HEALTH BELIEFS RELATED TO PHYSICAL ACTIVITY IN PATIENTS WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

by

Rebecca Susan Crawford

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SIGNED: REBECCA SUSAN CRAWFORD
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DEDICATION

Over the course of my career as a cardiovascular nurse it has been an honor and privilege to care for some of the most amazing patients and their families. Without the wonderful encounters provided by my cardiac patients over these many years this professional achievement would not be possible. I dedicate my doctoral dissertation to my patients and their families who without the openness with which they share their lives and lived experiences with heart disease I would not have had the insight to ask the questions that I pray may help them have improved outcomes.
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ABSTRACT

Low levels of physical activity (PA) are a significant predictor of early death among recipients of implantable cardioverter defibrillators (ICDs). Regular, moderate PA is associated with improved quality of life (QOL), reduced arrhythmia burden, and improved health outcomes in ICD recipients yet many do not engage in PA and the reasons for lack of engagement are unclear.

The purpose of this descriptive, cross-sectional study was to examine health beliefs related to PA and QOL in adults living with ICDs. The Health Belief Model provided the theoretical framework for this study. A convenience sample of 107 adult, ICD recipients (26 females and 81 males) were recruited from five cardiology clinic settings within the same private practice. Seventy-seven percent completed the study tasks (N=81). Subjects completed a Demographic Data Questionnaire, Self-Efficacy Expectations after ICD Scale, Exercise Self-Efficacy Scale, Health Belief Questionnaire, Incidental and Planned Exercise Questionnaire and Quality of Life Medical Outcomes Survey-SF36®. Clinical data was collected from the medical record.

Mean age of the subjects was 70.23 yrs. ± 11.76 yrs. The majority were male (71.6 percent) and 77.8 percent were White, non-Hispanic. Most were insured by Medicare (79 percent), were retired (50 percent) and reported incomes less than 20,000 dollars/year (39 percent). Over 98 percent were diagnosed with heart failure and almost 40 percent reported their physical activity had decreased since having an ICD implanted.
There were no differences in health beliefs and QOL scores between subjects who had an ICD as a primary or secondary prevention of sudden cardiac death. Predictors of PA participation in this population were Self-Efficacy for Exercise (SEE) beliefs, Self-Efficacy ICD (SEICD) beliefs, age and NYHA Class. Almost 33 percent of variance in PA participation can be explained by SEE ($b = 2.407$, $\beta = .390$, $t = 3.911$, $p < .01$); SEICD ($b = 2.304$, $\beta = .215$, $t = 2.149$, $p < .05$); age ($b = -.394$, $\beta = -.234$, $t = -2.277$, $p < .05$); and NYHA Class ($b = -6.373$, $\beta = -.198$, $t = -1.998$, $p = < .05$). Findings indicate the strength of self-confidence in influencing healthy behavior. Findings support the need for more research in identifying barriers and predictors of PA participation in adult, ICD recipients.
CHAPTER I: INTRODUCTION

Implantable cardioverter defibrillators (ICDs) save lives. Over 1.5 million ICDs have been implanted since 1993 and to date research regarding physical activity (PA) in this population is limited. Research involving PA in individuals living with ICDs is explicitly called for in a recent (2012) scientific statement from the American Heart Association’s Councils on Cardiovascular Nursing, Clinical Cardiology and Cardiovascular Disease in the Young. Specifically, research focused on behavioral strategies to increase PA participation in this population is thought to improve health outcomes (Dunbar et al., 2012). Examining the association between beliefs and engagement in PA is foundational to the development of successful interventions to improve engagement in PA and hence health outcomes. No research to date has examined the role beliefs, including self-efficacy, have on PA and quality of life (QOL) in ICD recipients. The purpose of this study was to examine beliefs related to PA and QOL in patients living with ICDs.

Background

Implantable cardioverter defibrillators are small, surgically implanted, electronic cardiac devices that can reestablish heart rate, rhythm and synchrony in patients who are at risk for or who survive sudden cardiac death (SCD) (Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011). Over thirty years of advances in technology coupled with expanded indications for ICDs, the number of devices implanted each year has increased (~10,000 implants per year in 1990 to ~ 250,000 implants per year in 2006) (Dougherty, Glenny, Kudenchuk, Malinick, and Flo, 2010; Hammill et al., 2009). Today’s technology in ICDs allows for greater diagnostic data,
greater management of cardiac arrhythmias and provides biventricular pacing therapies for heart failure management (Cuoco and Gold, 2008; Gami, Hayes, and Friedman, 2008).

**ICD Indications**

Recommendations for use of ICDs are determined by experts from the American College of Cardiology (ACC), American Heart Association (AHA) and Heart Rhythm Society (HRS). Current scientific, ACC/AHA/HRS published guidelines provide primary and secondary indications (Table 1) for ICD therapy (Epstein et al., 2008). An estimated twenty percent of ICD implantations are for secondary prevention and seventy-four percent are for primary prevention (Kremer, et al. 2013).

**ICD Patient Characteristics**

In 2006 the National ICD Registry began ongoing ICD implant data collection from almost 1500 participating acute care facilities in the United States. By the end of 2011 the registry has collected data from over 850,000 ICD implants (Kremers et al., 2013). This data provides valuable information which aids in determining best practices for ICD therapies; helps identify gender, racial or ethnic differences in implantation rates and adverse events; identifies medical characteristics/co-morbidities; and facilitates new and ongoing research with the aim of improving outcomes. Demographic and medical characteristics obtained from a review of the ICD Registry’s 2009 (Hammill, et al. 2010) and most recent 2010-2011 annual report (Kremers, et al. 2013) are listed in Table 2.

