PATIENT ASSISTED COMPUTERIZED EDUCATION FOR RECIPIENTS OF
IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (PACER): A RANDOMIZED
CONTROLLED TRIAL OF THE PACER PROGRAM

By

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To my friends and family who have been by my side throughout it all; my successes are your successes.

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By

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The implantable cardioverter defibrillator (ICD) is the treatment of choice for preventing

and correcting potentially-lethal cardiac arrhythmias. Although its effectiveness is supported by

data from several large-scale, randomized clinical trials, its psychological impact is less

favorable, mostly because of the shock mechanism by which the device corrects arrhythmias.

Patients with ICDs are vulnerable to depression and anxiety, including panic disorder and

avoidance behaviors, as a result of device placement and experiencing an ICD shock. There are

only a handful of randomized, controlled trials focused on enhancing the psychosocial

functioning of ICD recipients. Computers are becoming an increasingly useful tool in providing

psychological care due in part to their accessibility, convenience, anonymity, and cost

effectiveness. There is ample support for using computerized interventions to successfully treat

psychiatric dysfunction, including depression, panic disorder, generalized anxiety, and phobias.

There are currently no computerized interventions in the literature aimed at the psychosocial

fitness of ICD patients. Our study is a pilot study of a psychoeducational, computerized

intervention for ICD recipients entitled Patient Assisted Computerized Education for Recipients

of Implantable Cardioverter Defibrillators (PACER). We hypothesized that the PACER program

would increase patient knowledge about their ICD, decrease anxiety, and increase device acceptance, as compared to usual care patients. PACER patients were also hypothesized to demonstrated equivalent scores of anxiety, device acceptance, and quality of life compared to patients from a similar, in-person intervention from a related study. Thirty patients were recruited, and half were randomized to the treatment condition. At one-month follow-up, there were no differences in scores between treatment and control patients on an ICD knowledge test. Increases in ICD knowledge were associated with increases in device acceptance, but only among treatment patients. There was no impact of the program on anxiety. Compared to participants from an in-person treatment, PACER patients demonstrated similar scores of mental quality of life and device acceptance, but worse scores of anxiety and physical quality of life. A user survey demonstrated overwhelming support of the PACER program by participants, suggesting the utility of future testing amongst a larger sample.

CHAPTER 1
INTRODUCTION

Utility of Implantable Cardioverter Defibrillators

Each year, approximately 350,000 Americans experience sudden cardiac arrest (SCA)

related to the occurrence of cardiac arrhythmias, including ventricular fibrillation (VF) and

ventricular tachycardia (VT; American Heart Association, 2004). Ventricular tachycardia is

characterized by heartbeats in excess of 160 beats per minutes. Ventricular fibrillation is

characterized by both excessive heart rate and poorly-defined contractions wherein the heart

manifests a fast-paced, quivering motion. The result is a failure of the ventricles to completely

fill and contract, sending insufficient amounts of blood to the lungs and body. In the event of

SCA, treatment by defibrillation to shock the heart back into rhythm is necessary to prevent

death, which otherwise occurs within minutes. Individuals who experience SCA may be treated

pharmacologically (e.g., antiarrhythmic medications) or via implantable cardioverter defibrillator

(ICD), an internal device that detects, paces, and defibrillates arrhythmias including VF and VT.

Modern ICDs are equipped with multi-therapeutic pacing and graduated shock delivery, as well

as additional lead placement and algorithmic programming to differentiate ventricular from

supraventricular activity.

When an irregular rhythm such as VT or VF occurs, the ICD may send a small shock to

slow a fast heart rate (cardioversion), or a larger shock to stop the rhythm completely and

essentially "reboot" the heart's electrical system (defibrillation). Shock is not a rare

phenomenon, with 40-42% of all ICD patients experiencing one shock within the first year post-

implant (Credner, Klingenheben, Mauss, Sticherling, & Hohnloser, 1998). Twenty-two percent

will experience more than one shock during this initial year, while 17% will experience more

than three shocks. Although the shock mechanism means that a patient with an ICD is not likely

to die from SCA, there are secondary complications that can occur with ICD placement, such as the development of congestive heart failure (CHF) can continue despite reduction in cardiac arrhythmias.

The ICD is the treatment of choice for ventricular cardiac arrhythmias (Anti-arrhythmic versus Implantable Device [AVID] Investigators, 1997; Moss et al., for the Multicenter Automatic Defibrillator Implantation Trial Investigators, 1996), and nearly 60,000 Americans receive an ICD each year. Previous recipients include Vice President Dick Cheney in 2001. Several large-scale, randomized, controlled clinical trials have compared the effectiveness of the ICD versus standard care (e.g., medications). For example, the AVID Trial paired nearly 500 ICD recipients against 500 patients placed on antiarrhythmic medications (e.g., amiodarone, sotalol), and found a 27% reduction in mortality from the ICD at 2 years. These results were impressive enough to prematurely terminate the study in order to provide implantation for all at-risk patients. Throughout other studies (Connolly, et al., 2000; Kuck, Cappato, Siebels, & Ruppel for the Cardiac Arrest Study Hamberg Investigators, 2000; Moss et al.), the ICD has repeatedly outperformed medication management with mortality rates ranging from 31-74%. In another such study (Buxton, et al., for the Multicenter Unsustained Tachycardia Trial Investigators, 1999), patients randomized to medical management had mortality rates comparable to those of control patients receiving no treatment at all. While patients who take medication for SCA can reduce their risk of recurrence within 5 years to approximately 50%, those who receive an ICD have a mere 5% risk. Data such as these highlight the strength of the ICD in helping patients live with potentially life-threatening ventricular arrhythmias.

Psychological Sequelae of ICD Implant

Although the ICD has demonstrated impressive mortality rates, the device nonetheless presents as a potential instigator of psychological maladjustment in recipients. This is primarily

due to the shock mechanism necessary for the device to cardiovert and defibrillate potentially lethal arrhythmias. Another factor that may make an individual more susceptible to poor adjustment is lack of understanding and knowledge about their device (Sears, Burns, Handberg, Sotile, & Conti, 2001), implying that the need for sound patient education is great. Significant rates of panic symptoms (Godemann et al., 2004) and avoidance behaviors (Lemon, Edelman, & Kirkness, 2004) have been documented among this population, as have difficulties with depression, interpersonal functioning, and stress management (Sears & Conti, 2003). It would seem, therefore, that health care providers should consider issues related to quality of life, rather than just quantity of life, among these recipients. Unfortunately, there has been little published in the way of psychosocial interventions for ICD patients. What studies do exist (Frizelle et al., 2004; Kohn, Petrucci, Soto, Baessler, & Movsowitz 2000) suggest that cognitive-behavioral techniques, such as helping patients break classically-conditioned cycles of avoidance surrounding fear of shock exposure, may be of particular benefit.

Computerized Psychosocial Interventions

In this new era of psychological treatment, the Internet is becoming an increasingly common venue for reaching patients. Indeed, with nearly two-thirds of all Americans having Internet access (Lenhart et al., 2003), this appears to be an appropriate arena to which psychologists can extend themselves. Web-based interventions (WBIs) represent the current interface between modern technology and psychology. Already there appears to be much support for the use of WBIs in creating behavioral change, such as in treating panic disorder (Richards, Klein, & Carlbring, 2003) and eating disorders (Winzelberg et al., 2000). Similarly, Web programs that address cognitive components, such as with individuals with depression, also have been supported (Christensen, Griffiths, & Korten, 2002).

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To date, there have been no published studies of WBIs for ICD recipients. In fact, there has been relatively little done for cardiac populations in general in the way of Internet interventions. An online intervention that utilizes documented cognitive and behavioral techniques to improve patient acceptance and adjustment would be desirable. However, the reality of whether such an intervention could achieve any success is unknown. Clearly, there is a need for feasibility studies to determine whether computerized interventions are usable for the ICD population in the first place. Therefore, the main objective of the current proposal is to examine the effects of a WBI (The PACER [Patient-Assisted Computer Education for Recipients of Implantable Cardioverter Defibrillators] Program) designed for ICD patients in terms of increasing patient knowledge about their device, increasing patient device acceptance, and reducing anxiety among recipients. A secondary objective is to determine whether participants in this study display different outcomes (e.g., psychosocial ratings, quality of life) compared to participants in a related study who utilized the same intervention but in a structured, in-person group format.

CHAPTER 2
MATERIALS AND METHODS

Participants and Procedure

The current study lasted for two years. Participants were recruited from Shands Teaching

Hospital in Gainesville, FL. Initial inclusion criteria were that all participants will be newly

implanted (<3 months), be able to read and write English, and must have access to a computer.

Midway through the study, though, a change in the research protocol was implemented due to

low enrollment secondary to low implantation rates at Shands and recruitment difficulties (e.g.,

lack of patient referrals). The protocol was expanded to include all ICD patients and not just new

recipients. Permission was obtained by Institutional Review Board to contact these patients by

phone. Patients meeting these criteria were asked to participate either immediately following

implantation during inpatient hospitalization (new recipients) or via telephone (previous

recipients).

All patients were provided with a general description of the study and asked to participate.

After giving written consent, participants completed a packet of questionnaires assessing for

psychological functioning and device knowledge. Following completion, participants

randomized to the treatment condition received a CD-ROM containing a computerized psycho-

educational program (the PACER program) about how their device works and how to cope with

having an ICD. An Internet Service Provider was not necessary for participation.

At one-month follow-up, participants completed the same measures as at baseline.

Follow-up questionnaire packets for treatment participants included an addendum to the Florida

ICD Knowledge Questionnaire that contained a user survey to determine which parts of the

program were accessed and deemed effective. Control participants were wait-listed and at the

end of the study received the same CD-ROM as those in the treatment group. All participants

were allowed to keep the CD-ROM. Institutional Review Board (IRB) policies at the University of Florida were followed.

Medical variables gathered include the left ventricular ejection fraction, history of implantation, and other cardiac risk variables, medications, other illnesses or surgeries, length of hospitalization, length of time since implant, number of rehospitalizations, and number of medical procedures. Demographic information collected includes age, sex, race, educational status, family income, marital status, and employment status.

Instruments

ICD Device Knowledge: Florida ICD Knowledge Questionnaire

This measure was developed specifically for this study, since no measure of this construct currently exists. The patients' knowledge of ICDs was assessed using scores from six sections including basic knowledge about the device and shocks; stress management techniques for ICD recipients; improving cognitions and outlook; utilizing adaptive behaviors to increase adjustment; understanding family relationships; and preparing for device shock. Questions are multiple-choice with four- and five-choice answers. A utilization subscale was added to post-tests given at one-month follow-up. This subscale is a user satisfaction survey determining how often the participants accessed the program, how useful they found it, and what areas were most helpful.

Patient Acceptance: The Florida Patient Acceptance Survey (FPAS)

This measure was developed to examine device acceptance in pacemaker, implantable cardioverter defibrillator (ICD), and implantable atrioverter defibrillator (IAD) patients. It is comprised of 15 items with four valid and consistent factors: Return to Life, Device-Related Distress, Positive Appraisal, and Body Image Concerns. The FPAS total score and subscale

scores demonstrated both convergent and divergent validity with the SF-36, atrial fibrillation symptoms, the CES-D, STAI, and illness intrusiveness (Burns et al., 2004).

Shock Anxiety: The Florida Shock Anxiety Scale (FSAS)

This scale was developed for a previous study to assess the fear and anxiety that patients may have regarding the ICD and its shocks. This 16-item measure examines the cognitive, behavioral, emotional and social impact of shock anxiety. Full psychometric validation is currently being investigated (Kuhl, Dixit, Sears, & Conti, 2006).

General Anxiety: State-Trait Anxiety Inventory (STAI)

The STAI is a 40-item self-report questionnaire designed to measure both state and trait anxiety (Speilberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). For the purposes of this study, only the 20-item trait scale of this questionnaire was administered. Trait anxiety is defined as a relatively enduring personality characteristic, or more specifically, as anxiety proneness. The internal reliability of both the state and trait anxiety scales has been shown to be uniformly high across samples of adults ranging from .89 to .96. Test-retest stability coefficients for multiple samples of college students ranged from .73 to .86, with test-retest validity specifically for the trait scale being reported at .73 for males and .77 for females. Concurrent validity between the STAI and IPAT Anxiety Scale and the Taylor Manifest Anxiety Scale ranged from .83 to .73 (Spielberger et al., 1983).

Health-Related Quality of Life

Short Form-12 (SF-12). This measure was developed to gauge mental and physical functioning and can be separated into two components: physical component summary (PCS-12) and mental component summary (MCS-12). All scores of the SF-12 are comparable and highly correlated with scores from the SF-36, from which it was derived, (ranging from .63-.97) (Ware et al., 1995; Ware, Kosinski, & Keller, 1996). The SF-12 reproduced 90% of the variance in the

SF-36 PCS and MCS measures in the United States and on cross-validation in the MOS (Ware et al., 1996).

The Left Ventricular Dysfunction Questionnaire (LVD-36). This cardiac-specific measure was designed to assess the impact of left ventricular dysfunction on daily life and well-being. Responses are dichotomous (true or false). True responses are summed, which is then calculated as a percentage; higher scores indicate worse functioning (i.e., 0 = best possible score). The measure demonstrated high internal consistency in a sample with chronic left ventricular dysfunction (Kuder-Richardson coefficient = 0.95) (O'Leary & Jones, 2000). Higher scores indicate greater dysfunction, and poorer QOL.

Please see Appendix for printed copies of all measures.

