy of these methods in the management of cardiac device scars.

Several comparisons can be made between women who receive ICDs and women who undergo surgical treatment for breast cancer. In a recent study⁸¹ women who had undergone breast conservation treatment rated the presence of highly visible scars as the single most important determinant of their perception of the cosmetic outcome of the surgery. Similarly, women have reported significant displeasure with the cosmetic outcome of their surgery and the accompanying sexual and body image sequelae, and continued to overestimate their risk of developing future cancer.⁸² This scenario is strikingly similar to those women who receive ICDs for primary prevention of future cardiac events. Despite their protection from premature SCD by the device, patients have a tendency to overestimate their potential mortality by their heart condition.⁶⁴ Congruous with the breast cancer literature, the changes in physical appearance that
female ICD recipients experience may constitute difficulties in their perception of body image. Research indicates that women in general are more concerned with body image, possibly due to societal expectations that pressure women to strive for attractiveness. This pressure regarding their physical appearance may affect a woman’s social experiences, mood, and overall QOL.83

Unfortunately, there has been little examination of the impact of cardiac surgery on female body image.84 Although several studies have examined cardiac disease and body image in the context of perceived physical functioning, there has been virtually no examination of the impact of defibrillators on body image.85 The potential dissatisfaction of cosmetic outcome of device placement and consequent body image sequelae may act as a catalyst for psychological distress in female ICD patients. The imposition of the device on a woman’s body, in terms of visibility and scarring, warrants increased attention to body image concerns in relation to ICD implantation.

Effective multidisciplinary management of sexual health in cardiovascular patients has represented a challenge for many healthcare professionals. Researchers have highlighted the lack of adequate communication between patients and their healthcare providers with respect to their sexual functioning.86 Hatzichristou and colleagues87 assert the general lack of awareness for approaching sex management in patients with CVD, and that physicians often embrace a disease-centered model that fails to incorporate patient needs, such as sexual functioning.

While ICD patients are members of a broad population of what we refer to as cardiovascular patients, they represent a unique group of individuals who are faced with an equally novel set of barriers and challenges, specific to living with an implantable cardiac device. Patients are often forced to undergo lifestyle changes that include changes in marital and social
relationships, particularly with regard to sexual intimacy. Currently, sexual concerns in ICD patients are not well understood.\textsuperscript{88}

A recent study\textsuperscript{88} investigated the psychosocial sexual experiences of a group of ICD patients after device implantation and found that the most commonly expressed concerns among the group included fear of ICD shock during sex, varying interest and pattern of sexual activity, and a desire for more information and sexual counseling. Walker and colleagues\textsuperscript{50} identified that between 25 and 50\% of women with ICDs experience reproductive and sexual health concerns, yet have difficulty discussing these issues with their healthcare providers. While there exists a clear lack of empirical knowledge and rigorous research of the sexual functioning of ICD patients, the available research does suggest that patients often experience fears related to sexual activity that can lead to impairment in QOL.

Management strategies based on psychosocial needs have the clear potential for increasing patient QOL,\textsuperscript{86,89} and should focus on risk factor modification and lifestyle change,\textsuperscript{90} as well as discussion of the cardiac risk of sexual activity.\textsuperscript{91} Dougherty\textsuperscript{92} suggests that as the population of cardiovascular patients who eventually receive ICDs continues to grow, the development and implementation of ICD-specific sexual education for patients is largely warranted.

**Psychological Interventions**

Clinical trials using behavioral interventions for patients with CVD have included group formats that produced significant changes in both medical and psychosocial endpoints.\textsuperscript{93-95} Friedman and colleagues\textsuperscript{95} Recurrent Coronary Prevention Project reported a 44\% reduction in second cardiac events for those receiving group counseling that addressed psychosocial risk factors, when compared to patients receiving counseling that focused only on traditional risk
factors such as diet and exercise. Lifestyle interventions for patients with CVD have also demonstrated reversal of coronary atherosclerosis thereby decreasing cardiac disease severity.

In a recent literature review, Linden concluded that psychological interventions for cardiac patients lead to reduced mortality and reduced cardiac events. He asserts that the most efficient models for improving cardiac rehabilitation and medical outcomes would include group instructions in stress management, coping, and adherence and initiation of individual psychotherapy on a case-by-case basis if the patient exhibits extreme levels of distress or has a particularly difficult time adhering to lifestyle modifications.

The use of cognitive-behavioral therapy (CBT) with ICD patients has produced promising results. Kohn and colleagues found that CBT over the course of nine weeks was associated with a decrease in depression and anxiety, and an increase in perceived adjustment, particularly for shocked patients. Frizelle and colleagues saw similar results in their sample, with CBT resulting in a decrease in depression and anxiety and an increase in reported QOL. More recently, an investigation of CBT with ICD patients measured both psychological and physiological markers of anxiety. Results revealed an overall decrease in salivary cortisol and in self-reported anxiety, over the course of treatment. Table 2-1 presents the limited studies currently available regarding CBT interventions for ICD patients.

The provision of a CBT group intervention that addressed both device-specific concerns, such as stress, anxiety, and fear, as well as female-specific concerns, such as body image, sexual functioning, and relationship issues, is an appropriate step towards establishing a routine, comprehensive care plan for female ICD patients.