...
Table 1

*Primary and Secondary Indications for ICD Implantation*

<table>
<thead>
<tr>
<th>Primary Prevention Indications (80 % ICD Implants)</th>
<th>Secondary Prevention Indications (20 % ICD Implants)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with ischemic or non-ischemic cardiomyopathy and includes:</td>
<td>Patients who have experienced SCD due to:</td>
</tr>
<tr>
<td>• Left ventricular ejection fraction (LVEF) &lt; 35 percent and New York Heart Association (NYHA) functional class II-III heart failure (HF) symptoms; or, LVEF &lt; 30 percent and NYHA functional class HF I symptoms in patients with:</td>
<td>• Ventricular fibrillation (VF) or ventricular tachycardia not due to transient or reversible causes and not within 24-48 hours of acute myocardial infarction (MI),</td>
</tr>
<tr>
<td>o MI ≥ Forty days prior,</td>
<td></td>
</tr>
<tr>
<td>o Over three months since coronary revascularization procedure and</td>
<td></td>
</tr>
<tr>
<td>o Optimal medical treatment.</td>
<td></td>
</tr>
<tr>
<td>• LVEF &lt; 35 percent and NYHA functional class II-III HF symptoms; or LVEF &lt;30 percent and NYHA functional class I HF symptoms in patients with:</td>
<td>• Spontaneous VT or VF related to structural heart disease</td>
</tr>
<tr>
<td>o Non-ischemic heart disease and</td>
<td>o Hypertrophic cardiomyopathy,</td>
</tr>
<tr>
<td>o Optimal medical treatment.</td>
<td>o Dilated cardiomyopathies, and</td>
</tr>
<tr>
<td>• LVEF &lt; 40 percent in patients with:</td>
<td>o Arrhythmogenic right ventricular dysplasia,</td>
</tr>
<tr>
<td>o Prior MI,</td>
<td>• Genetic arrhythmias such as:</td>
</tr>
<tr>
<td>o Non-sustained VT or VF at electrophysiology study</td>
<td>o Arrhythmogenic Right Ventricular Dysplasia (ARVD)</td>
</tr>
<tr>
<td>o Over three months since any cardiac revascularization procedures</td>
<td>o Hypertrophic Cardiomyopathy</td>
</tr>
<tr>
<td></td>
<td>o Long QT Syndrome</td>
</tr>
<tr>
<td></td>
<td>o Brugada Syndrome</td>
</tr>
</tbody>
</table>
- With Cardiac Resynchronization Therapy (CRT) in patients with:
  - LVEF < 35 percent
  - NYHA functional class II-III and/or ambulatory class IV HF symptoms,
  - Presence of wide QRS complex (≥ 150 milliseconds), LV systolic dysfunction and
  - Optimal medical therapy

- Unexplained syncope in patients with:
  - Inducible sustained VT in electrophysiology study or
  - Left ventricular (LV) dysfunction on chronic, optimal medical therapy

( Epstein et al., 2008; Gami, Hayes, and Friedman, 2008; Hammill et al., 2009; Hammill et al., 2010; Smith, et al., 2006).

Table 2

National ICD Registry Recipient Characteristics

<table>
<thead>
<tr>
<th>Demographics (%)</th>
<th>ICD Recipient Co-morbidities (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td>Hypertension 72.5</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>Diabetes (type not specified) 27.5</td>
</tr>
<tr>
<td><strong>White</strong></td>
<td>Atrial Fibrillation 80.1</td>
</tr>
<tr>
<td><strong>African American</strong></td>
<td>Ischemic Heart Disease* 12.6</td>
</tr>
<tr>
<td><strong>Asian</strong></td>
<td>Previous MI* 1.3</td>
</tr>
<tr>
<td><strong>Hispanic</strong></td>
<td>Previous CABG* 5.2</td>
</tr>
<tr>
<td><strong>Native American/Alaskan</strong></td>
<td>Previous Percutaneous Coronary Intervention* 0.6</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Non-ischemic Dilated Cardiomyopathy 0.2</td>
</tr>
<tr>
<td><strong>Medicare/Medicaid</strong></td>
<td>History of Syncope* 71.2</td>
</tr>
<tr>
<td>*<em>Other Payor</em></td>
<td>History of SCD* 32.3</td>
</tr>
<tr>
<td><strong>Primary Prevention</strong></td>
<td>Heart Failure 73.8</td>
</tr>
<tr>
<td><strong>Secondary Prevention</strong></td>
<td>LVEF* 22.5</td>
</tr>
</tbody>
</table>

Note: N=259, 295 ICD recipients. MI = Myocardial Infarction; SCD = sudden cardiac death; LVEF = left ventricular ejection fraction. *Indicates 2009 data not reported in 2010-2011 registries.
Significance

Scientific evidence validates the substantial mortality benefits that ICDs provide to patients. Much of research to date focuses on interventions to manage arrhythmias, heart failure, reduce hospitalizations and manage psychological adjustment issues. Physical activity is an important component in prevention and management of heart disease (and other co-morbidities common to ICD patients) that has received limited attention in the ICD patient. Benefits of PA include reducing risk factors for heart disease, improving physical stamina, increasing self-efficacy beliefs, stabilization of autonomic function, protection against future arrhythmias, improving quality of life and reducing costs associated with hospitalizations (Dougherty, Glenny, and Kudenchuk, 2007; Dougherty, Glenny, Kudenchuk, and Flo, 2010; Lampman and Knight, 2000). Research shows a significant predictor of early mortality in ICD recipients is low levels of PA (Stein et al., 2009). Regular, moderate PA is safe in patients with ICDs yet many do not engage in PA and the reasons for lack of engagement are not clear.

Physical activity is correlated with health related quality of life and physical function (Dunbar et al., 2012; Sears et al., 2007; van Ittersum, de Greef, van Gelder, Coster, Brugeman, and van der Schans, 2003). Anxiety, depression and fear (psychological states associated with use of ICDs) are associated with the lack of engagement in PA therefore engagement in PA has the potential to improve QOL and health outcomes. Poor or worse physical function is associated with anxiety, depression and fear which in turn can diminish PA; hence these associations may be reciprocal.
That is, the lack of PA is associated with poor physical function and increased psychological stress thus a vicious cycle occurs which leads to poor outcomes (Carroll and Hamilton, 2005; Carroll, Hamilton, and Kenney, 2002; Edelman, Lemon, and Kidman, 2003; Kim et al., 2009; Luyster, Hughes, and Gunstad, 2009; Pedersen, Spindler, Johansen, Mortensen, and Sears, 2008; Sears et al., 2007; Stein et al., 2009).

Research supports the positive psychological and physical benefits of PA in the ICD population. The AHA reinforces the need for research that focuses on identifying interventions that promote PA (Dunbar et al., 2012). The more knowledge practitioners have of factors that influence any given health-behavior the greater the chance of designing successful, health-behavior interventions (DiClemente, Crosby, and Kegler, 2009). Development of appropriate interventions requires an understanding of the factors associated with engagement in PA. Understanding beliefs related to PA in the ICD patient may help identify strategies to increase participation in PA. No studies to date have examined the health behavior beliefs of this population with regards to physical activity.

**Theoretical Framework**

This study was guided by a theoretical framework that allows for health promotion research at the individual or patient-centered level. The Health Belief Model (HBM), developed in the 1950s by social psychologists, contains concepts from psychological and social theories that postulate behavior is a product of the individual’s values and expectations that if one takes part in a behavior that a particular outcome will occur. The model was originally developed to predict engagement in preventive behaviors in well populations and then later expanded to predict health behaviors in populations with illness/chronic disease (Li, 2008). Assumptions of
the HBM are that people will not participate in preventive behaviors unless they have knowledge and motivation, perceive that they are vulnerable, view the consequence of not participating in preventive behaviors or their illness as threatening, are convinced of the efficacy of the behavior/treatment and perceive no barriers to taking action (Biddle and Ashford, 1988). Self-efficacy, one of the most salient determinants for health behavior adoption, was added as a separate construct because for behavior change to be successful people must believe that they can make the change and/or overcome the obstacles to change (Champion and Skinner, 2008; Pender, Murdaugh, and Parsons, 2011).