Intervention Procedure

The intervention in this study is a psycho-educational, cognitive-behavioral program entitled "The PACER Program: Patient-Assisted Computer Education for Recipients of ICDs." Accessing a CD-ROM program only requires the user to insert the CD and double-click on the appropriate icon, and therefore involves considerably less experience on the part of the user. The intervention program provides information about coping, mood, relationships, device functioning, and other areas relevant to ICD patients' adjustment. As described earlier, it has been theorized that cognitive appraisals and classical conditioning contribute to ICD patient anxiety. Cognitive-behavioral techniques help dispel the cognitive distortions behind patients' attempts to predict shocks and avoid activities. The current intervention teaches participants about the unpredictability of shock; helps patients devise a plan to cope with shock, thereby assisting them in feeling more prepared; and provides coping techniques that allow patients to return to everyday activities and enjoy life again. The program is interactive and allows participants to apply concepts and strategies to their own situations and concerns.

Psychological and QOL scores from participants receiving the PACER intervention were compared to those of participants from a related study that utilized a similar intervention (Sears, Vazquez Sowell, Kuhl, et al., under review). In this original study, ICD recipients who had received a device shock were randomized to either a 6-week cognitive-behavioral stress management program or a one-day workshop control group. Both groups received the same information although the control group's information was abbreviated. The information presented is the same as the information contained in the PACER program. Post-treatment analyses indicate that the weekly intervention resulted in improved scores of mental QOL, anxiety, and decreased diurnal salivary cortisol production, which is a validated biological marker of stress. All participants demonstrated improved scores of depression and physical QOL. However, it is unclear whether the information itself provided the basis for change, or whether the didactic format of the groups was more influential. By comparing scores from participants in the original study to those using the PACER program, we will be able to better understand where to attribute outcomes. In order to control for the fact that the original study participants were shocked, baseline scores of anxiety between both groups were compared to determine whether or not anxiety should be used as a covariate.

Theoretical Basis for Change

Classic learning theory can be used to conceptualize how the PACER program will affect participants. Learning theory is built on concepts of reinforcement, shaping, and self-monitoring – all of which are addressed by this intervention. For example, participants are provided with psychoeducation to reduce avoidance behaviors and increase pleasant activities. As they engage in these behaviors, it will provide reinforcement for the notion that virtually all activities are safe for ICD patients, that they do not need to actively avoid objects/activities, and that such avoidance does not reduce their risk of shock. By encouraging participants to create a "shock

plan" in the event that their device fires, the program is shaping behaviors, such as preparedness and active coping. Lastly, participants are taught various forms of self-monitoring, such as relaxation techniques (which are directly built on the premise of self-monitoring for the stress response), and identifying and reframing cognitive distortions. It is believed that these are the primary pathways by which the PACER program is likely to produce changes in participants' thinking patterns and behaviors.

Questions and Hypotheses

The following questions and hypotheses are proposed and comprise the *a priori* analyses to be conducted after data collection is complete.

Question 1: Does the PACER Program Provide Improved Device-Specific Knowledge Acquisition?

- **Hypothesis 1:** Treatment participants will yield greater change in test scores from baseline to follow-up.

- **Analysis 1:** Descriptive and repeated measures analyses of covariance (R-MANCOVA) will determine changes in scores between the groups while controlling for the effects of age, education level, and disease severity (e.g., ejection fraction).

Question 2: Is Increasing Device Knowledge Related to Increasing Patient Acceptance?

- **Hypothesis 2:** Gains in knowledge will be associated with greater device acceptance scores at follow-up among both groups.

- **Analysis 2:** Separate hierarchical regression analyses will determine whether change in knowledge scores predict scores of device acceptance within both groups. In the first block, demographic variables related to knowledge acquisition including age and education level, will be entered. In the second block, medical variables will be entered. In the third block, change in knowledge score will be entered.

Question 3: Are Increases in Device Knowledge Related to Decreases in Anxiety? (Shock-related and Generalized)

- **Hypothesis 3:** Knowledge acquisition is related to shock anxiety and trait anxiety, with increases in knowledge being associated with a decrease in both types of anxiety.

- **Analysis 3:** Separate hierarchical regression analyses will determine whether change in knowledge scores predict scores of shock anxiety and trait anxiety within both groups. In

the first block, demographic variables related to knowledge acquisition including age and education level, will be entered. In the second block, medical variables will be entered. In the third block, change in knowledge score will be entered.

Question 4: Does Independent, Self-directed Use of This Program Produce Comparable Outcomes of Psychosocial and Quality of Life Ratings as an In-person, Group Education Setting?

- **Hypothesis 4:** Participants in this current study will produce scores of psychosocial adjustment and quality of life that are not significantly different from ratings of participants in a related study that utilized the same program but in an in-person, group format (Sears et a., in preparation).

- **Analysis 4:** Multivariate Analysis of Variance will be employed to explore differences by treatment group in trait anxiety (STAI), patient acceptance (FPAS), and quality of life (SF-12).

CHAPTER 3
LITERATURE REVIEW

The following literature review will describe how ICD patients adjust to their device, and what psychological treatments are recommended for this population. Further, it will review how the Internet has been utilized as a clinical tool by psychologists, and how Internet interventions apply to cardiac patients.

Psychological Distress and the ICD Patient

Descriptors and Prevalence

With mortality benefits of the ICD well established, the focus of its impact has shifted beyond the physiological outcomes of the patient and toward the psychosocial and quality of life issues that coincide with implantation. The shock mechanism by which the ICD attempts to correct arrhythmias is a unique experience to which few individuals can relate. Although most recipients say this phenomenon is more surprising than it is painful, and rate it as a 6/10 on a 1-to-10 scale of pain (Sears, Kovacs, Azzarello, Larsen, & Conti, 2004), it nonetheless is sometimes an anxiety-provoking and fearful experience (Herrman, et al., 1997; Luderitz, Jung, Deister, & Manz, 1996; Schuster, Phillips, Dillon, & Tomich, 1998; Sears, Todaro, Saia-Lewis, Sotile, & Conti, 1999). Other common concerns among ICD patients include fear of shock, device malfunction, battery failure, and sexual/intimacy concerns (Sears et al., 1999).

Approximately 15% of ICD patients struggle with psychological distress secondary to device placement (Sears et al., 1999). A large-scale national survey from Sears and colleagues (1999) found that ICD patients experience relatively high rates of anxiety compared to the general population. Specifically, about 24-48% of ICD patients have anxiety symptoms, with 13-38% meeting criteria for an anxiety disorder. Rates of depression are more similar to those seen in the general population. Approximately 12-24% of ICD patients describe symptoms of

depression, while about 9-15% actually meet criteria for clinical depression. Despite this, about 91% of ICD patients return to pre-implant levels of QOL within the first year of device implant (Sears et al. 1999, 2000). Quality of life for ICD patients appears to be as good as, if not better than, that of patients receiving pharmacological care (Sears & Conti, 2002). Irvine and colleagues (2001) found that ICD patients' QOL was better than those patients receiving only drug therapy, except in the areas of pain and social functioning. Although ICD patients have device-specific anxieties and concerns that are worthy of attention, a majority of these patients appear to experience good QOL.

Among the ICD patients who do experience distress, shock seems to be the primary culprit. Schron and colleagues (2002) found that experiencing more than one shock within the first year was associated with lower mental and physical QOL scores on the Short Form-36 questionnaire. Luderitz, Jung, Deister, and Manz (1996) suggest that five shocks may be the "magic number" in determining whether an ICD patient experiences significant anxiety. Other researchers (Kamphuis, de Leeuw, Derksen, Hauer, & Winnubst, 2003) emphasize time of shock rather than number, finding that shocks within the first 6 months are significantly associated with an increased risk of distress.

Regardless of whether it is related to when they occur or simply how many occur, the incidence and impact of shock cannot be overlooked. A recent large-scale study assigned half of post-bypass patients to receiving an ICD, while the other half was maintained via drug therapy (Namerow, Firth, Heywood, Windle, & Parides, 2002). It was reported that the ICD recipients experienced worse QOL than those taking medication. However, further analyses revealed that the non-shocked ICD patients did not differ significantly on QOL ratings from those assigned to the medical condition. The experience of shock solely accounted for the difference in groups.

Further, Godemann and colleagues (2004) studied diagnostic rates of panic disorder with agoraphobia among ICD patients and found that, when shocked, ICD patients were more likely to meet criteria for diagnosis (7% no-shocked versus 21% shocked).

While these studies clearly implicate shock in the advent of psychological distress, other studies suggest different risk factors are at hand. Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, and Kuhlkemp (1999) opine that anxiety in ICD patients is not related to shock, but rather to catastrophic thinking. Specifically, anxious patients in their study were prone to somaticizing and interpreting changes in their bodies as negative signs of failing health, which in turn can spiral into negative cognitions about one's health, life, and future. Sears and Conti (2003) further elaborate by suggesting that there are multiple risk factors for distress, such as young age (<50 years), female gender, poor device understanding, the presence of 3 or more shocks within a 24-hour period (aka., ICD "storm"), and a history of significant psychiatric distress.

Theories of Distress Among ICD Patients

How is it that some ICD patients adapt normally while others continually struggle with anxiety and health-related concerns? Several theories attempt to explain the development of psychopathology among some ICD recipients. Four such theories focus specifically on patients' perceptions of their device and shock.

The first theory is that of classical conditioning, introduced to psychology by Ivan Pavlov's research with his dogs. This theory holds that pairing a neutral stimulus with a negative or positive event can create a resulting association between the two items. In the case of ICD patients, the negative event is device shock. Pairing the existence of shock with an object, event, or place can result in avoidance (Lemon et al., 2004) due to the newly created negative association. This avoidance can subsequently lead to maladjustment (Sears & Conti, 2002). For

example, a patient who is shocked while gardening may associate being in the garden with the negative experience of being shocked, and therefore avoids working in the garden despite the fact that is a safe activity and possibly one that gives the patient enjoyment. Consider the same consequences when an individual is shocked while being intimate with a loved one. Suddenly, the conditioning of the patient to avoid contact with their loved one now not only affects the patient himself, but also the spouse. This can also lead to social isolation, depression, low self-image, and feelings of helplessness.

Similar to this theory is that of operant conditioning. Operant conditioning holds that individuals are motivated to do or avoid doing things for which they are reinforced. An ICD patient who believes they are avoiding shock by avoiding an activity is receiving negative reinforcement. A recent example of a female patient who was shocked while eating illustrates the serious consequences that this faulty reasoning can have.

Third is the theory of learned helplessness, developed by Seligman. This theory states that when we are presented with an aversive situation from which we cannot escape, we tend to give up and cease trying to find a way to avoid the negative consequences. In the case of an ICD patient, there is no way to avoid being shocked. Shock is not predictable or directly controlled by what a patient does, says, eats, behaves, etc. This clearly can lead to feelings of helplessness and despondency. Patients who come to believe that they will be shocked no matter what they do may give up trying to cope and adjust, feeling that they have no control over their lives or health. This in turn can lead to feelings of depression, withdrawal, social isolation, and fear.

The fourth theory, proposed by Sears and Conti (2003), is the theory of cognitive appraisal, also known as the *sickness scoreboard theory*. Patients who are shocked, and often times those who are not, may come to view device firing as a sign of failing health. Over time, patients may

"keep score" of whether their health is improving or declining by tracking device firings. In an attempt to gain control over their health, and therefore alter their score, they may avoid activities that they erroneously believe will lead to shock. This "score-keeping" also gives patients a false sense of control over their health, causing them to become hypervigilant of their body's changes and physical sensations. The occurrence of shock does not indicate failing health. In fact, as mentioned previously, shocks can occur for reasons unrelated to arrhythmias (e.g., lead dysfunction).

More recently, some researchers have suggested that patient personality characteristics may make them more vulnerable to distress following implantation, especially among patients who experience shock. Dunbar and colleagues (1999) studied mood disturbance in 207 ICD patients. Participants were asked to rate their levels of anxiety, anger, confusion, fatigue, and vigor at pre-implant, post-implant, 1-month, 3-months, 6-months, and 9-months follow-up. These scores yielded a total mood disturbance (TMD) rating. Statistical analyses determined that the only significant predictor of shock was TMD at time points 1 and 3, which also predicted shock at subsequent time points. Anxiety, confusion, and fatigue were all significant predictors of shock. Further, they found that there was no significant difference between pre-implant and post-implant TMD scores, signifying that the psychological variables acted as precursors to and not consequences of being shocked.

Results from Dunbar et al. (1999) are consistent with another recent study from Shedd and colleagues (2004) concerning device firing during the period immediately following the World Trade Center bombings on September 11, 2001. The authors examined rates of device shock among ICD patients at Shands Teaching Hospital and the Veterans Affairs Medical Center in Gainesville, FL, in the 30 days prior to and following the terrorist attacks. During this time,

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electrophysiologists in Florida witnessed a 2.8-fold increase in number of tachyarrhythmias. Similarly, electrophysiologists studying ICD patients at six hospitals in New York City and upstate New York also witnessed an increase in cardiac events post-September 11th (Steinberg et al., 2004). As with the Florida patients, the New York sample experienced a 2.3 fold increase in ventricular tachyarrhythmias from pre- to post-September 11th. Furthermore, there were no reports of cardiac events in the 3 days immediately following the bombings, and patients returned to baseline levels of events within a month. The authors note that this finding in particular differs from previous studies of traumas and cardiac events, which have reported immediate increases in activity. These fascinating data imply that not only can anxiety and fear from directly experiencing trauma impact one's heart rhythms, but that experiencing an event indirectly can affect cardiac functioning as well.

Anxiety and Cardiac Patients

As noted above, anxiety and depression have been identified as common comorbidities to ICD placement, and there are several theories as to why anxiety in particular may transpire so frequently in this population. This is particularly worrisome because of the devastating effects that anxiety can have to both one's emotional and physical self.