**Aims and Study Justification**

The review of the relevant literature suggests that ICD patient adjustment spans several domains, including shock anxiety, death anxiety, body image, and sexual functioning. Female
ICD patients not only experience general CVD differences when compared to males, but they are also highly at risk for the development of psychological distress following device implantation.

Table 2-1. Summary of studies of CBT interventions for ICD patients

<table>
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<th>Study</th>
<th>Major Purpose and Findings</th>
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<td>Kohn et al. (2000)²²</td>
<td>Purpose: Compared individual CBT treatment to usual care. Results: Individual treatment group reported less depression, less anxiety, less general distress ($p&lt;.05$), despite receiving a higher level of shocks ($p&lt;.07$).</td>
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<tr>
<td>Frizelle et al. (2004)²³</td>
<td>Purpose: Compared home-based exercise/CBT group treatment to wait-listed control group Results: Treatment group showed significant improvement in depression, anxiety, QOL, number and severity of ICD concerns, and distance achieved on an exercise ability measure.</td>
</tr>
<tr>
<td>Sears et al. (2007)²⁴</td>
<td>Purpose: Group biobehavioral intervention vs. a workshop group. Results: Both groups demonstrated benefit in reduced anxiety and salivary cortisol, although the long-term maintenance of depression in the control group was shorter than in the intervention group.</td>
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Psychosocial interventions for ICD patients have yielded promising results, although the provision of a gender-specific intervention for female ICD patients has never been studied. Understanding how shock anxiety, death anxiety, body image, and sexual functioning are related to the ICD, and female psychosocial adjustment, may provide clinicians with information to better prepare patients for ICD implantation. Therefore, the purpose of the proposed study is to examine the effects of a CBT intervention tailored specifically to females with ICDs across domains of psychosocial functioning. The following model illustrates the aforementioned female-specific adjustment issues for women after ICD implantation.

![Figure 2-1. Proposed model of female-specific distress](image-url)
Specific Aim

• **Aim:** To implement and test a psychosocial group intervention aimed at reducing shock anxiety and death anxiety in outpatient female ICD recipients vs. a wait list control group.

The four-hour one-day group intervention will include presentation of cognitive-behavioral didactic information and skills-training exercises aimed at reducing shock anxiety, death anxiety, and body image concerns. Exploration and discussion of female-centric topics including sex and intimacy, body image, and family role functioning will also be pursued. We will prospectively test the effectiveness of the group-based female intervention on an array of outcomes spanning the domains of psychosocial and broad health outcomes.

• **Primary endpoints:** shock anxiety, death anxiety
• **Secondary endpoints:** body image concern, sexual dysfunction
CHAPTER 3
METHODS

Patients

Female ICD patients (n = 30) will be recruited from outpatient cardiovascular clinics at Shands Hospital at the University of Florida, Shands at Alachua General Hospital, and Shands Jacksonville. Patients must be at least 18 years of age, be able to read and write English, and have had prior ICD implantation.

Procedures

After an introduction of the study and gathering of informed consent, women will be randomized to one of two conditions: intervention (n = 15) or wait list control (n = 15). Medical record review will be conducted to obtain data on the following variables: cardiovascular history, ICD placement duration, history of mental health problems or treatment, current pharmacologic regimen, cardiac risk factors, and shock history.

Women randomized to the intervention group will be required to participate in the intervention, choosing from a range of available dates on which to attend. The intervention will only be scheduled if three or more women plan to attend. The intervention will last approximately four hours. Upon arrival on the date of the intervention, patients will complete individual psychological assessment batteries, which will take approximately 15 minutes to complete. Upon completion of the psychosocial measures and participation in the intervention, patients will be compensated for $10. The focuses of the intervention are summarized and broken down by hour in Table 3-1.

One month after the intervention, patients will complete the follow-up psychosocial measures, either in person at outpatient cardiovascular appointments, or via mail. If patients successfully complete the psychosocial measures they will be compensated for $10. Four weekly
Table 3-1. Summary of intervention

**Part 1: Research Procedures and ICD Education**
- Fill out psychosocial questionnaires
- Welcome, personal introductions, introduction to program, and agenda

**Part 2: Heart Health**
- Cardiac functioning and rhythm management
- Understanding shock
- Developing a shock plan

**Part 3: Stress and Anxiety**
- Relationship between stress and anxiety
- Relaxation strategies
- Improving emotional and physical health
- When to consult a professional

**Part 4: Being a Woman**
- Family relationships
- Changes in your body
- Romantic relationships
- Strategies for increasing confidence
- Sex and intimacy

Newsletters will be sent to patients after completing the intervention, briefly summarizing and reminding women of the material we covered in the workshop. Women randomized to the wait list control group will complete the initial psychosocial measures at the time of recruitment, and one month after recruitment, in outpatient cardiovascular clinics at their residing institute of care or via mail. They will then be invited to participate in the intervention following their completion of data collection and will be compensated for $10. Figure 3-1 outlines the timeline for recruitment, participation, and data collection for women randomized to the intervention group and the control group.