Key components of the HBM include the individual beliefs regarding illness and preventive behaviors and factors that influence these beliefs and/or actions. The concepts that were the focus of this study include perceived benefits, perceived barriers and self-efficacy beliefs. Perceived benefits consist of an individual’s beliefs in the benefits of health behavior change whereas perceived barriers are the individual’s perception of costs or consequences of taking a health action. Self-efficacy beliefs are defined as an individual’s belief in their capacity to perform health behaviors. The HBM also takes into account modifying factors such as knowledge and sociodemographic variables that can exert an effect on an individual’s beliefs (Champion and Skinner, 2008; Janz and Becker, 1984). An additional focus of this study was to determine if there are differences in health beliefs or PA participation between recipients who were implanted for primary versus secondary reasons.

Understanding subjective health beliefs is pivotal to developing disease prevention and health promotion interventions (King, 1984). The HBM has been empirically tested and refined over several years and continues to be utilized to describe health promotion/prevention behaviors.
in health and illness (Goodson, 2010; Pender, Murdaugh, and Parsons, 2011). The model is used across many domains, many ethnic/cultural groups and in various nursing specialties (influenza vaccination, self-breast exams, high blood pressure screening, cardiac rehabilitation adherence and many other health promotion behaviors) (Janz and Becker, 1984; Shanks, 2009). The HBM is valuable to illuminating individual behavior characteristics that can increase a practitioner’s ability to anticipate the needs of patients. The model is very effective in understanding the role of individual beliefs related to PA in various chronic illness states and has been useful in this study by providing new insight in health promotion and risk reduction for the ICD patient population (Champion and Skinner, 2008; Koch, 2002).

**Study Purpose**

The purpose of this study was to explore the health beliefs related to PA (perceived benefits, perceived barriers and self-efficacy beliefs) and the association of these beliefs with PA participation and QOL in adult, ICD recipients. In addition, analyses were conducted to examine for relationships between modifying factors and PA participation; and if PA acts as a mediator between beliefs and QOL. An additional endpoint was to determine if there are any differences in health beliefs regarding PA or differences in PA participation in individuals who have received their ICD for primary or secondary prevention of SCD.

**Study Conceptual Model**

The model in this study, while following the tenants of the HBM (Champion and Skinner, 2008), considers the possible interactions between and among constructs and outcomes (Figure 1). The model reflects the questions that guide this study.
Figure 1. Study Conceptual Model.

Research Aims

The specific aims of this study were as follows:

Aim 1: Describe sociodemographic (age, gender, ethnicity, socio-economics, religion and knowledge) characteristics, health beliefs (benefits, barriers and self-efficacy), PA participation and QOL of the participants in this study.

Aim 2: Examine the relationships between type of ICD, New York Heart Association Heart Failure Classification, health beliefs (benefits, barriers and self-efficacy), modifying factors (age, gender, ethnicity, socio-economics, religion and knowledge), QOL, and PA participation in this sample of adult ICD recipients.
Aim 3: Test PA participation as a mediator between health beliefs (benefits, barriers and self-efficacy) and QOL.

Aim 4: Assess for differences in health beliefs and PA participation between ICD recipients who were implanted for primary versus secondary prevention of sudden cardiac death.

Aim 5: Predict PA participation using health beliefs (benefits, barriers and self-efficacy) and modifying factors while controlling for severity of heart disease (New York Heart Association Heart Failure Classification) and type of ICD (Single Chamber, Dual Chamber, or Bi-ventricular ICD).

**Definition of Terms**

**Health Behavior:** any activity taken by an individual to support, improve or restore normal health and prevent illness; actions reflect an individual’s health beliefs, expectations, goals, values and views. In this study, incidental or planned PA is the health behavior of interest (Glanz, Rimer, and Viswanath, 2008).

**Implantable Cardioverter Defibrillators:** small, surgically implanted, electronic cardiac devices that can reestablish heart rate, rhythm and synchrony in patients who are at risk for or who survive sudden cardiac death (SCD) (Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011).

- **Bi-ventricular Device:** an ICD that also provides an established, approved treatment for patients with severe heart failure by pacing both the right and left ventricle (biventricular pacing); cardiac resynchronization therapy (Hayes & Friedman, 2000/2008; Stevenson, et al., 2012).
New York Heart Association Functional Classification: (NYHA) a classification system that stages patients with a diagnosis of heart failure based on their physical activity limitations and/or symptoms (Heart Failure Society of America, 2011) (Table 3).

Table 3

*New York Heart Association Heart Failure Classification*

<table>
<thead>
<tr>
<th>*NYHA Class</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class I (Mild HF)</td>
<td>Physical Activity (PA)-no limitation; no symptoms from ordinary PA.</td>
</tr>
<tr>
<td>NYHA Class II (Mild HF)</td>
<td>Slight PA limitation; no symptoms at rest; symptoms (fatigue, palpitations and/or dyspnea) with ordinary PA.</td>
</tr>
<tr>
<td>NYHA Class III (Moderate HF)</td>
<td>Significant PA limitation; no symptoms at rest; symptoms (fatigue, palpitations and/or dyspnea) with less than ordinary activity.</td>
</tr>
<tr>
<td>NYHA Class IV (Severe HF)</td>
<td>Symptoms (dyspnea, palpitations, fatigue and/or angina) at rest; any level of PA increases symptom burden. (HFSA, 2011).</td>
</tr>
</tbody>
</table>

Perceived Barriers: the perceived consequences of PA participation that act as a barrier or obstacle to taking part in or adhering to PA; barriers to ICD recipients may be lack of information, fear of arrhythmias and/or shock from the device, fear of injury, lack of resources (time, costs, and facilities) to participate in PA (Janz and Becker, 1984; Rosenstock, 1974).

Perceived Benefits: refer to the beliefs an ICD recipient has regarding the effectiveness of PA in reducing disease threat, preventing death from heart disease, preventing or reducing symptoms (arrhythmias or shocks), improve mood and/or physical appearance, health function and QOL (Janz and Becker, 1984; Rosenstock, 1974).
Physical Activity: movement of the body that enhances health; involves using more energy than when resting (NHLBI, NIH, 2011). PA participation in this study will be determined by the type, duration and frequency of planned and incidental activities performed on average each week over a three month period.

- **Incidental PA**: includes self-care, household chores, gardening, and other activities outside the home (e.g. shopping, social activities, appointments, etc.).

- **Planned PA**: planned aerobic activities; examples of planned PA include exercise classes, use of home exercise equipment (stationary bike, treadmill or other) and other PA such as jogging, bicycling, dancing, golf, tennis, swimming, etc.

**Primary Indication for ICD Implantation**: implantation of an ICD as a primary preventive measure to protect an individual with diagnoses that place them at risk of sudden cardiac death; individual has not experienced sudden cardiac death (Epstein et al., 2008).