Anxiety has been identified as a significant contributor to the pathogenesis of cardiac disease (Kubzansky, Kawachi, Weiss, & Sparrow, 1998). Through activation of the sympathetic nervous system and subsequent release of catecholamines, anxiety is implicated in platelet aggregation, injury of arterial lining, and release of fatty acids into the blood – all of which promote the atherosclerotic process. Anxiety also may cause injury by decreasing heart rate variability and increasing the incidence of ventricular premature beats, thereby contributing to electrical instability. Finally, anxiety may trigger myocardial infarction due to the association between hyperventilation and coronary vasospasms. Behavioral mechanisms have also been

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established associating anxiety with health-compromising activities, such as smoking, decreased physical activity, or poor diet (Haywood, 1995; Januzzi, Stern, Pasternak, & DeSanctis, 2000). Myocardial infarction and sudden cardiac death are subsequently common outcomes (Januzzi et al., 2000). Clearly, anxiety is an important psychological and physical contributor that should be monitored in cardiac patients, such as ICD recipients.

Interventions for ICD Patients

Current research with ICD patients suggests that there is a great need for psychosocial interventions to help ICD patients cope with comorbid distress. Unfortunately, much of the research in this area is methodologically flawed due to problems such as small sample size and the use of interventions, such as support groups, that are unstructured and predominantly provide emotional support. While emotional support is undoubtedly an important component to patient adjustment, the use of patient education and cognitive-behavioral therapy techniques should not be ignored, and have been shown to be more effective in decreasing distress and improving QOL than emotional support alone.

Structured interventions for ICD patients based on cognitive-behavioral techniques have only recently been studied. In one landmark study (Kohn et al., 2000), ICD patients were randomized to a six-week individual psychotherapy intervention, or standard care. Measurements of depression, anxiety, and illness adjustment were taken pre-implant, and at 1, 3, 5, and 9 months following implant. The authors reported that providing individual cognitive-behavioral therapy to ICD patients resulted in significant decreases in depression and anxiety, and improved adjustment compared to a no-treatment control group. Even more notable, the experimental group contained more women and reported a greater number of shocks, both of which are recognized predictors of poorer adjustment.

An additional study (Frizelle et al., 2004) examined the impact of a cardiac rehabilitation program fitted with cognitive-behavioral techniques for ICD patients. Participants were randomized to a six-week treatment program or a wait-list control group. The intervention consisted of psychoeducation about the ICD and its functioning, relaxation techniques (e.g., breathing exercises), and goal-setting to help patients increase avoided activities. Post-treatment results revealed a significant improvement in anxiety and depression scores; improved QOL measurements; and a decrease in ICD-related concerns. Intervention patients also improved significantly on physical measures of exertional capacity (e.g., Shuttle test). Taken together, these few studies highlight the early success of these strategies in aiding ICD patients.

Patient education is a reasonable intervention for medical patients, and may be particularly helpful with reducing anxiety (Lee, Chui, & Gin, 2003; Poroch, 1995). Research has highlighted the benefits of patient education beyond merely reducing anxiety, such as increasing quality of life, compliance and patient satisfaction with care (Mills & Sullivan, 1996; Powell, Bentall, Nye, & Edwards, 2001; Sturdee, 2000). However, three meta-analyses of studies on psychoeducation programs for cardiac patients (Dusseldorp, van Elderen, Maes, Meulman, & Kraaij, 1999; Linden, Stossel, & Maurice, 1996; Mullen, Mains, & Velez, 1992) reported positive results for cardiac outcomes, but mixed results for psychosocial outcomes. Unlike the review from Linden and colleagues, Dusseldorp et al. found no significant effects of psychoeducation on anxiety or depression. The authors suggest that this could be due to various factors such as floor effects of their population, sex- or age-specific needs that were not addressed, or use of psychoeducation programs that were too general or vague in their content (e.g., group discussions of MI risk factors as a stress management intervention). Similarly, Mullen, Mains, and Velez suggest that individually tailored content focused on promoting behavioral change may help maximize

psychosocial outcomes. Given this, a psychoeducation program driven by patient-specific needs (e.g., shock anxiety among ICD patients) that aims to change behaviors and cognitions, rather than simply disseminate information, may be appropriate for cardiac patients and could potentially improve psychosocial outcomes.

Patient Acceptance and the ICD

In addition to psychological disturbances, health care providers should also be aware of patient acceptance among ICD recipients. Patient acceptance of medical treatment is a complicated variable (Cleary, 1999) that is worthy of attention due to its association with improved patient understanding and satisfaction with outcome, as well as adherence (McKinley, Manku-Scott, Hastings, French, & Baker ,1997; Renzi et al., 2001; Roberts, 2002; Zimmerman, 1988). Patient satisfaction may be contingent on several variables including disease severity, health-related quality of life, and, often times, patient-provider relationship.

Implantable cardioverter defibrillator recipients are confronted with significant burdens, particularly during the first 6 months after implant (Kamphuis et al., 2003), which can impact their level of device acceptance. Burns, Serber, Keim, and Sears (2005) state that ICD patient acceptance encompasses an understanding of device benefits and detriments, the likelihood of future recommendation of the ICD to other individuals, and an awareness of what benefits the patient perceives are being provided by their device. As a global term, patient acceptance is thought to be a construct of QOL, incorporating disease-specific aspects that may be lost on other general or even cardiac-specific measures of quality of life (Burns et al., 2005). Therefore, measuring patient acceptance in ICD recipients is crucial to understanding their unique experiences and forming an awareness of how the device impacts their functioning.

Cardiac Patients and the Internet

Cardiac patients are a prime population for Web-based care. According to CyberAtlas (Greenspan, 2002), there were 137 million Americans online in 2002, nearly one-third of which were age 50 or older. The U.S. Bureau of the Census and the National Center for Health Statistics reports there are 35 million Americans age 65 and older (Greenspan, 2003). An estimated 20 percent (7.6 million) of those are currently on the Internet, but that number is projected to more than double by 2007. Further, Harris Poll data (2002) suggest that men and women were nearly even among Internet use, with women slightly edging out men. By racial ethnicity, Caucasian users make up approximately three-fourths of all adults on the Web, with African-American users totaling 12% and Hispanic users 9%. A typical cardiac patient is a male Caucasian, age 65 or older, and therefore is well suited for a Web intervention. Moreover, a 2000 study (Dickerson, Flaig, & Kennedy) on Internet use among ICD recipients found that patients readily utilized the Internet for supportive communication and information exchanging, suggesting that the ICD population is an appropriate group for an online intervention, although no specific intervention was provided in their study.

Web-based interventions have been scarcely applied to cardiac patients. A majority of the studies conducted thus far concern enhancing professional development, medical monitoring, or improving technology. There are considerably fewer studies aimed at directly impacting patients via improved psychosocial and physical outcomes, though WBIs for cardiac-related risk factors such as obesity (Tate, Jackvony, & Wing, 2003), smoking (Feil, Noell, Lichtenstein, Boles, & McKay, 2003), and sedentary lifestyle (Napolitano et al., 2003) have gained attention. Studies of tertiary care populations show hopeful results for populations such as transplant patients (Dew et al., 2004), individuals with CHF (Delgado, Costigan, Wu, & Russ, 2003; Scherrer-Bannerman et al., 2000), and secondary prevention populations (Gordon, 2004). Other research suggests that

cardiac patients may benefit from computerized treatment by increasing education and communication (Delgado et al., 2003), as well as improving treatment adherence (Ruggerio et al., 2000). Further, Southard, Southard, and Nuckels (2004) demonstrated cost efficiency with a computerized nursing case management system developed as an alternative to cardiac rehabilitation. Participants in the treatment condition exhibited improved, though non-significant, outcomes in time spent exercising, fat intake, and cholesterol, along with significant improvements in weight loss and body mass index. In addition, among the treatment condition, there was a significant cost-savings per patient (net cost savings = $965) on hospitalizations and emergency department visits. These studies indicate that, though still nascent in their development, Web-based interventions for cardiac patients show potential.

Psychology and the Internet

Today's technology sees traditional psychosocial interventions merging with the world of high-speed computer programming to form psychosocial WBIs. Web-based interventions have been successfully utilized in various arenas including eating disorders (Winzelberg et al., 2000; Winzelberg et al., 1998), diabetes (Glasgow, Boles, McKay, Feil, & Barrera, 2003), weight loss (Tate, Jackvony, & Wing 2003), and toilet training (Cox, Borowitz, Kovatchev, & Ling, 1998). Internet interventions are noteworthy because of their potential to reduce some of the barriers encountered in traditional treatment (Ritterband et al., 2003).

There are four primary benefits to using WBIs for treatment. First, WBIs are convenient. The Internet is always on and is always open. Internet interventions do not require patients to make appointments, wait in line, or contend with scheduling. In fact, as long as the technology is available, patients don't even need to leave their home to access services, making WBIs exceedingly convenient.

A second benefit concerns accessibility. The Internet is easily reached at any time from nearly any place. Although use of the Internet does require some equipment, much of this technology now comes standard in computers today, and is available outside the home for people not wanting to personally invest in equipment. Further, with the advent of updated technology, such as wireless Internet cards, reliance on accessory equipment is becoming less necessary.

A third benefit is that WBIs can offer anonymity, which may be particularly helpful in addressing highly personal and sensitive topics that patients might not otherwise be inclined to address in face-to-face arenas (Tate & Zabzinsky, 2004). The ability to exchange dialogue or view text anonymously is likely appealing to many patients and could encourage a sense of honesty and openness that is not always easy to achieve in traditional settings. Individuals who are sensitive about in-person settings (e.g., those with physical disabilities) may be more likely to seek treatment from WBIs, which may gradually help them feel more comfortable to seek treatment in person in the future.

Last, because of their reliance on computers, WBIs allow for individual tailoring of treatments. Brug, Oenema, and Taylor (2002) write extensively about the benefits of individually-tailored interventions, particularly in the realm of providing psycho-education, and how computers adapt to those this method more easily than standard formats (e.g., pamphlets, print material). The authors found that when patients received information more relevant to their particular problem or situation, they were more likely stay engaged with the intervention, thereby increasing the chance of treatment effects. Computers are more adaptable to tailored interventions because of their capacity to create large databases of information combined with programming technique (e.g., use of "if then" statements to direct text) to selectively produce individualized information. In addition, a study of a computerized education program for cancer

patients (Agre, Dougherty, & Pirone, 2002) suggests that the CD-ROM format in particular is highly beneficial over other modes (such as the Internet) and is readily accepted by patients.

Web-based interventions are still relatively new, and thus early studies have limitations for future studies to attempt to correct and strengthen (Ritterband et al., 2003). For example, researchers have continually cited compliance as a major problem in making WBIs effective. Another important drawback concerns the disparity in access between different populations, also termed the "digital divide" (Lenhart et al., 2003). Individuals most likely to fall into this gap of non-users are ethnic minorities, residents of rural areas or residents in the Southern portion of the United States, individuals with annual incomes below $30,000, and individuals with a high-school education or less (Lenhart et al.). Other groups of people who are less likely to be online are individuals older than 65 years of age, children from low-income homes, and disabled individuals (Lenhart et al.). Other well-known concerns include lack of comfort with the Internet, lack of security and validity of information accessed, and initial cost in developing a WBI. Although cost has been suggested as a possible long-term benefit, in the short-term, developing the technology to initially provide WBIs (e.g., Web site design; programming fees; hardware costs) is expensive (Atkinson & Gold, 2002).

Despite the above-noted concerns, the Internet remains a promising option for which psychology to transition its traditional treatments and techniques. For example, one type of intervention that seems readily applicable to the Internet is that focusing on behavioral change techniques (Cavanagh & Shapiro, 2002). One study from Gega, Marks, and Mataix-Cols (2004) details three individual cases of psychotherapeutic change using three different WBIs to treat depression, panic with agoraphobia, and obsessive-compulsive disorder. Although this is only one study, and no definitive conclusions should be made regarding the efficacy of WBIs based

solely on these results, it does provide some promising and intriguing evidence on which future research can build. Therefore, it is reasonable to continue conducting effectiveness trials, such as the proposed study, to further investigate the viability of this treatment option.

Need for Further Research

The "structural," "plumbing," and "pumping" capacities of the heart directly impact its electrical performance. The near-epidemic proportion of coronary artery disease and cardiovascular diagnoses in this country ensures that, unfortunately, SCA will continue to occur and ICDs will continue to be necessary. The psychological distress that can accompany ICD placement is an important consideration. Anxiety in particular appears to be a common concern among this population, and given the deleterious effects it can have on one's physical and emotional well-being, it should also be of concern to health care providers looking after ICD patients.

Education is one reasonable method for addressing distress among medical patients, especially those with anxiety. A review of literature suggests that the application of WBIs to cardiac populations has been poorly achieved. Further, to date, there are no published intervention studies aimed at reaching ICD recipients via the computer. Although the typical ICD patient is older and therefore less likely to have experience with the Internet, Pew data indicates that this is a willing and burgeoning online population. Furthermore, CD-ROMs are considered a reasonable and accessible method for educating patients (Agre et al., 2002), and provide a good alternative for individuals without Internet access.

The proposed study's focus on ICD patients and computerized care is a unique feature, but there are other benefits of note. The results from this study will help contribute to the growing body of literature examining the usability of Web-based interventions in general, as well as adding to the meager research on cardiac populations. Further, the ICD may be viewed by some

patients as more of a "life destroyer" rather than a "life saver" due to the shock mechanism and perceived limitations it carries. This study contributes to understanding patient acceptance among ICD recipients and may provide information that could help this population feel more satisfied and comfortable with their device. This in turn should impact their treatment compliance and future adjustment.