**Measures**

**Demographics:** This measure is a brief self-report tool to facilitate collection of demographic information. It includes information such as age, ethnicity, level of education, work status, marital status, and past and/or present psychological/psychopharmacologic treatment.
Shock anxiety: The Florida Shock Anxiety Survey (FSAS)\textsuperscript{68} is a 10-item measure used to assess ICD-specific anxiety including the cognitive, behavioral, emotional and social impacts of shock; alpha coefficients suggest good reliability (Cronbach’s = .91, split-half = .92) and moderate correlation (r = -.65) with death anxiety. Higher scores on the FSAS indicate higher shock anxiety.

Death anxiety: The Multidimensional Fear of Death Scale (MFODS)\textsuperscript{76} is a 42-item assessment device with 5-point Likert response formatting. This scale is composed of eight factors: (1) Fear of the dying process, (2) Fear of the dead, (3) Fear of being destroyed, (4) Fear for significant others, (5) Fear of the Unknown, (6) Fear of conscious death, (7) Fear of the body
after death, and (8) Fear of premature death. For this study only the Fear of the Dying Process (6 items) and Fear of Premature Death (4 items) Scales will be used, with lower scores indicating higher death anxiety. Previous research has calculated the Cronbach’s alpha of reliability at .85.76

**Body Image Concern:** The Florida Patient Acceptance Survey (FPAS)\(^9\) is a valid and reliable 18-item measure used to assess patient acceptance of cardiac device treatment. Patient acceptance refers to achieving maximal benefit from a biomedical device such as an ICD. The FPAS is composed of four factors: 1) Return to Function, 2) Device-Related Distress, 3) Positive Appraisal, and 4) Body Image Concerns. The FPAS total score and subscale scores demonstrated both convergent and divergent validity with the SF-36, Atrial Fibrillation Symptom Severity Scale, CES-D, STAI, and the Illness Intrusiveness Rating Scale.\(^9\) For this study, the Body Image Concerns subscale will be used as a measure of body image, which is calculated using a subset of items from the measure. Higher scores on the Body Image Concerns subscale indicate higher levels of distress or concerns.

**Sexual Dysfunction:** The Arizona Sexual Experiences Scale (ASEX)\(^9\) is a valid, reliable, and sensitive tool for measuring sexual dysfunction. This 5-item measure has both a male and a female version of the scale, and scores are used to quantify sex drive, arousal, vaginal lubrication/penile erection, ability to reach orgasm, and satisfaction from orgasm. Scores range from 5-30 with higher scores indicating greater sexual dysfunction. For this study the female version of the measure will be used.

**Statistical Analyses**

The primary hypothesis is that the treatment group will experience greater reduction in psychosocial distress relative to the wait list control group. Descriptive and repeated measures analyses of variance (ANOVAs) will determine changes in scores between the groups. Statistical analyses will be performed to evaluate the proposed hypotheses for this research project using
the Statistical Package for the Social Sciences (SPSS). In order to correct for violations of the Box-M test and the Levene’s test for the assumption of homogeneity of variance, the relatively conservative Pillai’s trace will be used for the estimation of F-statistics in all analyses. When appropriate, Bonferroni corrections will be applied to rectify the possibility of Type I error.

**Statistical Power and Sample Size**

Previous studies by Kohn and colleagues\textsuperscript{22} and Frizelle and colleagues\textsuperscript{23} demonstrate positive effects of psychosocial stress management on ICD recipients. While no studies are available that are directly comparable to the proposed study, a small feasibility trial was conducted by Sears and colleagues\textsuperscript{24} and examined psychosocial outcomes between an intervention group vs. a workshop group. Given these similarities, sample size determination for the proposed study will be based on effect sizes (Hedges’ $d$) from Sears et al.\textsuperscript{24} for anxiety, $d = .71$ and patient device acceptance, $d = .57$.

When conducting analyses of variance, Cohen\textsuperscript{99} large effects size as those values exceeding 0.4. As such, even using the most conservative value of .57, this would require approximately 26 subjects per group for the recommended power of .80 when alpha = .05 two group comparisons. The average psychosocial effect size among those reported from the Sears et al.\textsuperscript{24} trial is approximately .70; we used this effect size to conduct power analysis for this study. A projected sample size of $n = 30$ gives a power of .80 for this estimated effect size. Figure 3-2 depicts the relationship between number of variables and power attained based on repeated measures analyses using the anxiety variable (utilizing the Greenhouse-Geisser Corrected F term).

**Significance of Study**

Our study represents advancement in the development of appropriately tailored interventions for female ICD recipients, as part of comprehensive facilitative care for women.
with CVD. Sudden cardiac death remains the most common cause of mortality for both men and women. The ICD has emerged as the most efficacious treatment choice for those patients at risk for SCD, but while the number of women who undergo ICD implantation annually continues to increase, the existing literature focused on female ICD populations is largely lacking in both breadth and depth. While QOL after ICD implantation is largely dependent on the degree of psychological distress experienced by patients, psychosocial interventions targeted at reducing psychological distress can produce QOL outcomes that make ICD therapy beneficial. The current study establishes the utility of a female-specific psychosocial intervention to reduce psychological distress and produce optimal QOL outcomes.