**Secondary Indication for ICD Implantation**: implantation of an ICD for secondary prevention of sudden cardiac death; individuals who have experienced and survived sudden cardiac death of irreversible cause/s who are at risk for future sudden cardiac death (Epstein et al., 2008).

**Self-Efficacy Beliefs**: describe an ICD recipient’s belief of how confident they are to participate in planned or incidental PA (Bandura, 1997; Dougherty, Johnston, and Thompson, 2007).

**Sick-Role Behaviors**: after being diagnosed with an illness/disease, behaviors taken in order to return to good health or prevent disease progression (Janz and Becker, 1984).

**Sudden Cardiac Death**: abrupt, unexpected death due to cardiac causes; cardiac conduction system malfunctions causing ventricular arrhythmias that are incompatible with life (ventricular
tachycardia or ventricular fibrillation); considered a major public health problem that causes 450,000 deaths in the United States each year (Hao and Morganti, 2011).

Summary

Understanding why healthy individuals do or do not participate in PA is a complex and important issue in health promotion research (Lovell, Ansari, and Parker, 2010). Understanding why individuals with chronic illness do not participate in PA is complex and central to developing interventions aimed at improving health. Physical activity is an essential part of secondary prevention to reduce risk for worsening heart disease, controlling hypertension, managing hyperlipidemia, diabetes management and improving quality of life in individuals living with chronic heart disease (Lloyd-Jones et al., 2010; Piepoli et al., 2011; Williams, et al., 2002). Current research supports the positive psychological and physical benefits of PA in the ICD population; however, no studies to date have examined the factors associated with engagement in PA among ICD recipients. There is a gap in knowledge of the factors that predict PA participation. This study has attempted to address this gap in knowledge and findings have given rise to the development of future inquiries and interventions that may help improve the health of ICD recipients.
CHAPTER II: LITERATURE REVIEW

Introduction

The following chapter presents an analysis of relevant research to support this study. This review contains a synthesis of research relevant to the concepts that are the focus of this study.

Health Belief Model and Implantable Cardioverter Defibrillator Recipients

No research prior to this study has been conducted with ICD recipients using the HBM as a theoretical framework. The following review of relevant literature will first discuss the reason for selection of three HBM concepts for this study. The remaining discussion will focus on synthesizing the literature relevant to those HBM concepts.

The constructs in the revised HBM include perceived susceptibility, perceived severity, perceived benefits, perceived barriers and self-efficacy beliefs (Glanz, Rimer, and Viswanath, 2008). A review of the literature suggests that perceived susceptibility and severity do not predict or influence behavioral intent specifically in individuals with chronic disease. In fact, perceived susceptibility (an individual’s belief about their chances of an event happening) and perceived severity (an individual’s belief of the severity of a condition) do not significantly impact participation in PA and/or have opposite the HBM’s proposed effects on health behaviors in individuals with chronic diseases (Al-Ali and Haddad, 2004; Goldring, Taylor, Kemeny, and Anton, 2002; Koch, 2002; Oldridge and Streiner, 1989; Shanks, 2009).

Living with an ICD is a daily reminder of the severity and seriousness of an individual’s heart disease. It is thought that this constant reminder of the seriousness and severity serve as explanation for ICD recipient’s tendency to avoid physical activity.
That is, perceived severity and seriousness do not effect behavioral intent in the direction that the HBM proposes (Frizelle, Lewin, Kaye, and Moniz-Cook, 2006; Lemon, Edelman, and Kirkness, 2004). However, a preponderance of research using the HBM as a theoretical guide in chronically ill individuals has shown repeatedly that perceived barriers, perceived benefits and self-efficacy beliefs exert greater influence on health behavior than the constructs of perceived severity and susceptibility (Janz and Becker, 1984; Lovell, Ansari, and Parker, 2010). It is for these reasons that the concepts of perceived benefits, perceived barriers and self-efficacy beliefs are the HBM concepts of interest in this study.

**Perceived Benefits and Barriers of Physical Activity**

Perceived benefits are an individual’s belief that the benefits of executing behaviors are beneficial or have a positive outcome. Perceived barriers are opposite in that the individual considers the perceived costs or possible consequence of taking action. Perceived benefits are important predictors of preventive behaviors. Perceived barriers are considered the more powerful predictor of preventive behaviors (Champion and Skinner, 2008; Janz and Becker, 1984; Lovell, Ansari, and Parker, 2010). Prior to this study no research has been conducted to determine the perceived benefits and barriers to PA in the ICD recipient. Thus the review of literature consists of research conducted to determine perceived benefits and barriers to PA in adults living with chronic disease.

Qualitative research in patients with heart failure (HF) found that participation in PA is influenced by the individual’s perceived cost/benefit of taking part in and whether they had the self-confidence to engage in PA (Tierney, et al, 2011). Not participating in PA or failure to adhere to prescribed exercises was attributed to barriers such as symptoms, co-morbidities, lack
of confidence, no support from others and lack of perceived benefits. Lack of instruction or knowledge and or vague instructions were similar complaints of ICD recipients in qualitative research exploring individual experiences living with an ICD and in research to determine reasons for participating in health promotion behaviors (Tagney, James, and Albarran, 2003; Tierney et al, 2011).

In a clinical investigation measuring the effects of health education interventions on health beliefs in patients with acute coronary syndrome symptoms, perceived benefits was a significant predictor of positive behavior changes (Katz et al., 2009). In research to determine PA in cardiac patients, perceived barriers were central to understanding PA participation. Perceived benefits were not measured in this study; however, the authors state their findings underscore the importance of understanding perceived barriers to PA. They further surmise that perceived barriers are more critical to promoting PA than positive benefits (Yates, Price-Fowlkes, and Agrawal, 2003). Perceived barriers did not have a significant impact on exercise attendance in patients with and without heart disease in a community based heart disease exercise program (Mirotznik, Feldman and Stein, 1995). Perceived benefits were found to have a significant impact on attendance to a supervised coronary heart disease exercise program; however, the direction of influence was opposite that predicted by the HBM. That is, patients who had higher levels of perceived benefits had lower levels of attendance. The retrospective design, exercise recall after six month enrollment and sick role versus prevention role in patients with and without cardiac disease may have confounded results. Timing of measures is also believed to be a moderator of behavior in this study. It is thought that the likelihood of finding
effects in the HBM’s predicted direction is lessened in measures that involve time between
behavior and measuring beliefs (Carpenter, 2010; Mirotznik, Feldman, and Stein, 1995).