CHAPTER 4
RESULTS

Sample

All participants were recruited from the University of Florida Health Science Center, were older than 18 years of age, and spoke and read English. Forty-six participants consented to participate in this project: 39 completed all baseline measures and 30 completed 1-month follow-up measures. Therefore, the total number of participants who completed all phases of the study was 30. Compared to the number of participants recruited, intent-to-treat attrition rate was 35%; attrition rate for study initiation was 24%. Known reasons for attrition included no longer being interested in participating in the study and having significant negative feelings about the device. Twenty-one participants were randomized to the treatment condition, and 18 were randomized to the control condition. Of the 30 completers, 15 were treatment participants and 15 were control participants.

Midway through the study, a change in the research protocol was implemented due to low enrollment secondary to low implantation rates at Shands and recruitment difficulties (e.g., lack of patient referrals). The protocol was expanded to include all ICD patients and not just new recipients. Permission was obtained by Institutional Review Board to contact these patients by phone. Therefore, not all participants were recruited post-implant during hospitalization, as originally outlined. Of the 46 participants who consented, 23 were new ICD patients recruited during the peri-implant period; the remaining half were recruited outpatient via telephone.

Regarding demographic data, 59 percent of the sample was male ($n = 23$) and 41 percent were female ($n = 16$). Mean age of the sample was 57.44 years ($S.D. = 14.28$). Three of participants (8%) identified themselves as African American, while 35 (90%) identified themselves as non-Hispanic White. Regarding marital status, 69% reported being married or

cohabitating, while 13% were divorced or widowed. Thirty-eight percent ($n = 15$) of the sample

reported having earned a high school education or less; however, of those 15 participants, only

one reportedly did not complete a high school degree. Fifty-five percent had at least two years of

college education, including three participants who reported having completed post-graduate

work. Seven participants (18%) reportedly were engaged in part- or full-time employment, while

31% were receiving disability and 41% were retired. Three participants were unemployed. Five

(13%) of the participants reported living in household with an annual income of less than

$15,000. Most (31%) participants reported earning between $15,000 and $29,000 annually.

Twenty-three percent ($n = 9$) reported earning at least $60,000 annually.

Information was also collected regarding current and past psychiatric treatment, and

current and past psychotropic medication use. Three participants reported currently receiving

psychological treatment for either depression, anxiety, or both. Ten participants (26%) reported

currently taking a psychotropic medication, including antidepressants (sertraline, fluoxetine, and

venlafaxine) and anxiolytics (buproprion, escitalopram, alprazolam, and paroxetine). Four

participants (10%) reported having received psychological treatment previously, most recently in

2003. Two of these participants reported being treated for depression, one reported being treated

for anxiety, and one patient reported being treated for a non-mood disorder. Six participants

(15%) endorsed having previously taken psychotropic medications (citalopram, paroxetine,

buproprion, and diazepam).

Medical data on cardiac diagnoses, current medication, and ICD-related information was

gathered. Mean time since implantation was 11.77 months (*S.D.* = 21.53). Mean ejection fraction

was 29.87 (*S.D.* = 11.36). Respondents' medical history was significant for ventricular

tachycardia (28%), ventricular fibrillation (13%), coronary artery disease (56%), and myocardial

infarction (26%). Sixty-nine percent of the sample had been diagnosed with congestive heart failure, with 31% in NYHA Class II, 26% in Class III, and 3% in Class IV. Five (13%) participants had a history of sudden cardiac arrest, with one patient having multiple episodes. Medication use was as follows: 56% endorsed taking aspirin, 28% Coumadin, 82% beta-blockers, 13% calcium channel blockers, 46% ACE inhibitors, 23% angiotensin receptor blockers, 44% diuretics, 8% amiodarone, and 5% sotalol. Thirty-eight percent ($n = 15$) of the participants were implanted with a bi-ventricular device.

Descriptive Analyses

Descriptive analyses were run to examine baseline ratings of psychological, ICD-related medical, and demographic variables. Except for the FSAS total scores and the follow-up physical QOL score, no variables violated the *Kolmogorov-Smirnov* test of normality or Levene's test of homogeneity of variance. The FSAS total scores variable underwent logarithmic transformation and subsequently displayed normal distribution; the physical QOL score underwent square root transformations. There were no differences on any measures of demographic or medical variables by treatment group (see Table 4-1), nor were there group differences on any of the psychological measures (see Table 4-2).

Given that the original intent of the study was to investigate new ICD recipients, baseline analyses also included examining demographic, medical, and psychological variables of new ICD recipients (< 3 months) versus previous recipients. In these analyses, all demographic and medical variables were comparable. As shown in Table 4-3, significant differences were found on all baseline psychological measures except on device knowledge and the Return to Life subscale of the device acceptance measure. Direction of effects were such that newer patients reported greater trait anxiety, worse physical and mental QOL, lower device acceptance, greater device-related distress, less use of positive device-related appraisals, greater body image

concerns, and greater shock anxiety. However, they also reported better scores on a measure of cardiac-specific QOL that assesses symptoms of ventricular dysfunction.

There was no difference in number of months since implantation by treatment group (t *[37]* $= 0.35$, $p = 0.72$). There were no differences in any variables by whether or not participants were taking psychotropic medications, nor were there differences by whether not participants were currently receiving or had previously received psychological treatment. Examination of baseline ratings of drop-outs revealed no differences compared to completers.

Hypothesized Analyses

The following statistical analyses were performed to evaluate the proposed hypotheses for this research project. The Statistical Package for the Social Sciences (SPSS) was utilized to perform all the analyses.

Hypothesis 1

This first analysis was conducted to examine effects of the intervention on ICD-related knowledge, operationalized by changes in scores on baseline and follow-up administrations of the Florida ICD Knowledge Survey. A Repeated Measures Analysis of Covariance was conducted to examine changes in scores while controlling for age, education level, and disease severity. Examination of Box's M and Levene's statistic revealed no significant violations of assumptions. The overall model was not significant (*Pillai's Trace* $= 0.02$, $p > 0.50$). This analysis suggests there was no difference in test scores between intervention and control participants over a one-month time period.

Hypothesis 2

Separate hierarchical regression analyses examined whether change in knowledge scores predict scores of device acceptance within both groups. In the first block, demographic variables related to knowledge acquisition (e.g., age and education level) were entered. In the second

block, medical variables (e.g., ejection fraction and length of time since implant) were entered. In the third block, change in knowledge score was entered. Among treatment participants, the full model was significant (F = 3.96, p = 0.04) and accounted for 69% of the variance in device acceptance at follow-up (*Adj R^2* = 0.51). The first block accounted for 26% of the variance, while adding medical variables accounted for an additional 12% of variance, which was a non-significant change in R^2. However, adding the knowledge change score significantly accounted for an additional 30% of variance in device acceptance (*F-Change* = 8.71, p = 0.02). As shown in Table 4, age and knowledge change score were both significant independent predictors of device acceptance at follow-up.

Overestimated R^2 values can result from having a small sample size relative to the number of predictors entered into a model. Most recommendations suggest a minimum of 5, and as many as 20, subjects per predictor in order to sufficiently power the analysis. Although planned analyses included examining all five predictors, the above regression was re-examined using only three predictors in order to investigate the possibility of falsely-inflated R^2 values. Eliminated predictors were determined by examining zero-order correlations between education, age, EF, and length of time since implant with device acceptance. Based on lack of significance with the criterion, there was not a need to control for the variables age and EF, and they were therefore eliminated from the model. The analysis was run with education entered in the first block, length of time since implant in the second, and knowledge change in the third. The full model remained significant (F = 3.69, p = 0.04) and accounted for 50% of the variance in device acceptance at follow-up (*Adj R^2* = 0.37). Although this represents a decrease from the five-predictor model, it is nonetheless a significant finding. The first block accounted for 23% of variance, while the second block contributed less than 1% of additional variance. However, as

with the five-predictor model, knowledge added a significant proportion of variance explained in device acceptance (R^2-*change* = 0.26; p = 0.03). In this new model, the only significant independent predictor was knowledge (β = 0.56, p = 0.03).

Among control participants, the full model fell short of significance (R^2 = 0.54, *Adj R^2* = 0.21, F = 1.66, p = 0.26). None of the blocks accounted for a significant proportion of variance in device acceptance; in particular, the knowledge variable accounted for only an additional 6% of variance beyond the demographic and medical variables. Therefore, the hypothesis that increases in knowledge would be associated with increased device acceptance at follow-up was only observed among treatment participants. There was no relationship between knowledge and device acceptance among the control participants.

Hypothesis 3

Separate hierarchical regression analyses examined whether change in knowledge scores predict scores of trait anxiety and shock-related anxiety within both groups. The same demographic and medical variables were entered into blocks one and two, respectively, as in the previous analyses. In the third block, anxiety was entered. Among treatment participants, the full model was not significant in predicting either trait anxiety (R^2 = 0.59, *Adj R^2* = 0.36, F = 2.56, p = 0.10) or shock anxiety (R^2 = 0.12, *F = 0.26, p = 0.92*). None of the blocks accounted for a significant proportion of variance in shock anxiety. In the trait anxiety model, however, the demographic block explained 54% of the variance in anxiety (*Adj R^2* = 0.46, F = 7.05, p = 0.01) with age (β = -0.57, p = 0.04) being the only significant independent predictor. In both models, knowledge accounted for an additional 1% of variance in anxiety.

Among control participants, the full model was not significant in predicting either trait anxiety (R^2 = 0.14, F = 0.23, p = 0.94) or shock anxiety (R^2 = 0.47, *Adj R^2* = 0.09, F = 1.24, p = 0.38). None of the blocks accounted for a significant proportion of variance in shock anxiety or

trait anxiety, and there were no significant independent predictors in either model. Change in knowledge explained an additional 8% of the variance in trait anxiety and 7% in shock-related anxiety.

Hypothesis 4

There were no differences of baseline anxiety between the PACER participants and the in-person treatment participants, t = -0.73, p = 0.47, and thus no need to use anxiety as a covariate. A Multivariate Analysis of Variance was employed to explore differences by treatment study in trait anxiety, device acceptance, and mental and physical QOL at follow-up. There were no violations of Box's M test of homogeneity; however, Levene's test statistic was significant for trait anxiety (p = 0.00). Therefore, the more conservative *Pillai's Trace* was used in interpreting the multivariate model. The omnibus F was significant (*Pillai's Trace* = 2.94, p = 0.04, *partial* η^2 = 0.28). Separate tests of between-subjects effects demonstrated a significant effect on the dependent variable physical QOL (F = 8.71, p = 0.006), while the ANOVA for trait anxiety approached significance *(F = 3.23, p = 0.08)*. The direction of effect was such that participants in the in-person study had greater scores of physical QOL post-intervention, and a trend toward lower scores of trait anxiety (see Table 4-5). Given the violation of the Levene's statistic, a separate ANOVA using the Kruskal-Wallis rank test for non-parametric data was employed to examine scores of trait anxiety. In this analysis, no differences in trait anxiety between study participants was demonstrated (χ^2 = 1.13, p = 0.29). Scores of anxiety for PACER patients increased slightly from baseline to post-treatment (33.81 vs. 36.25), though not significantly (t = -1.12, p = 0.28).

In order to examine whether there were changes in physical QOL and trait anxiety over time, a repeated measures design was employed. There was no violation of Box's M test; however, there was a violation of Mauchly's tests of sphericity (*Mauchly's W* = 0.38, p = 0.00).

Violation of the sphericity assumption can result in inflated F-ratios. Therefore, the *Huynh-Feldt* correction was applied on tests of within-subjects effects. The multivariate model was significant, *Pillai's Trace* = 3.87, *p* = 0.02, *partial-η²* = 0.28, and within-subjects time by group effects were also significant, *F* = 4.69, *p* = 0.01. Parameter estimates demonstrated significant group differences for physical QOL over time, but not for trait anxiety.

User Survey Data

Following completion of the follow-up knowledge survey, treatment patients were asked brief questions about their opinions of the PACER program (see Table 4-6). Thirteen participants completed this portion of the questionnaire. When asked when would be the most effective time to receive the PACER Program, 10 said following implant and two said immediately following their clinic visit.

Regarding ease of use, six rated the program as "easy," four as "moderately easy", and three as "excellent." All respondents stated that they would recommend the program to another device recipient. When asked to rate which sections were most helpful, four selected information about managing stress, five selected information about the device itself, two selected information about device shock, and one selected information on managing family relationships. Seven participants rated the program as "somewhat helpful" and six rated it as "extremely helpful." When asked about which topics they would want additional information, four selected stress management, three selected device information, and two selected family relationships.

Post-Hoc Analyses

The following section addresses additional interesting findings and post-hoc analyses that were conducted after the initial planned statistical analyses. Due to the addendum nature of these analyses, caution should be utilized in interpreting this data.