Figure 3-2. Power analysis and sample size
Sample

Table 4-1 provides demographic and medical information for the total sample, intervention group, and wait list control group. The majority of the sample identified themselves as being Caucasian (93.1%), married (75.9%), having had at least some college education (72.3%), and being retired (41.4%). With regards to psychological history, the majority of women reported past psychopharmacologic (44.8%) or psychological (37.9%) treatment. Five women endorsed current psychopharmacologic treatment and one women reported being in individual psychotherapy (for reasons unrelated to her device or illness).

Patients’ medical records were reviewed to obtain cardiovascular and ICD-specific history. For the total sample, mean time since ICD implantation was 3.78 ± 3.07 years. Thirty-four percent of women had received shock therapies prior to enrollment in the study. Regarding cardiovascular diagnoses, 72.4% had congestive heart failure, 37.9% had coronary artery disease, and 10.3% had long QT syndrome. Twenty-four percent of women had a history of sudden cardiac arrest, and 24% had suffered a myocardial infarction.

Chi-square analyses were conducted for all demographic and medical variables to assess for any significant differences between groups at study onset. No significant differences in variables existed between the intervention and control groups (using $p < .05$), suggesting that these groups were similar, on average, across psychosocial and health-related domains.
Table 4-1. Demographic and medical variables by total sample and groups (%)

<table>
<thead>
<tr>
<th></th>
<th>Total Sample n = 29</th>
<th>Intervention n = 14</th>
<th>Control n = 15</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (M ± SD)</strong></td>
<td>55.6 ± 15.5</td>
<td>57.4 ± 14.8</td>
<td>53.9 ± 16.4</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Black/African American</td>
<td>3.4</td>
<td>7.1</td>
<td>0.0</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>3.4</td>
<td>7.1</td>
<td>0.0</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>93.1</td>
<td>85.7</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>6.9</td>
<td>7.1</td>
<td>6.7</td>
</tr>
<tr>
<td>Divorced</td>
<td>13.8</td>
<td>21.4</td>
<td>6.7</td>
</tr>
<tr>
<td>Married</td>
<td>75.9</td>
<td>71.4</td>
<td>80.0</td>
</tr>
<tr>
<td>Living with a partner</td>
<td>3.4</td>
<td>0.0</td>
<td>6.7</td>
</tr>
<tr>
<td><strong>Level of Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>27.6</td>
<td>28.6</td>
<td>26.7</td>
</tr>
<tr>
<td>Some college</td>
<td>41.4</td>
<td>35.7</td>
<td>46.7</td>
</tr>
<tr>
<td>Associate’s degree</td>
<td>17.2</td>
<td>21.4</td>
<td>13.3</td>
</tr>
<tr>
<td>University degree</td>
<td>13.7</td>
<td>14.2</td>
<td>13.3</td>
</tr>
<tr>
<td><strong>Occupational Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>20.7</td>
<td>21.4</td>
<td>20.0</td>
</tr>
<tr>
<td>Homemaker</td>
<td>3.4</td>
<td>7.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Unemployed</td>
<td>3.4</td>
<td>0.0</td>
<td>6.7</td>
</tr>
<tr>
<td>Retired</td>
<td>41.4</td>
<td>42.9</td>
<td>40.0</td>
</tr>
<tr>
<td>Medically disabled</td>
<td>31.0</td>
<td>28.6</td>
<td>33.3</td>
</tr>
<tr>
<td><strong>Psychopharmacologic Treatment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past</td>
<td>44.8</td>
<td>42.9</td>
<td>46.7</td>
</tr>
<tr>
<td>Current</td>
<td>17.2</td>
<td>21.4</td>
<td>13.3</td>
</tr>
<tr>
<td><strong>Psychological Treatment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past</td>
<td>37.9</td>
<td>42.9</td>
<td>33.3</td>
</tr>
<tr>
<td>Current</td>
<td>3.4</td>
<td>7.1</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Years with ICD (M ± SD)</strong></td>
<td>3.78 ± 3.07</td>
<td>4.12 ± 3.75</td>
<td>3.46 ± 2.35</td>
</tr>
<tr>
<td><strong>Positive shock history</strong></td>
<td>34.5</td>
<td>42.9</td>
<td>26.7</td>
</tr>
<tr>
<td><strong>Cardiovascular History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>72.4</td>
<td>64.3</td>
<td>80.0</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>37.9</td>
<td>42.9</td>
<td>33.3</td>
</tr>
<tr>
<td>Long QT syndrome</td>
<td>10.3</td>
<td>7.1</td>
<td>13.3</td>
</tr>
<tr>
<td>Prior sudden cardiac arrest</td>
<td>24.1</td>
<td>28.6</td>
<td>20.0</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td>24.1</td>
<td>28.6</td>
<td>20.0</td>
</tr>
</tbody>
</table>

Outcome Variables

A series of repeated-measures analyses of variance (ANOVAs) were employed to examine differences in psychological outcomes over the course of the study. For all analyses, time
(baseline, 1-month follow-up) was the within-subjects factor and treatment condition (intervention group vs. control group) was the between-subjects factor. In order to correct for violations of the Box-M test and the Levene’s test for the assumption of homogeneity of variance, the relatively conservative Pillai’s trace was used for the estimation of F-statistics in the analyses that follow. Table 4-2 provides means, standard deviations, and levels of significance for the intervention and control groups for all psychological endpoints.