In an effort to describe the effect of HBM variables on exercise participation in Jordanian
MI patients, Al-Ali and Haddad, (2004) conclude that perceived benefits did not have a
significant impact on exercise participation. Perceived barriers to exercise had significant
negative correlation with exercise participation \( (r = -0.210, p < .05) \). The significance of
modifying variables was especially apparent in this research with regards to culture, age,
knowledge and gender. For instance, the authors pointed out that in Arab-Jordanian culture there
is reliance on the ‘will of God’ thus many are fatalistic in their views and resign themselves to
the disease without thought of taking action to prevent or reduce risk. Lack of knowledge about
the benefits of exercise for risk reduction was thought to be a direct result of the lack of mass
media medical education. Age and gender significantly impacted exercise participation and
beliefs. Older patients reported more barriers and participated in exercise less; and female
patients reported less exercise participation (Al-Ali and Haddad, 2004). High socio-economic
status and higher levels of education of the participants in the aforementioned community-based
coronary heart disease exercise prevention study (Mirotznik, Feldman and Stein, 1995) may have
confounded results with regards to barriers to and benefits of exercise. These results underscore
the influence of sociodemographic variables on health beliefs and behaviors.

Perceived benefits and barriers to participation in exercise in adult African American
women with Type II Diabetes were significantly (both with \( p < 0.001 \)) correlated with adherence
to regular aerobic exercise. Participants who took part in exercise regularly reported fewer
barriers to exercise and had greater perceived benefits. Likewise those who did not exercise
reported more barriers and perceived less benefits (Koch, 2002). Similar results were found in a study to determine if perceived barriers impacted self-care behaviors in patients with type 2 Diabetes. Patients who participated in PA more frequently had significantly fewer barriers than did those who did not participate in PA (Aljasem, Peyrot, Wissow, and Rubin, 2001). In research to determine the effects of perceived benefits and barriers to exercise participation in adults with multiple sclerosis Stroud, Minahan, and Sabapathy, (2009) concluded perceived barriers play a more significant role in exercise change than do benefits. They further added that self-efficacy beliefs are vital to promoting exercise in this population.

**Self-Efficacy Beliefs and Physical Activity**

Self-efficacy (SE) is an individual’s confidence or belief that they have the capacity to perform a health behavior. Empirical studies have found that SE increases the explanatory power of the HBM (Champion and Skinner, 2008; Rosenstock, Strecher, and Becker, 1988). To foster perceived SE it is necessary for individuals to have the awareness and ability to make appropriate behavior changes to improve or manage health. Perceived SE is said to exert effects on the biological systems that mediate health and disease. It also impacts health status and functioning through its effect on health habits. Enhancing perceived SE can exert powerful influences on physiological functioning (Bandura, 1997; Pajares, 2002).

SE is well documented in the literature with regards to health behavior and is considered to be one of the most significant determinants for PA participation in adults with and without heart disease (Allison and Keller, 1999; Costello, Kafchinski, Vrazel, and Sullivan, 2011; Konopack, Marquez, Hu, Elavsky, McAuley and Kramer, 2008; Oka, Demarco, and Haskell, 1999; Sol, van der Graaf, van Petersen, and Visseren, 2011; and Tierney et al., 2011).
High levels of SE are correlated with adherence to exercise programs such as cardiac rehabilitation in post-MI and cardiac surgery patients (Dougherty, Johnston, and Thompson, 2007). Interventions aimed at enhancing SE beliefs are thought to lessen levels of anxiety by allowing the ICD recipient a sense of control. This sense of controllability increases confidence in the ability to participate in PA without experiencing a shock from the defibrillator (Vasquez, Conti, and Sears, 2010). To date only a few studies have been conducted measuring SE beliefs in ICD recipients. Most measured SE’s effects on psychological adjustment, health status and QOL in ICD recipients. The following review will discuss these and other studies measuring the effects of SE on PA participation in cardiac patients.

**Self-efficacy and ICD recipients.** It is well documented in the literature that ICD recipients experience a great deal of anxiety as a result of living with an ICD (Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011; Vasquez, Conti, and Sears, 2010). Self-efficacy beliefs of ICD recipients have been shown to be inversely associated with anxiety levels and directly associated with their ability to engage in PA, self-care and other activities (driving, sexual relations and work). ICD recipients with low SE scored higher on anxiety measures and reported greater inability to engage in PA, self-care and other activities. The reverse was seen in those with high SE scores (Dougherty, Johnston, and Thompson, 2007; Schuster, Phillips, Dillon, and Tomich, 1998). The few studies conducted measuring SE beliefs of ICD recipients highlight the need for nursing interventions geared towards increasing SE beliefs in order to facilitate psychological and physical adjustment to living with an ICD (Dougherty, Johnson-Crowley, Lewis, and Thompson, 2001; Tierney et al., 2011). An ongoing, stratified random two-group clinical study using a theory guided exercise intervention with the goal of stabilizing
arrhythmias and decreasing the number of ICD shocks by increasing control over the autonomic nervous system is worth mentioning as it supports the utility of SE as a construct for understanding health behavior. Based on earlier work with ICD recipients, the authors hypothesize SE will significantly impact performance in cardiac-related lifestyle changes, motivation levels and emotional reactions to change (Dougherty, Glenny, Kudenchuk, Malinick, and Flo, 2010).

**Heart disease, self-efficacy and physical activity.** In a cross-sectional study of 1024 patients with coronary heart disease low SE scores were correlated with higher levels of symptom burden, Odds Ratio (OR)=2.1, \( p<0.001 \), increased physical limitation, OR=1.8, \( p<0.0001 \), lower QOL, OR=1.8, \( p<0.0001 \) and lower overall health status, OR=1.9, \( p<0.0001 \) (Sarkar, Ali, and Whooley, 2007). Results of the study give weight to the stance that intervention to increase SE have the potential to significantly impact health status, symptom burden and overall health functioning in patients with coronary heart disease. Self-efficacy contributed significantly to self-reported physical functioning in sixty-five HF and fifty-six chronic obstructive heart disease patients (Arnold et al, 2005). Increased levels of SE in these patients correlated with increased self-reported levels of physical functioning.

In a study to measure the relationship of SE scores at baseline and after completion of a six week cardiac rehabilitation program, Everett, Salamonson, and Davidson, (2009) found that patients (\( N = 110 \) cardiac patients) with higher SE scores at baseline and after completion of the cardiac rehab program had statistically significant greater distances on their six minute walk tests. Findings were similar in a study to determine the correlates of PA in patients (\( N = 555 \) cardiac patients) not attending cardiac rehabilitation. Increases in SE were significantly
correlated with increases in PA participation from baseline to six months (Blanchard et al., 2006). In an exploratory study to determine determinants of PA initiation and participation in elderly cardiac rehabilitation patients, Allison and Keller (1999) found SE to be significantly correlated with PA ($r = .564$, $p = 0.002$). Similar results were seen in experimental research aimed at improving cardiovascular lifestyles of patients with chronic vascular, cardiac or cerebrovascular disease. Participants ($N = 125$) participated in a one year self-management intervention which included measures of SE at baseline and one year. Improved SE scores were significantly correlated with improved PA adherence (Sol, van der Graaf, van Petersen, and Visseren, 2011). In a study to determine predictors of PA in patients with chronic HF, Oka, Gortner, Stotts, and Haskell, (1996) found SE to be the strongest predictor ($p = 0.015$).