Effects on New Recipients versus Previous Recipients

The original intent of the study was to include only new recipients of ICDs. As noted earlier, recruitment difficulties resulted in new and previous recipients being enrolled in the study simultaneously. A post-hoc analysis was conducted to search for possible differences in scores between new and previous ICD patients, with length of time since implant being dichotomized according to whether or not someone was a very recent recipient (e.g., < 3 months). Zero-order correlations revealed an association between dichotomized length of time and improvement in knowledge score, device acceptance at follow-up, and shock anxiety at follow-up. New ICD recipients had a mean change in knowledge score from baseline to follow-up of 4.14 points (*S.D.* = 3.98), while previous recipients had a mean change score of less than 1 point (*M* = 0.71, *S.D.* = 2.79); this difference was statistically significant (*t* = 2.64, *p* = 0.01). Improvement in knowledge was dichotomized by whether or not an individual's score increased from baseline to follow-up. Being a new recipient was associated with improved knowledge scores *(r* = 0.50, *p* = 0.01), but lower device acceptance (*r* = 0.38, *p* = 0.04) and greater shock anxiety at follow-up (*r* = 0.42, *p* = 0.02). A chi-square analysis indicated that new recipients were significantly more likely to have improved knowledge at one month (χ^2 = 7.04, *p* = 0.01), accounting for 73% of the cases of improved knowledge scores. There were no differences by treatment condition among the new recipients (*p* > 0.50).

Although at baseline new recipients differed from previous ones on nearly all psychological measures, a MANOVA examining QOL, shock anxiety, and device acceptance was employed because these were the only follow-up variables correlated with being a new recipient. Further, at follow-up, the only variables that differed between new and previous recipients were device acceptance and shock anxiety, with new patients having worse scores on both measures. The overall model failed to reach significance (*Pillai's Trace* = 1.56, *p* = 0.22,

partial η^2 = 0.21). Although the omnibus F was not significant, tests of between-subjects effects

were examined in order to inform possible directions for future research. These separate

ANOVAs revealed significant results for the dependent variables device acceptance (*F* = 4.35, *p*

= 0.04) and shock anxiety (*F* = 5.65, *p* = 0.02), with new recipients demonstrating lower scores

of device acceptance and greater scores of shock anxiety at follow-up than previous ICD

recipients.

Effects of Knowledge on Quality of Life

Two of the *a priori* analyses in this study examined knowledge as a potential predictor in

device acceptance and anxiety. Post-hoc, the relationship between knowledge and QOL was

examined. In this analysis, a hierarchical regression was employed to examine whether

knowledge at follow-up predicted mental QOL at follow-up among all participants. In the first

block, demographic variables related to knowledge acquisition (e.g., age and education level)

were entered. In the second block, medical variables (e.g., ejection fraction and length of time

since implant) were entered. In the third block, knowledge score at one month was entered. The

full model was not significant (*F* = 2.10, *p* = 0.11) and accounted for 26% of the variance in

mental QOL at follow-up (*Adj R^2* = 0.14). However, the knowledge change score significantly

accounted for an additional 13% of variance in device acceptance (*F-Change* = 4.03, *p* = 0.05)

beyond demographic and medical variables. Age (*ß* = 0.39, *p* = 0.04) and knowledge at follow-

up (*ß* = 0.37, *p* = 0.05) were both significant independent predictors of mental QOL at follow-

up. When examined separately by treatment condition, both regression analyses failed to meet

significance. Further, when the same model was examined using physical QOL as the criterion,

all analyses failed to meet significance.

Table 4-1. Social and demographic variables by treatment condition

Characteristics	Treatment Condition	Control Condition	Test statistic	p-value
Gender	Male = 62% Female = 38%	Male = 56% Female = 44%	$\chi^2 = 1.61$	$p = 0.69$
Mean age	56.05 (SD = 15.11)	58.72 (SD = 12.10)	$t\,(1, 37) = -0.60$	$p = 0.55$
Ethnicity			$\chi^2 = 3.82$	$p = 0.15$
White	81%	100%		
Black	14%	0%		
Marital status			$\chi^2 = 3.78$	$p = 0.44$
Single, never married	10%	0%		
Separated, divorced	10%	0%		
Widowed	5%	11%		
Married/remarried	62%	56%		
Living with partner	10%	11%		
Education			$\chi^2 = 5.88$	$p = 0.55$
High school degree or less	43%	33%		
College degree or some college	48%	50%		
Graduate	10%	6%		
Employment			$\chi^2 = 0.84$	$p = 0.93$
Retired	43%	39%		
Disability/ government	33%	28%		
Part time	10%	11%		
Full time	10%	6%		
Unemployed	5%	11%		
Income (annual)			$\chi^2 = 4.52$	$p = 0.61$
Less than $30,000	10%	17%		
$30,000-$60,000	33%	33%		
More than $60,000	33%	11%		

Table 4-2. Psychological variables at baseline, by treatment condition

Measure	Treatment Condition	Control Condition	Test statistic	*p*-value
ICD Knowledge	M = 18.30 (S.D. = 3.60)	M = 17.76 (S.D. = 3.09)	*F = 0.23*	*p > 0.50*
STAI	M = 34.93 (S.D. = 9.80)	M = 33.76 (S.D. = 7.22)	*F = 0.00*	*p > 0.50*
FSAS	M = 14.80 (S.D. = 5.98)	M = 16.17 (S.D. = 7.76)	*F = 0.31*	*p > 0.50*
FPAS				
Return to Life Scale	M = 53.75 (S.D. = 20.16)	M = 62.87 (S.D. = 25.62)	*F = 1.23*	*p = 0.28*
Body Image Scale	M = 11.67 (S.D. = 20.30)	M = 14.70 (S.D. = 18.87)	*F = 0.19*	*p > 0.50*
Device Related Distress Scale	M = 20.31 (S.D. = 19.36)	M = 16.56 (S.D. = 18.59)	*F = .31*	*p > 0.50*
Positive Appraisal Scale	M = 87.50 (S.D. = 16.08)	M = 86.02 (S.D. = 18.69)	*F = 0.05*	*p > 0.50*
Total Score	M = 76.19 (S.D. = 15.25)	M = 79.22 (S.D. = 18.34)	*F = 0.24*	*p > 0.50*
SF-12				
Mental QOL	M = 52.31 (S.D. = 8.71)	M = 51.39 (S.D. = 11.67)	*F = 0.06*	*p > 0.50*
Physical QOL	M = 32.34 (S.D. = 10.60)	M = 35.00 (S.D. = 10.15)	*F = 0.53*	*p = 0.47*
LVD-36	M = 59.07 (S.D. = 30.14)	M = 58.16 (S.D. = 27.86)	*F = 0.03*	*p > 0.50*

Table 4-3. Baseline Psychological Variables of New and Previous
Recipients

		Mean	SD	F	Sig.
ICD Knowledge				0.72	0.40
	New	17.29	2.93		
	Previous	10.93	30.62		
Trait Anxiety				4.09	0.05
	New	36.52	8.74		
	Previous	30.80	7.04		
Mental QOL				14.4	0.00
	New	46.42	10.19		
	Previous	57.93	6.15		
Physical QOL				6.41	0.01
	New	29.76	9.52		
	Previous	38.27	9.44		
Device Acceptance Total Score				6.89	0.01
	New	70.88	18.23		
	Previous	84.66	9.536		
Device Acceptance: Return To Life Scale				2.53	0.12
	New	52.57	24.71		
	Previous	65.41	20.30		
Device Acceptance: Device-Related Distress Scale				6.76	0.01
	New	25.88	21.45		
	Previous	10.00	10.52		
Device Acceptance: Positive Appraisal Scale				4.22	0.04
	New	80.51	18.99		
	Previous	92.50	12.98		
Device Acceptance: Body Image Concern Scale				4.71	0.03
	New	19.85	22.56		
	Previous	5.83	11.44		
FSAS Total Score				4.33	0.04
	New	17.82	8.33		
	Previous	12.93	5.58		
LVD Total Score				19.50	0.00
	New	41.99	26.25		
	Previous	76.48	15.91		

Table 4-4. Independent predictors of device acceptance at follow-up, among treatment participants

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Correlations		
						Zero-order		
	B	Std. Error	Beta				Partial	Part
(Constant)	2.936	1.799		1.632	.137			
Age	.032	.014	.498	2.285	.048	.253	.606	.426
Highest grade completed	.203	.098	.461	2.067	.069	.484	.567	.385
Ejection Fraction	.023	.019	.266	1.207	.258	.146	.373	.225
How long had ICD? (months)	.002	.008	.065	.263	.798	.182	.087	.049
Change in score from pre to post	.171	.058	.642	2.952	.016	.448	.701	.550

Table 4-5. Post-intervention psychological variables from the PACER Study and the in-person study.

	Study	M	SD	Sig.
Physical QOL	PACER	36.35	7.96	
	In-person	44.85	8.74	$p < 0.01$
Mental QOL	PACER	55.14	7.38	
	In-person	55.25	5.49	ns
Trait Anxiety	PACER	36.25	11.60	
	In-person	30.67	5.90	ns
FPAS Total	PACER	78.23	15.93	
	In-person	83.43	11.12	ns

Table 4-6. User Survey of PACER Program

Number of times program accessed	1.77 times	What areas of the program were most beneficial?	
Number of minutes spent viewing program	28.69 minutes	Stress Management	31%
		Shock Management	15%
When should PACER be given?		Device Information	39%
Following implant	83%	Family Relationships	8%
Following clinic visit	17%	Other	8%
How easy would you rate the program?		Would you recommend this program to other ICD recipients?	
Moderately Easy	46%	Yes	100%
Easy	31%		
		What areas of the program would you like more information?	
Excellent	23%	Stress Management	40%
		Device Information	30%
How beneficial was the program?		Family Relationships	20%
Somewhat beneficial	54%	Other	10%
Very beneficial	46%		

CHAPTER 5
DISCUSSION

The primary findings from this pilot study of a computerized psychoeducation program for ICD recipients were as follows: 1) Increases in device-related knowledge were predictive of better device acceptance, but only among treatment patients; and 2) treatment participants using the PACER program demonstrated comparable improvements in mental QOL and device acceptance, significantly lower scores of physical QOL, and a trend toward higher trait anxiety post-treatment, as compared to individuals in an in-person intervention.

Acquisition of Knowledge Between Groups

There was no identifiable difference between treatment groups in learning, as measured by the ICD Knowledge Questionnaire. It may be that patients in the control condition sought information on their own, or that much of the information in the program overlapped with information all patients received from their healthcare providers or other resources encountered during routine care. The PACER program is considered a psychoeducation tool because it provides not only descriptive facts about the device and its functioning, it also relays psychological techniques for returning to full activities. Because these are more complex concepts, it may be that treatment participants failed to learn more due to lack of human interaction to explain, teach, demonstrate, and answer questions.

A recent meta-analysis of online CBT programs for depression and anxiety (Spek, et al., 2007) suggested that treatment effects may be strongly influenced by whether or not an intervention is supplemented with minimal therapist involvement. The authors defined minimal involvement as being brief, supportive, and facilitative, such as answering questions about using the intervention or providing brief reinforcement for using the material. They did not include studies that utilized clinician involvement that would be considered more traditional and

analogous to in-person therapy. Among 12 randomized-controlled studies, the authors found a mean effect size of 0.24 for all studies examined. When analyzed by design characteristics, they found a significantly smaller effect size for studies without clinician involvement *(d* = 0.24) than for studies that provided therapist assistance (d = 1.00). It is hypothesized that treatment patients in the current study may have failed to demonstrate a quantifiable difference in learning score due to lack of therapist support. Previous participants (Carlbring, Ekselius, & Andersson, 2003) have reported that while at-home, self-guided treatments are convenient, they require more self-discipline in adhering to assignments and attending to information. They also note that a group setting in which patients could discuss content and concerns with one another may enhance motivation (Carlbring et al., 2003). Supplementing the PACER program with brief support, such as random phone calls to inquire about participant questions and to provide positive feedback , may be an easy and effective way to optimize the effects of the intervention.

Qualitatively, there was overwhelming support of the PACER program from treatment participants. All recipients noted that they thought the program was worth recommending to others, and described it as being beneficial. Research from Shea (2004) and others (Steinke et al., 2005) reveal that patients often require additional education about sexual activity, driving, and managing device shock. In this sample, treatment patients reported benefiting from and desiring more information about stress management and about the device in general (e.g., non-shock related information, post-implant adjustment). Because of its aversive nature, it is somewhat surprising that more participants did not endorse needing and benefiting from information related to device shock. While education about firings, such as making a shock plan, is arguably important and necessary for patient adjustment and good QOL (Sears & Conti, 2003), healthcare providers should not overlook the importance of other domains. In particular, participant

feedback about the importance of stress management speaks to the necessity of psychological

assistance as an integral part of comprehensive care in this population. User ratings from this

sample suggest that there is an audience for further testing of computerized programs in the ICD

population, which may help clarify how and in what ways these patients understand and process

information about their device.

Relationship of Knowledge to Device Acceptance

As stated previously, treatment participants in this study did not demonstrate a quantifiable

change in aggregate knowledge compared to usual care patients. However, the fact that they

demonstrated improvements in device acceptance relative to gains in knowledge, whereas

control participants did not exhibit this pattern, is important. It may be that while the intervention

did not substantially increase the amount of information learned, the intervention was effective at

increasing acceptance without increasing knowledge differentially. Similarly, psychological

treatments target change in adjustment, and not didactic knowledge. Therefore, the PACER

program, though psycho-educational in content, may be more analogous to a therapeutic tool

rather than an educational one. This may also somewhat account for post-hoc findings of

improved mental QOL among PACER patients, but not physical QOL.

Control patients had access to public information resources, such as the Internet, which

could help them increase their ICD-related knowledge. They also likely could acquire through

public resources generalized, simplified concepts of CBT, such as engaging in pleasant activities

and developing a positive outlook to reduce stress. However, what PACER provides, that the

control patients likely would not discover on their own, is a structured, specific application of

empirical techniques to the unique stressors faced by this population. For example, the

intervention does not generically teach cognitive reframing. Rather, it explains how negative

cognitions about the ICD impact one's physical and emotional functioning, and provides

examples regarding device shock and avoidance activities to aid patients in using CBT in such a way to increase their understanding and acceptance of the device. This reflects the core of what the FPAS measures, and thus, it is reasonable that such an intervention – if effective – would yield improvement in this domain. Despite this, without a control group exposed to similar content of information minus the CBT modules, it is difficult to attribute effects solely to the psychological material.