Table 4-2. Mean (standard deviation) scores on psychological measures at baseline and post-treatment

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSAS (baseline)</td>
<td>22.79 (10.76)</td>
<td>19.73 (8.65)</td>
<td>.026</td>
</tr>
<tr>
<td>(post-treatment)</td>
<td>17.93 (6.02)</td>
<td>19.13 (7.85)</td>
<td></td>
</tr>
<tr>
<td>MFODS</td>
<td>26.07 (11.13)</td>
<td>27.93 (9.60)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>27.50 (9.84)</td>
<td>28.47 (10.73)</td>
<td></td>
</tr>
<tr>
<td>FPAS (Body Image Concerns)</td>
<td>28.57 (34.47)</td>
<td>17.50 (23.05)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>24.11 (32.32)</td>
<td>19.17 (20.52)</td>
<td></td>
</tr>
<tr>
<td>ASEX</td>
<td>16.43 (6.00)</td>
<td>15.93 (4.45)</td>
<td>.016</td>
</tr>
<tr>
<td></td>
<td>18.21 (5.01)</td>
<td>17.07 (5.61)</td>
<td></td>
</tr>
<tr>
<td>FPAS (total)</td>
<td>69.52 (16.30)</td>
<td>70.89 (19.76)</td>
<td>.026</td>
</tr>
<tr>
<td></td>
<td>78.93 (17.03)</td>
<td>71.11 (19.33)</td>
<td></td>
</tr>
</tbody>
</table>

FSAS = shock anxiety, MFODS = death anxiety, FPAS (Body Image Concerns Subscale) = body image concerns, ASEX = sexual dysfunction, FPAS (total) = device acceptance

*p-value statistic for time by group interaction effects
NS = non-significant

**Shock anxiety and death anxiety:** Pre-post measures of shock anxiety demonstrated a significant time by group interaction effect with the intervention group having a significantly greater decrease in anxiety (*Pillai’s trace* = 5.58, *p* = .03, *ηp2* = .17) than the control participants at one-month follow-up. This reduction in shock anxiety in the intervention group was significant at the *p* = .05 level. Measurement of death anxiety at baseline and 1-month follow-up did not produce significant changes or interactions in the intervention or control groups.
**Body image concern and sexual dysfunction:** There were no significant changes or interactions across the study in reported body image concerns, among the two groups. Measures of sexual dysfunction in the study demonstrated a significant time by group interaction effect with the intervention group having a significantly greater increase in reported sexual dysfunctions \((\text{Pillai's trace} = 6.66, \ p = .02, \ \eta^2_p = .20)\) than the control participants. This increase in sexual dysfunction in the intervention group was significant at the \( p = .05 \) level.

**Device acceptance:** The FPAS, a measure of device acceptance, was administered at baseline and 1-month follow-up. Pre-post measures of device acceptance revealed a significant time by group interaction effect with the intervention group having significantly greater increases in reported device acceptance \((\text{Pillai's trace} = 5.80, \ p = .02, \ \eta^2_p = .18)\) than the control participants. The intervention group increase in overall device acceptance was significant at the \( p < .01 \) level.

**Exploratory Analyses**

Exploratory analyses were conducted to examine differences in rates of total device acceptance between the intervention and control groups, as this construct has emerged as an endpoint of interest among the cardiac device population. Additionally, differences in self-reported shock anxiety, sexual functioning, and device acceptance among three age groups of females were also examined, as recent literature suggests significant differences in psychosocial functioning among varying aged females. Finally, as rates of sexual dysfunction among women with ICDs has previously been unexplored, self-reported sexual functioning was examined across the entire sample at baseline, to identify and define base rates of sexual dysfunction in the general female ICD population.

**Age group differences:** For categorical age analyses, women in the intervention group were divided into three groups: young \((\leq 50 \text{ years of age}; \ n = 4)\), middle-aged \((51-64; \ n = 6)\), or
older (≥65 years of age; n = 4). Significant time by group interactions were found across the domains of shock anxiety, sexual functioning, and device acceptance. With regards to shock anxiety, a significant interaction effect (Pillai’s trace = 5.05, p = .046, η² = .32) was found, such that women under the age of 50 experienced greater reduction in shock anxiety, than their middle-aged cohorts. Notably, young women had higher rates of shock anxiety (M = 30.75) than middle- (M = 18.00) and older-aged (M = 22.00) women at baseline. All age-groups showed reduction in shock anxiety from baseline to one-month follow-up, on average. Rates of sexual dysfunction increased (Pillai’s trace = 5.91, p = .03, η² = .35), with a significant time by group interaction effect such that young women and older women reported significantly higher rates of dysfunction at follow-up than their middle-aged cohorts. Significant time by group interactions were found for reported device acceptance at baseline and one-month follow-up (Pillai’s trace = 9.35, p < .01, η² = .46). Young women reported greater increased in device acceptance than both the middle- and older-aged groups, and women between the ages of 51 and 64 reported higher rates of device acceptance increase than women over 65. Again, it is notable than young women reported poorer device acceptance on average (M = 55.42) than middle-aged and older-aged women (M = 75.28 and M = 75.00, respectively). However, all groups reported greater increases in total device acceptance increased across time, on average.