**Quality of Life**

Quality of life (QOL) for ICD recipients is very important to consider. Sparse research to date regarding PA and its effect on QOL has been conducted (Dunbar, et al, 2012). A literature search using CINAHL, Medline-OVID and Google-Scholar using the terms QOL, ICD and PA yielded three research articles. The term PA was changed to exercise yielding five articles and then to cardiac rehabilitation which yielded two additional articles. Of the ten articles located, one was a systematic review of nine cardiac rehabilitation programs aimed at improving outcomes of ICD recipients. Evidence supports the safety and efficacy of cardiac rehabilitation (CR) in improving aerobic capacity and indicates ICD recipients who participate in CR are likely to experience fewer ICD shocks than those who do not (Isaksen, Morken, Munk and Larsen, 2011). One would assume that improved aerobic capacity and fewer shocks would be associated with improved QOL; yet none of the studies the authors reviewed report data to make
any conclusions regarding psychological distress or QOL changes. Dunbar, et al. (2012) concluded similar results in their review of research focused on exercise and CR in ICD recipients. In fact, this review led to one of several scientific inquiry recommendations from the AHA; that is, there is a great need for more research that focuses on the physical and psychological benefits (specifically QOL) of PA in ICD recipients.

The psychological issues (QOL, anxiety, depression, etc.) often associated with living with an ICD have not been studied with the same intensity as pathological/physical outcomes in clinical trials. The psychological issues are only beginning to be understood in the context of living with an ICD. Sears and Conti (2002), describe QOL as an important outcome to consider when determining if ICDs are a successful therapy. Common problems such as loss of control, low self-efficacy, fear of shock, decreased levels of physical activity, physical intimacy, restrictions on work, driving or other hobbies associated with living with an ICD have been reported to affect QOL (Dickerson, Kennedy, Wu, Underhill and Othman, 2010; Brouwers, Van Den Broek, Denollet and Pedersen, 2011). In an analysis of science involving ICDs and QOL measures (Dunbar, et al., 2012) found there were no significant differences in reported QOL between patients receiving an ICD versus patients treated with antiarrhythmic medications (no ICD). Further, no significant differences have been noted in primary versus secondary ICD recipients. In a review of science to determine gender differences in psychological distress and QOL, Brouwers, Van Den Broek, Denollet and Pedersen (2011) concluded that a meta-analysis of the literature examining QOL was not feasible given the heterogeneity of study designs, instruments used to measure QOL and the lack of control for confounders. Of the science they did review, there was not enough evidence to suggest significant gender differences in QOL and
psychological distress; however, more research is necessary that specifically addresses the ICD recipient characteristics (age, gender, socio-economics, spirituality, co-morbidities, etc.). The same is true regarding differences in QOL with respect to the age of the ICD recipient; that is, the research has been mixed in interpreting age discrepancies with regards to living with an ICD (Dunbar, et al., 2012).

**Discussion**

Sixty-three percent of adult ICD recipients less than forty years of age report being concerned about engaging in PA (Dougherty, Glenny, Kudenchuk, Malinick, and Flo, 2010). Almost sixty percent of all ICD recipients report avoiding people, places and/or activities to avoid shock from their device (Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011, p. 314). The benefits of physical activity for secondary prevention are well documented for patients with chronic heart disease and chronic HF (Leon et al., 2005). Although limited, research to date determining the safety of PA in the ICD recipient has established efficacy, feasibility and safety of cardiac rehabilitation (CR) and PA in ICD recipients. This makes sense, given that over sixty-five percent of ICD recipients have heart disease and almost eighty percent have chronic HF (Hammill et al., 2010). Very few studies have focused on psychological outcomes and no studies have focused on long-term adherence to PA in ICD recipients (Dunbar et al., 2012). It is clear from the lack of data, that more information is necessary to design tailored programs aimed at improving PA participation in this population. The literature supports investigating perceived benefits, barriers and self-efficacy beliefs as a means to understand why individuals do or do not take part in preventive health behaviors. There is a gap in knowledge of ICD recipient’s health beliefs. Do ICD recipients understand the benefits of PA? What are the
barriers that prevent them from participating in daily PA and how confident are they at participating in PA?
CHAPTER III: METHODS

The aims of this study were to gain an improved understanding of ICD recipient’s perceived benefits, barriers, self-efficacy beliefs and PA and to examine the association of these beliefs with PA participation and QOL in adult, ICD recipients. Further, PA was examined as a mediator between health beliefs and QOL. Another aim was to determine if PA participation can be predicted by health beliefs (benefits, barriers and self-efficacy) modifying factors such as age, gender, role of religion and knowledge, while controlling for severity of heart disease. An additional endpoint was to describe any possible differences between beliefs and diagnostic indication for ICD implantation (secondary or primary). That is, do recipients of ICDs for secondary prevention of SCD have different health beliefs than those implanted for primary prevention; and, are differences occurring in their PA participation? The following is a discussion of the methods used for this study.

Research Design

A descriptive cross-sectional design was used to address the aims of this study. Cross-sectional designs are observational in nature and allow for a description of characteristics that exist in a certain population. The design is convenient in that it allows for gathering numerous data from a single group (adult ICD recipients) at a single point in time. The design allowed for data collection on attitudes and behaviors in adult, ICD participants which has aided in identifying relationships that could be the subject of future investigation (Stommel and Wills, 2004).
Setting

The study was conducted in a large, private, research intensive cardiology group consisting of twenty cardiologists with specialties ranging from non-invasive, pharmacologic cardiovascular disease management, invasive cardiovascular disease management and cardiac electrophysiology. The practice has multiple office locations in urban and rural areas of eastern North Carolina. ICD recipients come for in-office follow-up visits in six locations (three rural and three urban). Recruitment occurred in five of the clinic locations (three rural and two urban).

Sample

The study population was a convenience sample of adult ICD recipients greater than twenty years of age. The inclusion criteria for study participation included; (a) ICD implanted for greater than or equal to six months, (b) able to read and write English and answer paper and pencil questionnaires individually or via interview, and (c) be documented by the physician as medically approved for PA participation. The reason for waiting six months after implant is to allow the ICD recipient adequate time for recovery after surgical implantation of the ICD. Routine discharge instructions after implantation require that individuals limit moving the arm on the same side of the implant for approximately six weeks to prevent ICD lead dislodgement (Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011). In some cases personal driving is often restricted ranging from one month to as long as six months; and most often, commercial driving is suspended permanently (Reiffel and Dizon, 2002; Vijgen et al., 2010).

Exclusion criteria for the study population included recipients who were contraindicated for PA and were unable to complete study tasks. Recipients of ICDs may have advanced chronic
heart disease (such as heart failure exacerbation) and other co-morbid conditions that may prevent them from participation in PA.