The ecological validity implied by this finding should not be minimized. An increase in a test score alone would likely hold little practical meaning to a patient. If, however, learning something new about their device allows ICD patients to ultimately feel more comfortable and confident, then the quantity of information learned becomes less salient. To say that the PACER intervention was developed to help ICD patients become more educated about their does not fully capture the purpose its design. The goal of the program was not merely to serve as a didactic tool, but to ultimately provide psychological benefit in adjustment and outlook. If this is occurs, even without significantly increasing patients' knowledge base, than it should be considered a success. Further, the additional benefits of low cost and high convenience increase PACER's utility and importance.

Knowledge and Anxiety

In this sample, there was no relationship between gains in knowledge and trait or shock anxiety. Anxiety tends to be cognitive in nature, and can be deeply engrained and resistant to change. Self-directed treatments that are entirely computer-based may have difficulty reducing anxiety for these reasons. Self-directed programs to treat anxiety disorders, including panic disorder and phobias, may be successfully conducted via computer (Barlow, et al., 2005). However, effective programs have typically included structured homework assignments and exposure techniques. Some researchers (Kenwright & Marks, 2004; Schneider, Mataix-Cols,

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Marks, & Bachofen, 2005) have supplemented their computerized interventions with brief clinician contact by telephone. In their pilot study on panic and phobias, Kenwright, Liness, and Marks (2001) required participants to utilize a computer treatment in the presence of a nurse, who was available to answer questions and review content from previous sessions. Other researchers (Carlbring, Ekselius, & Andersson, 2003) used brief contact by both telephone and email to remind patients about skills (e.g., reminders to engage in relaxation), review homework assignments, and answer questions. Marks and colleagues (2004) found that a computerized program for anxiety that utilized minimal clinician contact demonstrated comparable effect sizes for treatment outcomes versus an in-person CBT group, yet managed to reduce clinician time per-patient by 73%. Therefore, the brief addition of human interaction to a self-guided, at-home program such as PACER may effectively treat anxiety, while still reducing provider workload and treatment burden.

Controllability (or lack thereof) has been identified as an influential factor in the development and persistence of clinical anxiety (Moulding & Kyrios, 2006), such as OCD. In these populations, successful therapeutic interventions utilize role playing, behavioral modification, relaxation, and Socratic questioning (Moulding & Kyrios). While computerized interventions have been able to significantly improve functional and psychosocial outcomes in OCD patients (Mataix-Cols & Marks, 2006), these studies still integrated human interaction to some degree. Although the current study did not examine OCD, these comparisons may be valuable because controllability is very pertinent to ICD patients. Researchers (Sears & Conti, 2003) have hypothesized that the uncontrollable, unpredictable nature of ICD firings may be largely responsible for the development of psychiatric distress in shocked patients, via learned helplessness (Goodman & Hess, 1999) or negative cognitions (Pauli et al., 1991, 2001). It may

be that factors such as negative appraisals and lack of controllability are more difficult to address in the absence of therapist support, and do not necessarily remit as a result of having increased one's knowledge about the ICD.

Computerized versus In-Person Treatments

One unique aspect of the current project is that, to date, no published study has compared in-person and computerized psychoeducation interventions for ICD recipients. The PACER program demonstrated comparable improvements in mental QOL and device acceptance as an in-person intervention. However, the in-person group reported better physical QOL and less trait anxiety than PACER patients, despite the fact that they were drawn from a sample of patients who had experienced device shock.

The in-person treatment examined in the present study used a multi-visit protocol in which patients had the opportunity to repeatedly discuss previous topics and were reminded of concepts taught in prior sessions. Homework assignments allowed participants to individually apply concepts to their own adjustment difficulties, and they were encouraged to discuss these findings in subsequent sessions. Conversely, the PACER program is entirely self-directed. Patients can choose to use the program as little or as frequently as they wish, and may involve themselves in the topic matter to whatever degree they feel necessary. Attending group treatments may reduce perceptions of self-burden, as the presence of both the healthcare provider and other attendants provides opportunities for learning that do not directly require the patient to remain actively involved throughout. Future research with the PACER Program should consider a more equivalent approach to the in-person treatment, such that group effects can be accounted for (e.g., including a moderated chat room).

New versus Established ICD Recipients

Although post-hoc analyses should not be used to draw definitive conclusions, the results from current analyses comparing new recipients to previous recipients are revealing. Regarding future research, these data may be valuable in informing clinicians about which patients may benefit the most from education interventions. Patients typically do receive some education about their device prior to implant, but they may nevertheless feel uninformed and require greater information from providers about topics such as sexual concerns, device shock, driving, and working (Steinke et al., 2005; Shea, 2004). Analyses from the current sample imply that providing information sooner rather than later could give patients an added advantage in optimizing their adjustment to the ICD.

New recipients demonstrated worse scores of psychological functioning on nearly every measure, compared to previous recipients, suggesting that they may be an appropriate target for psychotherapeutic treatment. Interestingly, they also demonstrated better scores of cardiac-specific QOL via a measure of symptom assessment. Given that ICDs are being increasingly implanted prophylacticly, before patients exhibit severe symptoms, this might account for why newer patients endorsed fewer symptoms, thus improving their score on this measure. Despite their increase in learning, new patients were also more likely to report less device acceptance and greater shock-related anxiety at follow-up. This finding supports the utility of psychological referral for new patients – perhaps even prior to implant – and not simply disseminating literature as a means of addressing patient concerns. Understandably, information regarding the ICD may be overwhelming and anxiety-provoking to some patients. Involving psychological professionals in the education of ICD recipients may help them better comprehend and apply information given. In some patients, psychiatric distress (e.g., panic disorder, phobias) may be less tractable, and education interventions will not be sufficient. Again, by keeping psychological

professionals involved at the onset of implantation, patients will have greater access to care, which increases their chances of treatment adherence and satisfaction.

Limitations

Results from this pilot study of the PACER program are somewhat encouraging. However, they should be considered in light of some study limitations. Notably, small sample size is problematic for numerous reasons, including low statistical power, lack of generalizability, and poor representation of the ICD population as a whole. Cross-sectional data may be useful for quickly acquiring a point-in-time view of a sample, but can mask effects of time and limits one's ability to make causal interpretations. As such, longitudinal collection is necessary to fully appreciate the short- and long-term effects of the treatment at hand. Given that this study was designed as a feasibility program, conclusive generalizations cannot be made from these data alone. Rather, this study may be used as a springboard for broader, more sophisticated protocols designed to test in-depth the effectiveness of PACER for ICD patients.

The fact that the sample consisted of both new and previous recipients makes drawing conclusions about knowledge and learning more difficult. Although post-hoc analyses attempted to parse out effects based on time of implant, a sample composed entirely of new recipients would help alleviate this problem to some degree. Simply by having had the device longer, previous recipients are exposed to practice effects of living with and adjusting to the ICD. This is relevant for both greater opportunities to learn and accept the device, but also greater opportunities to experience difficulties and struggle with the device. Therefore, the relevance and usefulness of the intervention may not be consistent across both types of patients.

Other potential barriers include the fact the sample was drawn from a single site and therefore likely reflects a sampling bias, and heavily relied on self-report measures, which are influenced by demand-characteristics and may not accurately reflect patient functioning. In

particular, use of the PACER program was not monitored and thus effects cannot be interpreted

in light of factors such as length of time spent using the techniques taught (e.g., relaxed

breathing).

CHAPTER 6
FUTURE WORK

There is more research being conducted on computerized psychological interventions at this time than at any time before. Data supporting the development of these novel programs is exciting and helps to enrich the healthcare profession as a whole. The current study contributes to this body of research in several ways: One, it is among few computerized interventions intended for cardiac patients to optimize their adjustment to illness; two, there are currently no published computerized interventions for ICD patients specifically; and three, there are currently no published interventions comparing computerized psychosocial treatments to in-person treatments for either cardiac patients or ICD patients specifically.

In this sample, knowledge gained from the PACER program was associated with improved device acceptance. Further, the program produced comparable improvements in mental QOL and device acceptance as an in-person psychosocial CBT treatment for shocked patients. Patients who used the program reported feeling very satisfied with its content and level of ease, and overwhelming supported its recommendation to other recipients. Taken together, these outcomes support future testing of PACER and similar programs in this unique population. Lack of findings in aggregate knowledge and anxiety are informative for future program development. Subsequent trials of PACER can easily be supplemented with limited therapist assistance, which may substantially improve some of the null outcomes demonstrated by this sample.

Post-hoc analyses lend further support to the integration of psychological care with standard clinical care in this population. In this sample, new recipients predominantly accounted for patients who demonstrated an improvement in learning. Given that participants reported benefiting from and wanting more information about stress management, this suggests that involving psychologists at the onset of device implantation may be an effective way of

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addressing educational and psychological needs concurrently. The current study, though,

provides an interesting starting point for such research and upholds the importance of increasing

our understanding in this area.

In sum, findings from this study lend support for further use of computerized psychosocial

interventions for ICD patients. The PACER program showed promising results in improving

mental QOL and device acceptance, relative to an in-person group, and minor changes in design

methodology may further strengthen PACER's ability to maximize patient outcomes in future

trials.

APPENDIX
MEASURES

FPAS

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 circling the appropriate response.

	Strongly Disagree	Mostly Disagree	Neither Agree or Disagree	Mostly Agree	Strongly Agree
1. Thinking about the device makes me depressed.	1	2	3	4	5
2. When I think about the device I avoid doing things I enjoy.	1	2	3	4	5
3. I avoid my usual activities because I feel disfigured by my device.	1	2	3	4	5
4. It is hard for me to function without thinking about my device.	1	2	3	4	5
5. My device was my best treatment option.	1	2	3	4	5
6. I am confident about my ability to return to work if I want to.	1	2	3	4	5
7. I am safer from harm because of my device.	1	2	3	4	5
8. The positive benefits of this device out-weigh the negatives.	1	2	3	4	5
9. I have continued my normal sex life.	1	2	3	4	5
10. I would receive this device again.	1	2	3	4	5
11. I know enough about my device.	1	2	3	4	5
12. I am careful when hugging or kissing my loved ones.	1	2	3	4	5
13. I have returned to a full life.	1	2	3	4	5
14. I feel that others see me as disfigured by my device.	1	2	3	4	5
15. I feel less attractive because of my device.	1	2	3	4	5
16. I am knowledgeable about how the device works and what it does for me.	1	2	3	4	5
17. I am not able to do things for my family the way I used to.	1	2	3	4	5

18. I am concerned about resuming my daily physical activities.	1	2	3	4	5

LVD-36

Please answer the following questions as you are feeling **these days**. Circle either true or false for each question. *If you do these activities for any reason other than your heart condition, then please mark false*.

Because of my heart condition:	**True**	**False**
1. I suffer with tired legs	T	F
2. I suffer with nausea (feeling sick)	T	F
3. I suffer with swollen legs	T	F
4. I am afraid that if I go out I will be short of breath	T	F
5. I am frightened to do too much in case I become short of breath	T	F
6. I get out of breath with the least physical exercise	T	F
7. I am frightened to push myself to go to far	T	F
8. I take a long time to get washed or dressed	T	F
9. I have difficulty running, such as for a bus	T	F
10. I have difficulty either jogging, exercising or dancing	T	F
11. I have difficulty playing with children/grandchildren	T	F
12. I have difficulty either mowing the lawn or hovering/vacuum cleaning	T	F
13. I feel exhausted	T	F
14. I feel low in energy	T	
15. I feel sleepy or drowsy	T	F
16. I need to rest more	T	F
17. I feel that everything is an effort	T	F

18. My muscles feel weak	T	F
19. I get cold easily	T	F
Because of my heart condition:	**True**	**False**
20. I wake up frequently during the night	T	F
21. I have become frail or an invalid	T	F
22. I feel frustrated	T	F
23. I feel nervous	T	F
24. I feel irritable	T	F
25. I feel restless	T	F
26. I feel out of control of my life	T	F
27. I feel that I can not enjoy a full life	T	F
28. I've lost confidence in myself	T	F
29. I have difficulty having a regular social life	T	F
30. There are places I would like to go to but can't	T	F
31. I worry that going on holiday could make my heart condition worse	T	F
32. I have had to alter my lifestyle	T	F
33. I am restricted in fulfilling my family duties	T	F
34. I feel dependent on others	T	F
35. I feel it is a real nuisance having to take tablets for my heart condition	T	F
36. My heart condition stops me doing things that I would like to do	T	F

SF-12 HEALTH SURVEY

INSTRUCTIONS: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

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

Ə	Ə	Ə	Ə	Ə
Excellent	**Very good**	**Good**	**Fair**	**Poor**

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

	Yes, Limited A lot	**Yes, Limited A little**	**No, Not Limited At All**
2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	Ə	Ə	Ə
3. Climbing **several** flights of stairs	Ə	Ə	Ə

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

	YES	**NO**
4. **Accomplished less** than you would like	Ə	Ə
5. Were limited in the **kind** of work or other activities	Ə	Ə

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

	YES	NO
6. **Accomplished less** than you would like	ɘ	ɘ
7. Didn't do work or other activities as **carefully** as usual	ɘ	ɘ

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

ɘ	ɘ	ɘ	ɘ	ɘ
Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

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

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9. Have you felt calm and peaceful?	ɘ	ɘ	ɘ	ɘ	ɘ	ɘ
10. Did you have a lot of energy?	ɘ	ɘ	ɘ	ɘ	ɘ	ɘ
11. Have you felt downhearted and blue?	ɘ	ɘ	ɘ	ɘ	ɘ	ɘ

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

ɘ   ɘ   ɘ   ɘ   ɘ

All of the time   Most of the time   Some of the time   A little of the time   None

SAS (Shock Anxiety Scale)

I am scared to exercise because it may increase my heart rate and cause my device to fire.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I am afraid of being alone when the ICD fires and I need help.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I do not get angry or upset because it may cause my ICD to fire.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

It bothers me that I do not know when the ICD will fire.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I worry about the ICD not firing sometime when it should.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I am afraid to touch others for fear I'll shock them if the ICD fires.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I worry about the ICD firing and creating a scene.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

When I notice my heart beating rapidly, I worry that the ICD will fire.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I have unwanted thoughts of my ICD firing.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

I do not engage in sexual activities because it may cause my ICD to fire.