Rates of sexual dysfunction in total sample: The ASEX, a measure of self-reported sexual dysfunction, was completed by all participants. Sexual dysfunction has been defined as a total ASEX score ≥ 19, any one item with a score ≥ 5, or any three items with a score ≥ 4. Previous rates of sexual dysfunction are unknown for female ICD recipients. Of the total sample (N = 29), 9 women (31%) had a total baseline ASEX score ≥ 19, 2 (7%) had any one item with a
score ≥ 5, and 0 women had any three items with a score ≥ 4. In all, 11 out of 29 women (38%) met criteria for sexual dysfunction at baseline measurement based on ASEX scoring criterion.
CHAPTER 5
DISCUSSION

Summary of Results

Our major objectives were to investigate the effectiveness of a psychosocial intervention tailored for female ICD recipients across a variety of outcomes. Specifically, this study investigated through repeated measures analyses of variance, the effect of the intervention on self-reported shock anxiety, death anxiety, body image concern, and sexual dysfunctions.

Results suggest that psychosocial treatment for female ICD recipients is effective in improving QOL outcomes across several domains. Historically, the provision of psychosocial interventions utilizing CBT strategies for the general ICD population has resulted in decreased anxiety \(^{22,23,100}\) and depression. \(^{22,23}\) More recently, a CBT intervention program resulted in reductions in both psychological and physiological markers of anxiety in shocked ICD patients.\(^{13}\) While psychosocial treatment has demonstrated utility for the general ICD population, it has been suggested that these interventions are not “one size fits all,” and that interventions tailored to meet the specific needs of particular ICD subgroups are warranted. This study provides evidence that tailored interventions have both clinical and research utility in the female ICD population.

Shock Anxiety and Death Anxiety

Intervention group members in the study reported significant reductions in shock anxiety after participation in the intervention. The experience of ICD shock has been associated with poor QOL \(^{12}\) and has been implicated in the development of anxiety \(^{101}\) and depression. \(^{102}\) However, while a sizable portion of ICD patients will experience shock within the first year after implantation, the majority of patients will not. \(^{103}\) Despite these statistics, many more patients experience clinical symptoms of distress associated with shock fears, than experience shock.
itself, suggesting that shock anxiety is an appropriate target for psychosocial treatment. Shock is an uncontrollable and often aversive situation that is unavoidable by ICD patients. As such, the prospect of shock can lead to feelings of helplessness. Pauli and colleagues\textsuperscript{104} suggest that distress may be related to the specific thinking patterns that ICD patients engage in. Catastrophic cognitions are especially harmful for ICD patients as they lead to negative appraisal of the device through fear centered on the possibility of shock.

It has been well established that patients desire more knowledge about their device.\textsuperscript{13} Patient education is an essential component to psychosocial treatment, particularly with regards to identifying and challenging ICD-specific concerns, such as how the device functions, events that may trigger shock, and what to do in the event of a shock.\textsuperscript{105} In this study, the delivery of psychoeducation regarding shock experience and developing a shock plan, as well as encouraging members to process their shock history were all components of the intervention, providing further evidence in the importance of ICD-specific education and the targeting of shock anxiety.

Shock anxiety can be defined as the fear or anticipation of ICD shock that often results in increased heart-focused anxiety symptoms, as well as the development and maintenance of avoidance behaviors to minimize their perceived risk of shock. Shock anxiety represents a device-specific and novel anxiety that is distinctly related to the ICD, versus a more generalized or trait anxiety. Therefore, psychosocial interventions that provide psychoeducation about the ICD and device-related fears and concerns may be particularly valuable in reducing shock anxiety because they address this novel stressor in the appropriate context.

Women in our study did not report significant reductions in death anxiety. Many female ICD recipients have experienced sudden cardiac death and have been faced with the prospect of
dying. While the ICD has been widely established as a life-saving device, some patients appear to have significant anxiety related to the device and fears of death.\textsuperscript{104} Despite a lack of significant results in this study, death anxiety still appears to be a particularly relevant construct to this population of patients, given the onset of their cardiac disease coupled with the implantation of an ICD as a constant reminder of their potential mortality. Death anxiety is a multidimensional construct characterized by cognitive and affective changes, physical alterations, and stress. Death anxiety can be particularly salient for patients suffering from a life threatening illness. As described in the background, death anxiety is considered to be fundamental to human existence. It is a dynamic factor that changes with an individual’s age, experiences, and health. It is a construct that varies in intensity over time. However, death anxiety can certainly be viewed as a continuous, albeit variable, construct throughout the lifespan, influenced by a variety of societal and personal factors. As such, the provision of a psychosocial treatment in a one-day group intervention may not be the most effective treatment delivery in targeting the construct of death anxiety.