Sample size was calculated using recommendations from Field, (2009) regarding estimating the minimum sample size for testing individual predictors in research that requires correlational and regression analysis. There are several methods appropriate for determining sample size. One method is to use ten to fifteen cases per predictor variable in the study. The minimum sample size could also be calculated using the formula, \( N = 50 + 8k \) with \( k \) representing the number of predictor variables being measured. This formula is based on testing the overall fit of the regression model. The formula for testing individual predictors is 104 +\( k \). It is recommended that the researcher use the largest value of the two (Field, 2009, p. 222). A more simplified approach is to determine sample size based on the level of the effect size one expects predictors to have. For a large effect size with up to twenty predictor variables, eighty is a sufficient sample size; and, for medium with six or less predictor variables, 100 are sufficient (Field, 2009, p. 223). Based on these calculations for three predictor variables (self-efficacy beliefs, perceived benefits and perceived barriers) in this study, the sample size ranged from 30 (ten to fifteen per predictor) to 107 (104 +\( k \)). Based on the principle of ‘larger being better’ (Field, 2009, p. 222), the study sample size was set at 107 adult, ICD recipients.

**Sample Recruitment**

Prior to recruitment, practice physicians, clinic nurses and nurse practitioners were educated by the principal investigator (PI) on the aims of the study, study method and eligibility criteria. In order to protect patient privacy the potential subjects were first identified by the practice physician, clinic nurses and nurse practitioners with firsthand knowledge of the patient’s
medical history and the study’s eligibility criteria. One method of recruitment was the use of recruitment flyers posted by the principal investigator (PI) at the reception desk in each clinic and given out by clinic nurses, nurse practitioner and physicians (Appendix A). An additional method of recruitment occurred in the following manor, (a) the physician or nurse practitioner asked if the potential subject would be interested in hearing more about a study being conducted by a doctoral nursing student, (b) if they said yes, the physician or nurse practitioner would ask if it was okay for the doctoral nurse to contact them by phone, or if they had time (on days the nurse researcher was in the clinic setting) would they like to speak to her in the office, and (c) if the potential subject chose to be contacted at home, the physician or nurse practitioner would have them write their contact information and best time to be contacted on the recruitment flyer (the flyer was locked in a secure file cabinet and given to the PI when she was in the clinic setting) and (d) if the potential subject chose to speak with the PI during their clinic visit, the physician or nurse practitioner would introduce the potential subject to the PI in a private office in the clinic setting. All of the potential subjects who expressed interest in hearing more about the study and granted permission for the PI to contact them chose to meet with the PI during that office visit.

Once potential subjects agreed to participate, the PI gave them the option of completing the consent forms and questionnaires in the clinic setting; completing the consent forms and taking the questionnaires home to be mailed back to the PI after completion; taking the formal consent and the questionnaires with them to be mailed back to the PI after completion; or having them mailed to their homes for completion and then returned by mail to the PI. Of the 107 subjects that agreed to participate in this study 105 chose to complete the consent forms in the
Two of the subjects who agreed to participate chose to consent and answer the questionnaires in the clinic setting. Their reasons given to complete the questionnaires in the clinic setting was so that they could ask questions of the PI if necessary and one stated “If I take it home I might forget to mail it back”.

**Human Subjects Protection Plan**

Study approval was obtained from the Human Subjects Protection program at the University of Arizona in accordance with federal regulations and ethical standards to protect human subject’s rights (Appendix B). Written permission to recruit potential subjects and review medical records was received from the cardiology practice and attached to the application for study approval (Appendix C). The cardiology practice is a private group and defers institutional review board (IRB) approval to the University of Arizona’s IRB.

All data collected for the study did not contain any names or identifying information. Questionnaires were number coded with the number assigned to each subject. For example, subject number one’s questionnaires were coded with number one (001), subject number two, with number two (002) and so forth. Coding the documents allows for information to remain confidential and private. The PI has maintained and secured all questionnaires and study materials in a locked file cabinet. Records that link coded documents to names were kept in a different, locked file cabinet. At study completion consent forms and records linking names to questionnaires were transported to the College of Nursing building at the University of Arizona where they are locked in a file cabinet in the Research Office. Study questionnaires and clinical data forms were destroyed by the PI using a paper shredder upon completion of data analysis.
Data Collection Procedures

The potential subjects who chose to hear more about the study in the clinic setting met with the PI in a private, clinic office or exam room. The PI explained the study and procedures and when the subjects confirmed their agreement to participate, the PI consented the subjects and gave them the study questionnaires in a self-addressed, postage paid, return envelope (for those who chose to take the study questionnaires home for completion). The PI provided her contact information and gave a two week time frame with which to complete the material and send it back in the postage-paid envelope. At the end of the two week period, the PI contacted the subjects by phone to remind them of the questionnaire and answer any questions.

For the subjects who chose to answer the questionnaires in the clinic setting the PI provided a quiet, private office for the subjects to answer the study questionnaires. Once the consenting process was completed the subjects were administered the study questionnaires which included a Demographic Data Questionnaire, Self-Efficacy Expectations after ICD Scale, Self-Efficacy for Exercise Scale, Health Belief Questionnaire, Incidental and Planned Exercise Questionnaire and Quality of Life Medical Outcomes Survey-36®. The PI was available to answer questions. Time allotted for answering questionnaires was approximately one and one half hours (to allow for any questions/clarification). The time it took for the two subjects to complete the questionnaires ranged from thirty-five to fifty-six minutes. Once the questionnaires were completed, the PI reviewed for missing responses. There were no missing responses in the questionnaires completed in the clinic setting. There were missing data in questionnaires that were mailed back to the PI. The PI phoned those subjects who had missing data to ask the subject if they overlooked the missing information or if they needed further instruction/assistance.
in answering the questions. Most of the missing data occurred by error and the subjects answered the questions via phone. Missing data can alter the results of the analysis so inferences made from the results may not be representative of the population. A reduction in missing data provides the researcher with data that is usable and allows for better analysis (De Leeuw, 2001).

Data collection also included information from the consented subject’s medical record. The PI reviewed the subject’s medical record and collected clinical data specific to the aims of the study (NYHA Class, Biventricular ICD, Single chamber ICD or Dual Chamber ICD, diagnostic indication for ICD, presence of atrial fibrillation and medical clearance for PA participation). Clinical data was recorded on a form that was coded to match the patient enrollment code. No other personal identification was documented on the clinical data form.

Completed questionnaires and consents were stored in separate locked file cabinets in the PI’s home. The clinical data form was kept in a third, locked, separate file cabinet to protect the subject’s privacy.

**Instrumentation**

Data collection most often involves formal, written instruments and is the most commonly used means of collecting information by nurse researchers (Polit and Beck, 2012). The following is a discussion of the questionnaires used for this study (Table 4).