1	2	3	4	5
Not at all	Rarely	Some of the time	Most of the time	All the time

Self-Evaluation Questionnaire
STAI Form Y-2

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you **generally** feel.

	Almost never	Some-times	Often	Almost Always
1. I feel pleasant.	1	2	3	4
2. I feel nervous and restless.	1	2	3	4
3. I feel satisfied with myself.	1	2	3	4
4. I wish I could be as happy as others seem to be.	1	2	3	4
5. I feel like a failure.	1	2	3	4
6. I feel rested.	1	2	3	4
7. I am "calm, cool, and collected."	1	2	3	4
8. I feel that difficulties are piling up so that I cannot overcome them.	1	2	3	4
9. I worry too much over something that really doesn't matter.	1	2	3	4
10. I am happy.	1	2	3	4
11. I have disturbing thoughts.	1	2	3	4
12. I lack self-confidence.	1	2	3	4
13. I feel secure.	1	2	3	4
14. I make decisions easily.	1	2	3	4
15. I feel inadequate.	1	2	3	4
16. I am content.	1	2	3	4
17. Some unimportant thought runs through my mind and bothers me.	1	2	3	4
18. I take disappointments so keenly that I can't put them out of my mind.	1	2	3	4

19. I am a steady person.	1	2	3	4
20. I get in a state of tension or turmoil as I think over my recent concerns and interests.	1	2	3	4

The Florida ICD Knowledge Questionnaire

Education About Your Heart, ICD, and Shocks

1. What does ICD stand for?
    1. Internal cardiac device
    2. Implanted cardioverter device
    3. Implantable cardioverter defibrillator
    4. Internal cardiac defibrillator

2. True or False: Approximately one-third of all ICD patients will experience distress, such as depression or anxiety?
    1. True
    2. False

3. The ICD's main function is to _____.
    1. Remind you of heart disease
    2. Prevent cardiac arrest
    3. Let you know when to go to the hospital
    4. Keep you awake

Managing Stress Before Stress Manages You

4. Which of the following is *not* a healthy way to reduce stress?
    1. Deep breathing
    2. Worrying about your health
    3. Changing thinking patterns
    4. Exercising

5. Good coping skills include _____.
    1. Managing your attitude
    2. Having a drink
    3. Eating junk food
    4. Watching television

6. How many ICD patients feel stress within the first month after the implantation of their device?

1. A few
2. Most
3. None
4. All

7. What percent of ICD patients report having the same or better quality of life after one year?
   1. 15%
   2. 42%
   3. 60%
   4. 85%

8. Most patients report that their emotional well-being is _____ it was before receiving an ICD.
   1. Worse than
   2. Different from
   3. Better or about the same as
   4. No different from

9. The top 10 challenges faced by ICD patients include all *except:*
   1. Socializing with friends
   2. Sexual concerns
   3. Generalized fear
   4. Stress management

Your Outlook Can Make the Difference

10. Which of the following thinking patterns results from exaggerating the negative impact of an event to the highest extent?
    1. Catastrophizing
    2. All-or-Nothing
    3. Blaming
    4. All of these

11. Which thought pattern can be addressed by realizing that life is a balance of both good and bad elements?
    1. Catastrophizing
    2. All-or-Nothing
    3. Blaming
    4. None of these

12. Which of the following thought patterns often develops into anger or resentment directed at others?
    1. Catastrophizing
    2. All-or-Nothing

3. Blaming
4. None of these

13. The term "sickness scoreboard" refers to _____.
   1. Keeping score of your condition and counting shocks
   2. Comparing your shocks to others' shocks
   3. Seeing if you have more symptoms than your friends
   4. None of these

14. The problem with the "sickness scoreboard" approach is that_____.
   1. It makes you sicker
   2. It annoys your spouse
   3. It is not accurate because shocks do not serve as health indicators
   4. There are no problems with it

15. True or False: Receiving more shocks means you are getting sicker?
   1. True
   2. False

16. True or False: Research shows that having a positive attitude can affect how you react to illness and medical procedures?
   1. True
   2. False

Take Control By Taking Action

17. Which of the following activities should you avoid solely because of your ICD?
   1. Being in a crowd
   2. Sex
   3. Having an argument
   4. None of these

18. True or False: Certain everyday activities have been known to trigger shock?
   1. True
   2. False

19. Good coping skills include _____.
   1. Improving your sleep
   2. Having a drink
   3. Eating junk food
   4. Watching television

A Family Affair

20.   Family relationships can be improved by:
       1. Providing praise to you loved one in front of others
       2. Giving your time and attention to loved ones
       3. Letting loved ones know their support is helping you
       4. All of these

21.   True or False: ICD patients should avoid sex because the increased heart rate caused by sex could trigger a shock?
       1. True
       2. False

22.   True or False: Sex is especially straining on the heart?
       1. True
       2. False

23.   The best predictor of a couple's satisfaction with their sex life is _____.
       1. How frequently they have sex
       2. How healthy both partners are
       3. How comfortable they are discussing their sexual relationship
       4. Their age

Planning For and Coping With Shocks

24.   Your ICD shock plan should include all of the following parts ***except:***
       1. Preparing for shock
       2. Actions immediately following shock
       3. A long-term plan
       4. Fearing shock

25.   True or False: If someone is touching you when you receive a shock, they will be hurt?
       1. True
       2. False

26.   Which of the following can interfere with the functioning of your ICD?
       1. Microwaves
       2. Irons
       3. Televisions
       4. None of these

LIST OF REFERENCES

Agre, P., Dougherty, J., & Pirone, J. (2002). Creating a CD-ROM program for cancer-related patient education. *Oncology Nursing Forum, 29*, 573-580.

American Heart Association. Heart Disease and Stroke Statistics—2004 Update. Dallas, TX: American Heart Association, 2004.

Atkinson, N.L., & Gold, R.S. (2002). The promise and challenge of eHealth interventions. *American Journal of Health Behaviors, 26*, 494-503.

AVID Investigators. (1997). A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. *New England Journal of Medicine, 337,* 1576-1583.

Barlow, J.H., Ellard, D.R., Hainesworth, J.M., Jones, F.R., & Fisher, A. (2005). A review of self-management interventions for panic disorders, phobias, and obsessive-ocmpulsive disorders. *Acta Psychiatry Scandinavia, 111*, 272-285.

Brug, J., Oenema, A., & Campbell, M. (2003). Past, present, and future of computer-tailored nutrition education. *American Journal of Clinical Nutrition, 77*, 1028S-1034S.

Burns, J.L., Serber, E.R., Keim, S., & Sears, S.F. (2005). Measuring patient acceptance of implantable cardiac device therapy: Initial psychometric investigation of the Florida patient acceptance survey (F-PAS). *Journal of Cardiovascular Electrophysiology,* In press.

Buxton, A.E., Lee, K.L., Fisher, J.D., Josephson, M.E., Prystowsky, E.N., Hafley, G., et al., for the Multicenter Unsustained Tachycardia Trial Investigators. (1999). A randomized study of the prevention of sudden death in patients with coronary heart disease. *New England Journal of Medicine, 341*, 1882-1890.

Carlbring, P., Ekselius, L., & Andersson, G. (2003). Treatment of panic disorder via the Internet: A randomized trial of CBT vs. applied relaxation. *Journal of Behavioral Therapy and Experimental Psychiatry, 34,* 129-140.

Cavanagh, K., & Shapiro, D. (2004). Computer treatment for common mental health problems. Journal of Clinical Psychology, 60, 239–251.

Christensen, H., Griffiths, K.M., & Korten, A. (2002). Web-based cognitive behavior therapy: Analysis of site usage and changes in depression and anxiety scores. *Journal of Medical Internet Research, 4*, e3.

Cleary P. (1999). The increasing importance of patient surveys. *British Medical Journal,* 319, 720-721.

Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences,* 2nd edition. Lawrence Erlbaum Associates: Hillsdale, NJ.

Cohen, J. (1992). The Power Primer. *Psychology Bulletin, 112*, 155-159.

Connolly, S.J., Gent, M., Roberts, R.S., Dorian, P., Roy, D., Sheldon, R.S., et al. (2000). Circulation Canadian implantable defibrillator study (CIDS): A randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation, 101*, 1297-302.

Cox, D.J., Borowitz, S.M., Kovatchev, B., & Ling, W. (1998). Contributions of behavior therapy and biofeedback to laxative therapy in the treatment of pediatric encopresis. *Annals of Behavioral Medicine, 20*, 70-76.

Credner, S.C., Klingenheben, T., Mauss, O., Sticherling, C., & Hohnloser, S.H. (1998). Electrical storm in patients with transvenous implantable cardioverter defibrillators. *Journal of the American College of Cardiology, 32,* 1909-1915.

Delgado D.H., Costigan J., Wu R., & Ross H.J. (2003). An interactive Internet site for the management of patients with congestive heart failure. *Canadian Journal of Cardiology, 19*, 1381-5.

Dew, M.A., Goycoolea , J.M., Harris, R.C., Lee, A., Zomak, R., Dunbar-Jacob, J., et al. (2004). An internet-based intervention to improve psychosocial outcomes in heart transplant recipients and family caregivers: development and evaluation. *Journal of Heart and Lung Transplant, 23*, 745-758.

Dickerson, S.S., Flaig, D.M., & Kennedy, M.C. (2000). Therapeutic connection: help seeking on the Internet for persons with implantable cardioverter defibrillators. *Heart and Lung, 29*, 248-255.

Dunbar, S.B., Kimble, L.P., Jenkins, L.S., Hawthorne, M., Dudley, W., Slemmons, M., et al. (1999). Association of mood disturbance and arrhythmia events in patients after cardioverter defibrillator implantation. *Depression and Anxiety, 9*, 163-168.

Dusseldorp, E., van Elderen, T., Maes, S., Meulman, J., & Kraaij, V. (1999). A meta-analysis of psychoeducation programs for coronary heart disease patients. *Health Psychology, 18*, 506-519.

Feil, E.G., Noell, J., Lichtenstein, E., Boles, S.M., & McKay, H.G. (2003). Evaluation of an Internet-based smoking cessation program: Lessons learned from a pilot study. *Nicotine and Tobacco Research, 5*, 189-194.

Frizelle, D.J., Lewin, R.J.P., Kaye, G., Hargreaves, C., Hasney, K., Beaumont, N., et al. (2004). Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: A pilot study. *British Journal of Health Psychology, 9*, 381-392.

Gega, L., Marks, I., & Mataix-Cols, D. (2004). Computer-aided CBT self-help for anxiety and depressive disorders: experience of a London clinic and future directions. *Journal of Clinical Psychology, 60*, 147-157.

Glasgow, R.E., Boles, S.M., McKay, H.G., Feil, E.G., & Barrera, M., Jr. (2003). The D-Net diabetes self-management program: long-term implementation, outcomes, and generalization results. *Preventive Medicine, 36*, 410-419.

Godemann, F., Butter, C., Lampe, F., Linden, M., Schlegi. M., Schultheiss, H.P., et al. (2004). Panic disorders and agoraphobia: Side effects of treatment with an implantable cardioverter defibrillator. Clinical Cardiology, 27, 321-326.

Goodman, M., & Hess, B. Could implantable cardioverter defibrillators provide a human model supporting the learned helplessness theory of depression? *General Hospital Psychiatry, 21,* 382-385.

Gordon, N.F. (2003). New methods of delivering secondary preventive services: The promise of the Internet. Journal of Cardiopulmonary Rehabilitation, 23, 349-351.

Greenspan, R. (2002). *Two-thirds hit the net* [Online]. Retrieved October 15, 2003,

Greenspan, R. (2003). Surfing with seniors and boomers [Online]. Retrieved October 15, 2003, from
http://cyberatlas.internet.com/big_picture/demographics/article/0,,5901_1573621,00.html

Haywood, C. (1995). Psychiatric Illness and cardiovascular disease risk. *Epidemiology Review, 17*, 129-138.

Herrman, C., von zur Muhen, F., Schaumann, A., Buss, U., Kemper, S., Wantzen, C., et al. (1997). Standardized assessment of psychological well-being and quality-of-life in patients with implanted defibrillators. *Pacing and Clinical Electrophysiology, 20,* 95-103.

Irvine, J., Dorian, P., Baker, B., O'Brien, B.J., Roberts, R., Gent, M., et al. (2002). Quality of life in the Canadian Implantable Defibrillator Study. *American Heart Journal, 144*, 282-289.

Januzzi, J.L., Stern, T.A., Pasternak, R.C., & DeSanctis, R.W. (2000). The influence of anxiety and depression on outcomes of patients with coronary artery disease. *Archives of Internal Medicine, 160*, 1913-1921.