**Body Image and Sexual Functioning**

Although rates of body image concerns did not significantly improve across the study, women reported a reduction in concerns, on average. Previous research has established that women tend to report body image disturbances after physical scarring.\textsuperscript{77} Anxiety about appearance secondary to implantation of an ICD can result from the noticeable scarring that can affect body image in recipients. Women in western societies may be more concerned with body image, possibly due to societal expectations that pressure women to strive for attractiveness and affect social experiences, mood, and overall QOL.\textsuperscript{83} Nonetheless, very little research has investigated rates of body image concerns in female ICD populations.\textsuperscript{85} While the current study did not yield significant results with regards to body image, further exploration of this construct
is certainly warranted. In particular, female ICD recipients would likely benefit from well-developed treatment protocols that include a variety of implant options, pre- and post-operative education, and plastic surgery consultation. Prior to scheduling device implantation, female patients may benefit from being offered all placement options available, in addition to the standard device information routinely offered ICD patients pre-operatively. The measurement and development of biopsychosocial interventions that target the body image construct in this population of women would certainly be valuable.

Women in the current study reported higher rates of sexual dysfunction after participation in the intervention. However, there is no reason to believe that this intervention created an adverse effect of increasing sexual dysfunction. We suggest that discussion of sexual functioning and intimate relationships during the intervention might have encouraged women to think more accurately about their sexual health, thus reporting higher rates than they did at baseline. Likely, women felt more comfortable reporting their actual level of sexual dysfunctions at the one-month follow-up period, versus disclosing such sensitive information before establishing rapport. As such, the post-test data is likely to be a more accurate interpretation of rates of sexual dysfunction among women with ICDs. Walker and colleagues identified that between 25-50% of women with ICDs experience reproductive and sexual health concerns yet have difficulty discussing these issues with their healthcare providers. They might also have difficulty identifying these issues themselves. While it makes sense heuristically that ICD patients face challenges associated with sexual intimacy, sexual concerns in ICD patients are currently not well understood.

This study is the first to our knowledge to establish base rates of sexual dysfunction in the female ICD population. Based on our results, approximately 38% of females with ICDs report
symptoms consistent with a diagnosis of some sexual dysfunction. These results suggest the overwhelming importance of attention to this aspect of female health. It has been suggested that physicians have a general lack of awareness for approaching sex management in patients with cardiovascular disease. An area that is frequently overlooked by physicians is that of intimacy, despite the fact that a clear opportunity exists for cardiologists to help enhance emotional well-being and overall QOL in their patients by approaching this area of health functioning.

Psychologists possess a unique perspective for treating sexual dysfunctions, and can contribute significantly in the management by healthcare team. For instance, psychologists would be proficient in addressing patient fears of sexual activity that often prevent complete rehabilitation sexually from cardiovascular disease. Psychologists also have the expertise needed to help patients with lifestyle modification such as weight loss and increasing physical activity, in an effort to promote better overall vascular health. Hatzichristou and colleagues point out that management strategies should center around the fact that patients and their partners are constantly forced to adjust to the chronicity of heart disease and the ever-changing reality of their sex lives; health psychologists obviously have a mastery of a set of broad-based skills necessary to help patients adjust with such illnesses.

There exist many barriers to the effective management of sexual health in female cardiovascular patients. Results from this study suggest that multidisciplinary effort, involving effective treatment strategies focused on patient medical, psychological, and social needs should certainly be pursued.

**Age Differences**

As in other studies of female ICD recipients, women under the age of 50 reported higher rates of shock anxiety, more sexual dysfunction, and poorer rates of device acceptance.
than their older cohorts. While the absolute numbers for each age group were very small, results still showed greater rates of change in this group of females after participation in the intervention, suggesting that they are highly appropriate candidates for psychosocial treatment subsequent to device implantation. It could be argued that age findings were significant due to younger women reporting poorer rates of psychosocial functioning at baseline. However, as all age groups tended to improve across the course of the study, on average, it is unlikely that this is the case. Regardless, young women appear to be a particularly at-risk group for the development of psychological distress after implantation, and would benefit from psychosocial treatment targeting device-specific concerns.

Previous data have suggested the investigation of females with ICDs is warranted. Two reviews by Yarnoz and Curtis\textsuperscript{110,111} comprehensively detailed the literature on gender differences in electrophysiology and arrhythmia outcomes, as well as medical treatment interventions (i.e., ICD placement and cardiac resynchronization therapy [CRT]). Across both reviews, female gender was determined to be associated with greater heart rate, greater incidence of inappropriate sinus tachycardia, greater prevalence of atrial fibrillation (AF), greater AF symptom frequency and AF-related complications, greater prevalence of congenital and acquired long QT syndrome, and lower ICD implantation rates. Women are generally underrepresented in ICD and CRT trials, likely in part because they may present with symptoms at a later age than men, are less likely to have heart failure and CAD prior to cardiac arrest, and are less likely to have severe systolic dysfunction – all of which make indication for treatment less noticeable. The ICD appears to provide equal survival benefit across genders, however. Women’s experiences with electrophysiological disorders are also uniquely affected by sex-specific factors such as pregnancy, menopause, and hormonal triggers.\textsuperscript{110,111}
Given women’s under representation in these intervention trials, it is not surprising that there is a dearth of literature elucidating the effects of gender on psychological adjustment to the ICD. However, in an updated review of adjustment in ICD patients from Sola and Bostwick, six studies found female recipients being disadvantaged toward poorer psychological adjustment, including depression, anxiety, body image distress, social role loss, and/or sleep difficulties. In a sample of more than 450 ICD patients with non-ischemic cardiomyopathy, women were more likely to report greater declines in physical health-related QOL than men. Although no differences in depression and anxiety were noted, Smith et al. found in their sample of approximately 250 ICD recipients that women were more likely to be younger in age, to be unmarried, to have greater heart failure severity, and reported greater functional status declines, more symptoms of pain, and more sleep loss.