Kamphuis, H.C., de Leeuw, J.R., Derksen, R., Hauer, R.N., & Winnubst, J.A. (2003). Implantable cardioverter defibrillator recipients: quality of life in recipients with and without ICD shock delivery: a prospective study. *Europace, 5*, 381-389.

Kenwright, M., Liness, S., & Marks, I. (2001). Reducing demands on clinicians by offering computer-aided self-help for pobic/panic. A feasibility study. *British Journal of Psychiatry, 179*, 456-459.

Kenwright, M., & Marks, I.M. (2004). Coputer-aided self-help for phobia/panic via internet at home: A pilot study. *British Journal of Psychiatry, 184*, 448-449.

Kohn, C.S., Petrucci, R.J., Soto, D.M., Baessler, C., & Movsowitz, C. (2000). The effect of psychological intervention on patients' long-term adjustment to the ICD: A prospective study. *Pacing and Clinical Electrophysiology, 23*, 450-456.

Kubzansky, L.D., Kawachi, I., Weiss, S.T., & Sparrow, D. (1998). Anxiety and coronary heart disease: a synthesis of epidemiological, psychological, and experimental evidence. *Annals of Behavioral Medicine, 20*, 47-58.

Kuck, K.H., Cappato, R., Siebels, J., & Ruppel, R., for the Cardiac Arrest Study Hamberg Investigators. (2000). Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest. *Circulation, 102*, 748–754.

Lee, A., Chui, P.T., & Gin, T. (2003). Educating patients about anesthesia: A systematic review of randomized controlled trials of media-based interventions. *Anesthesia & Analgesia, 96*, 1424-1431.

Lemon, J., Edelman, S., & Kirkness, A. (2004). Avoidance behaviors in patients with implantable cardivertoer defibrillators. *Heart Lung, 33*, 176-82.

Lenhart, A., Horrigan, J., Rainie, L., Allen, K., Boyce, A., Madden, M., et al. (2004). The ever-shifting Internet population. A new look at Internet access and the digital divide. Pew Internet Project Report. Available at: http://207.21.232.103/PPF/r/88/report_display.asp Accessed July 2, 2004.

Linden, W., Stossel, C., & Maurice, J. (1996). Psychosocial interventions for patients with coronary artery disease. *Archives of Internal Medicine, 156*, 745-752.

Luderitz, B., Jung, W., Deister, A., & Manz, M. (1996). Quality of life in multiprogrammable implantable cardioverter-defibrillator recipients. In *Interventional Electrophysiology: A Textbook* (Eds. Saskena, S. & Luderitz, B.), p. 305-313. Armonk, N.Y.: Futura Publishing Co., Inc.

Mataix-Cols, D., & Marks, I.M. (2006). Self-help with minimal therapist contact for obsessive-compulsive disorder: A review. *European Psychiatry, 21*, 75-80.

Marks, I.M., Kenwright, M., McDonough, M., Whittaker M., & Mataix-Cols, D. (2004). Saving clinicians' time by delegating routine aspects of therapy to a computer: A randomized controlled trial in phobia/panic disorder. *Psychology and Medicine, 34*, 9-17.

McKinley, R., Manku-Scott, T., Hastings, A., French, D., & Baker, R. (1997). Reliability and validity of a new measure of patient satisfaction with out of hours primary medical care in the United Kingdom: Development of a patient questionnaire. *British Medical JournaL, 314*, 193-198.

Mills, M.E., & Sullivan, K. (1999). The importance of information giving for patients newly diagnosed with cancer: a review of the literature. *Journal of Clinical Nursing, 8*, 631-641.

Moss, A. J., Hall, W. J., Cannom, D. S., Daubert, J. P., Higgins, S. L., Klien, H., et al., for the

Moulding, R., & Kyrios, M. (2006). Anxiety disorders and control related beliefs: The exemplar of obsessive-compulsive disorder (OCD). *Clinical Psychology Review, 26*, 573-583.

Mullen, P.D., Mains, D.A., & Velez, R. (1992). A meta-analysis of controlled trials of cardiac patient education. *Patient Education and Counseling, 19*, 143-162.

Multicenter Automatic Defibrillator Implantation Trial Investigators. (1996). Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. *New England Journal of Medicine, 335*, 1933-1940.

Namerow, P.B., Firth, B.R., Heywood, G.M., Windle, J.R., & Parides, M.K. (1999). Quality of life six months after CABG surgery in patients randomized to ICD versus no ICD therapy: findings from the CABG Patch trial. *Pacing and Clinical Electrophysiology, 22,* 1305–1313.

Napolitano, M.A., Fotheringham, M., Tate, D., Sciamanna, C., Leslie, E., Owen, N. et al. (2003). Evaluation of an Internet-based physical activity intervention: a preliminary investigation. *Annals of Behavioral Medicine, 25*, 92-99

O'Leary, C. J., & Jones, P. W. (2000). The left ventricular dysfunction questionnaire (LVD-36): Reliability, validity, and responsiveness. *Heart, 83*, 634-640.

Pauli, P., Wiedemann, G., Dengler, W., Blaumann-Benninghoff, G., & Kuhlkemp, V. (1999). Anxiety in patients with an automatic implantable cardioverter defibrillator: What differentiates them from panic patients? *Psychosomatic Medicine, 61*, 69-76.

Pauli, P., Wiedemann, G., Dengler, W., & Kuhlkamp, V. (2001). A priori expectancy bias and its relation to shock experience and anxiety: A naturalistic study in patients with an automatic implantable cardioverter defibrillator. *Journal of Behavioral Therapy and Experimental Psychiatry, 32,* 159-171.

Poroch D. (1995). The effect of preparatory patient education on the anxiety and satisfaction of cancer patients receiving radiation therapy. *Cancer Nursing, 18*, 206-14.

Powell, P., Bentall., R. P., Nye, F.J., & Edwards, R. (2001). Randomised controlled trial of patient education to encourage graded exercise in chronic fatigue syndrome. *British Medical Journal, 17*, 387-395.

Renzi, C., Abeni, D., Picardi , A., Agostini, E., Melchi, C.F., Pasquini, P., et al. (2001). Factors associated with patient satisfaction with care among dermatological outpatients. *British Journal of Dermatology, 145,* 617–623

Richards, J., Klein, B., & Carlbring, P. (2003). Internet-based treatment for panic disorder. *Cognitive Behaviour Therapy, 32*, 125-135.

Ritterband, L.M., Gonder-Frederick, L.A., Cox, D.J., Clifton, A.D., West, R.W., & Borowitz, S.M. (2003). Internet Interventions: In review, in use, and into the future. *Professional Psychology: Research and Practice, 34*, 527-534.

Roberts, K. J. (2002). Physician-patient relationships, patient satisfaction, and antiretroviral medication adherence among HIV-infected adults attending a public health clinic. *AIDS Patient Care and STDs, 16*, 43-50.

Ruggerio, C.M., Barr, E., Davis, J., Lau, R., Minassian, P., Selecky, C.E., et al. (2001). Disease management and e-Health can be successfully merged. Paper presented at the 2001 Annual HIMSS Conference and Exhibition. New Orleans, LA.

Scherrer-Bannerman, A., Fofonoff, D., Minshall, D., Downie, S., Brown, M., Leslie, F., et al. (2000). Web-based education and support for patients on the cardiac surgery waiting list. *Journal of Telemedicine and Telecare, 6*, S72-4.

Schneider, A.J., Mataix-Cols, D., Marks, I.M., & Bachofen, M. (2005). Internet-guided self-help with or without exposure therapy for phobic and panic disorders. *Psychotherapy and Psychosomatics, 74,* 154-164.

Schron, E.B., Exner, D.V., Yao, Q., Jenkins, L.S., Steinberg, J.S., Cook, J.R., et al. (2002). Quality of life in the antiarrhythmics versus implantable defibrillators trial: Impact of therapy and influence of adverse symptoms and defibrillator shocks. *Circulation, 105*, 589-594.

Schuster, P. M., Phillips, S., Dillon, D. L., & Tomich, P. L. (1998). The psychosocial and physiological experiences of patients with an implantable cardioverter defibrillator. *Rehabilitation Nursing, 23,* 30-7.

Sears, S.F., Burns, J.L., Handberg, E. Sotile, W.M., & Conti, J.B. (2001). Young at heart: Understanding the unique psychosocial adjustment of young implantable cardioverter defibrillator recipients. *Journal of Pacing and Clinical Electrophysiology, 24*, 1113-1117.

Sears, S.F., & Conti, J.B. (2002). Current views on the quality of life and psychological functioning of implantable cardioverter defibrillator patients. *Heart, 87*, 488-493.

Sears, S.F., & Conti, J.B. (2003). Understanding implantable cardioverter defibrillator shocks and storms: Medical and psychosocial considerations for research and clinical care. *Clinical Cardiology, 26*, 107-111.

Sears, S.F., Kovacs, A.H., Azzarello, L., Larsen, K., & Conti, J.B. (2004). Innovations in health psychology: the psychosocial care of adults with implantable cardioverter defibrillators. *Professional Psychology Research Practice, 5*, 1-7.

Sears, S.F., Kovacs, A.H., Serber, E.R., Kuhl, E.A, Vazquez, L.D., Handberg, E.M., et al. Psychosocial treatment to optimize quality of life in implantable cardioverter defibrillator patients. In preparation.

Sears, S.F., Todaro, J.F., Lewis, T.S., Sotile, W., & Conti, J.B. (1999). Examining the psychosocial impact of implantable cardioverter defibrillators: A literature review. *Clinical Cardiology, 22,* 481-489.

Shedd, O., Sears, S.F., Harvill, J.L., Arshad, A., Conti, J.B., Steinberg, J.S. et al. (2004). The World Trade Center attack: Increased frequency of defibrillator shocks for ventricular arrhythmias in patients living remotely from New York City. *Journal of the American College of Cardiology, 44*, 1265-1267.

Smith, M. L., & Glass, G. V. (1977). Meta-analysis of psychotherapy outcome studies. *American Psychologist, 32*, 752-760.

Southard, B.H., Southard, D.R., & Nuckolls, J. (2003). Clinical trial of an Internet-based case management system for secondary prevention of heart disease. *Journal of Cardiopulmonary Rehabilitation, 23*, 341-348.

Spek, V., Cuijpers, P., Nyklick, I., Riper, H., Keyzer, J., & Pop, V. (2007). Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: A meta-analysis. *Psychology and Medicine, 37*, 319-328.

Steinberg, J.S., Arshad, A., Kowalski, M., Kukar, A., Suma, V., Volka, M.E., et al. (2004). Incidence of life-threatening ventricular arrhythmias in implantable defibrillator patients after the World Trade Center attack. *Journal of the American College of Cardiology, 44,* 1261-1264.

Sturdee, DW. (2000). The importance of patient education in improving compliance. *Climacteric, 3*, 9-13.

Tate, D.F., & Zabinski, M.F. (2004). Computer and Internet applications for psychological treatment: Update for clinicians. *Journal of Clinical Psychology, 60*, 209-220.

Tate, D.F., Jackvony, E.H., & Wing, R.R. (2003). Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *JAMA, 289*, 1833-1836.

Ware, J. E., Kosinski, M., & Keller, S. D. (1995). *SF-12: How to Score the SF-12 Physical and Mental Health Scales* (2nd ed.). Boston, MA: The Health Institute, New England Medical Center.

Ware, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233.

Winzelberg, A.J., Taylor, C.B., Sharpe, T., Eldredge, K.L., Dev, P., & Constantinou, P.S. (1998). Evaluation of a computer-mediated eating disorder intervention program. *International Journal of Eating Disorders, 24*, 339-49.

Winzelberg, A.J., Eppstein, D., Eldredge, K.L., Wilfley, D., Dasmahapatra, R., Dev, P., et al. (2000). Effectiveness of an Internet-based program for reducing risk factors for eating disorders. *Journal of Consulting and Clinical Psychology, 68*, 346-350.

Zimmerman, R.S. (1988). The dental appointment and patient behavior. Differences in patient and practitioner preferences, patient satisfaction, and adherence. *Medical Care, 26*, 403-414.

BIOGRAPHICAL SKETCH

Emily Ann Kuhl was born on July 19, 1978, at Lakenheath Royal Air Force Base in Lakenheath, England. The daughter of an Air Force pilot, she spent her childhood living in three countries, including England, Germany, and the United States, and several states, including Virginia, California, New York, and Texas. She graduated from Monterey High School in Lubbock, Texas, at the age of 17. She then enrolled in Texas Tech University, where she received her bachelor's degree in psychology at the age of 20.

Following undergraduate training, Emily spent two years working as a features writer at the Manassas Journal Messenger and the Potomac News in suburban Washington, D.C. She later enrolled in the clinical psychology master's program at East Carolina University in the fall of 2001. At this time, she began studying health psychology and developed what has become her primary interest within behavioral medicine – cardiac psychology. In 2002, Emily was awarded the Department of Clinical Psychology's Graduate Student of the Year award. Emily was accepted to the doctoral program with the Department of Clinical and Health Psychology at the University of Florida in August 2003. There, she honed her expertise in cardiac psychology with foci in patients with implantable cardioverter defibrillators and adults with congenital heart disease. She has several publications in peer-reviewed journals and has presented at numerous conferences. In June 2006, Emily began her year-long pre-doctoral internship at the VA Maryland Health Care System/University of Maryland Psychology Internship Consortium.

Upon receipt of her Ph.D., Emily will begin a postdoctoral position as a research associate at the University of Maryland Medical Center in Baltimore, MD. She has one sister, Amy Lazerson, and two nieces: Rebecca, age 7, and Sarah, age 5. Emily will have a nephew in late August.