As noted above, younger age has been identified as a predictor of future psychological difficulties in ICD patients. Bainger and Fernsler found both young age and unemployment status to be associated with greater QOL deficits. In a review that included 16 studies, Thomas et al. state explicitly that younger recipients “are at highest risk” for future psychological and QOL difficulties (p. 389). Further, our recent investigation of female ICD patients revealed that women under the age of 50 appear to be at greater risk for the development of psychosocial distress associated with shock anxiety, death anxiety, and body image. Dubin and colleagues examined QOL in recipients less than 40 years of age and found high rates of concerns related to how the device would impact clothing, social functioning, and sexual activity. Results from this study further strengthen this body of literature, and emphasize the utility of tailored psychosocial treatment for this group of females.
Strengths and Limitations

When interpreting results from this study, there are several strengths and limitations that should be taken into consideration. Analyses evaluating this sample found participants to be relatively equivalent to each other in regards to demographic and medical variables. Despite power analyses suggesting an adequate sample size, our study population may be considered relatively limited in the number of patients participating in data collection. This limitation may have resulted in reduced significant findings regarding the stated hypotheses.

As with all research, consideration of self-report measures should be made; self-report measures may be influenced by patient demand characteristics, such as participant perception of how they should respond or would like themselves to be perceived. The measures used in assessing psychosocial functioning in patients were restricted to the use of standardized and validated measures that were chosen for their established reliability and validity in measuring the constructs of interest. We also attempted to minimize the influence of demand characteristics by assuring confidentiality of responses and anonymity after data collection.

Clinical Implications

Collectively, results from this study highlight the utility of comprehensive psychological care for women with ICDs. The existing lack of research in the female-specific adjustment to the ICD represents absence of innovation in the area of comprehensive care for women. Without such innovation, healthcare professionals fail to provide universal comprehensive care to the female ICD recipients. With appropriate facilitative care, some female ICD patients may return to previous levels of physical and psychosocial functioning. The current study identifies the utility of this tailored psychosocial intervention for females with ICDs across a variety of QOL outcomes, particularly for those under the age of 50. This study also identifies further avenues for research and clinical attention, namely female sexual health. Clinicians can utilize this
information to improve outcomes in ICD recipients by providing patients with increased attention to their psychological needs and referrals for psycho-educational interventions when indicated.

This study provides evidence that female ICD patients may experience improved health outcomes through a combination of optimal medical treatment and tailored psychosocial care, including the delivery of psychoeducation and affiliation with other females in a support group format. This process can be facilitated by the integration of cardiac psychologists as an essential component of the electrophysiology team. As therapies continue to advance, female ICD patients, particularly those under the age of 50, may benefit from well-established guidelines that take into consideration the unique issues women face with the implantation of a cardiac device.

**Research Implications**

The review of the relevant literature to date suggests that the female-specific adjustment to the ICD has not been thoroughly assessed. The current study substantially adds to this body of literature, in the investigation of the first psychosocial intervention tailored to female ICD recipients. The continued investigation of the unique issues women face in living with an ICD, as well as effective treatment strategies are noteworthy, as they could largely improve QOL, adjustment, and psychological fitness of female ICD recipients.

Future research focused on attention to female sexual health among the device population is also indicated. The current study provides useful information in this regard, but future studies could more specifically address this topic. While this type of analysis was beyond the original scope of the current study, it is clearly an extension that is implicated from the findings and should be incorporated in future research endeavors.
Conclusions

In summary, the ICD is a life-saving device whose use is increasing annually. Although the effectiveness of its life-saving utility is well established, QOL and adjustment issues persist. Women in particular appear to be a vulnerable subpopulation for developing subsequent distress after implantation, especially those under the age of 50. The current study suggests that structured interventions for female ICD patients involving ICD-specific education, CBT strategies, and group social support can provide improvements in shock anxiety and device acceptance.

In closing, the findings from this study suggest that female ICD patients should be referred for psychological intervention to minimize adjustment difficulties and possible declines in QOL after ICD implantation. Subsequent to implant, young women appear to be highly at risk for the development of psychosocial distress. More considerable attention is warranted in women under the age of 50 by researchers and clinicians alike, as this population has been identified to be increasingly more likely to receive an ICD as the indications for implantation continue to grow exponentially.36
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BIOGRAPHICAL SKETCH

Lauren Danielle Vazquez graduated cum laude from the University of Florida in May 2004 with a Bachelor of Health Science degree in health science and a Bachelor of Science in psychology. She also earned a Master of Science degree in psychology from UF in May 2006. She has been pursuing a Ph.D. in the UF Department of Clinical and Health Psychology since August 2004. Her clinical and research interests lie in medical and health psychology, with a focus on cardiovascular disease and heart rhythm management.