**Demographic data questionnaire.** The demographic data questionnaire designed by the PI consists of sociodemographic questions about gender, age, race, marital status, employment status, occupation, medical insurance status, educational level, and annual household income (Appendix D). Health history questions include types of medications (beta-blockers and/or antiarrhythmic medications), ICD shock history (whether they recall receiving shocks from their
ICD), presence of co-morbidities (diabetes, heart failure, previous heart attack, previous heart surgery and/or lung disease), height and weight, and if they have ever participated in any type of physical rehabilitation or attended ICD support group meetings. Other questions related to knowledge of the ICD and/or activity instruction include; (a) if they know the heart rate at which their ICD will deliver therapy (at what heart rate can they safely achieve with PA to avoid shock), (b) what PA to avoid and (c) if they have been given instructions about PA from their doctors/nurses since receiving an ICD.

An assumption of the HBM is that sociodemographic and knowledge factors exert effects on an individual’s beliefs (Champion and Skinner, 2008; Janz and Becker, 1984). These data along with health history information are valuable for comparing to the National ICD Registry patient characteristics to determine if the sample was representative of the ICD population.

**Self-efficacy scales.** Currently there are very limited questionnaires/surveys specifically for ICD recipients (Dunbar et al., 2012). In 2007, Dougherty, Johnston, and Thompson, (2007) developed and tested the only SE scale for ICD recipients. The Self-Efficacy-ICD (SE-ICD) scale was developed using the results of grounded theory research that looked at the most common concerns and difficulties of individuals during their first year after survival of sudden cardiac death (SCD) and implantation of an ICD. The scale’s purpose is to help clinicians identify and enhance SE beliefs of ICD recipients which may lead to considerable behavior change and improved outcomes. The scale consists of sixteen items (eight items measuring SE beliefs and eight items measuring SE behaviors) of an individual’s perceived ability to manage common problems encountered after surviving SCD and receiving an ICD. Subjects are asked to rate their self-confidence or behavior on a zero to ten, Likert scale with zero meaning “not
confident at all” and ten meaning “very confident”. Statements that the subjects are asked to rate include items that ask them to rate how confident you feel today or to what extent you have dealt with physical changes, limitations on work or activity, pressures or stresses and the ability to deal with activation of the ICD. The scores are tabulated by totaling the numerical ratings and calculating the average score by dividing the total score by the number of questions. The score range for SE-ICD is zero to ten. The SE-ICD has an excellent Cronbach’s alpha of .93 and has good construct and concurrent validity. The scale’s responsiveness to change was tested in a study comparing a nursing intervention to enhance SE with usual care. The measure showed statistically significant change in the appropriate direction after three months with an effect size of .46, \( p = .01 \) (Dougherty, Johnston, and Thompson, 2007).

The SE-ICD scale is thought to be a reliable and valid tool for nurses to assess ICD recipients and design strategies to enhance SE and health function. A possible disadvantage is that the scale was administered to individuals who were implanted secondary to experiencing SCD and is a general self-efficacy measure. Prior to this study it had not been tested in those who are implanted for primary prevention or with the intent of measuring PA self-efficacy although some of the questions are specific for confidence in returning to normal daily activity and exercise (Dougherty, Johnston, and Thompson, 2007).

Questions two, three, four and number sixteen were modified to be appropriate for primary and secondary indication for ICD implantation. The terms ‘cardiac arrest’ was eliminated from questions two, three and four as not all patients have experienced SCD. Time to complete the SE-ICD scale and reading level were not reported. Permission was granted for use and modification via electronic mail which is attached in Appendix E.
Table 4

Table of Questionnaires

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Age Range</th>
<th>Concept</th>
<th>Psychometric Properties</th>
<th># Items and Completion time</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE-ICD Scale (Dougherty, Johnston, and Thompson, 2007)</td>
<td>SE-ICD ≥ 21 years</td>
<td>Self-efficacy Beliefs of ICD Recipients</td>
<td>Internal consistency α=.93</td>
<td>16 items 5-10 minutes</td>
</tr>
<tr>
<td>Self Efficacy for Exercise Scale (Resnick and Jenkins, 2000)</td>
<td>ESE Scale-40-85 years</td>
<td>Self-efficacy for exercise</td>
<td>Internal consistency α = .92</td>
<td>9 items Est. 5 minutes</td>
</tr>
<tr>
<td>HBQ (Mirotznik, Feldman, and Stein, 1995) Subscales</td>
<td>Adults &gt; 18 years</td>
<td>Measure perceived benefits of exercise r/t CHD and perceived costs (barriers) of exercise.</td>
<td>Benefits Cronbach’s α-.73-.92 Barriers Cronbachs α-.86-.88</td>
<td>14 items Estimated 10 minutes</td>
</tr>
<tr>
<td>MOS-SF36® (Ware, 2004)</td>
<td>Adults ≥ 14 years</td>
<td>Quality of Life</td>
<td>In adult ICD recipients ranged Cronbach’s α .75 to .87 s (Kao, Friedman, and Thomas, 2010; Hamilton and Carroll, 2003; Probst et al., 2011).</td>
<td>36 items. 5-10 minutes</td>
</tr>
<tr>
<td>IPEQ-WA(Delbaere, Hauer, and Lord, 2010)</td>
<td>Elderly Adults-age not stated</td>
<td>Incidental and Planned Exercise</td>
<td>Intraclass correlation = 0.84.Cronbach’s α of 0.61)</td>
<td>10 items Estimated 10 minutes</td>
</tr>
<tr>
<td>Demographic Data Questionnaire</td>
<td>≥20 years</td>
<td>Socio-demographics.</td>
<td>N/A</td>
<td>32 items. Est. 20-30 mins</td>
</tr>
</tbody>
</table>

The Self-Efficacy for Exercise Scale (SEE) was used as an additional measure specific to exercise. The SEE was developed by Resnick and Jenkins (2000) to explore factors in older
adults that might affect participation in exercise. The SEE was originally tested in older adults (average age eighty-five years) living in a retirement community and has been subsequently tested in an exercise intervention program in adults (forty to sixty-five years) with type II diabetes (Gleeson-Kreig, 2006; Resnick and Jenkins, 2000). The SEE has been validated in elderly African Americans, Latino-Americans and in older Thai adults (Harnirattisai and Johnson, 2005; Resnick, Luisi, Vogel and Junaleepa, 2004). The SEE consists of nine situations that may affect a person’s confidence in participating in a prescribed exercise regimen (three times per week for twenty minutes). Situations consist of items that range from weather related hindrances, boredom or dislike of exercise, physical (pain or fatigue) and/or emotional (depressed, stressed, lonely) factors that may affect one’s confidence to exercise. For each of the nine situations there is a scale ranging from zero (not confident) to ten (very confident) to describe the confidence one has to exercise three times a week for twenty minutes each time. The answers are totaled and averaged by the number of items for a range of scores of zero to ten. A low score indicates little confidence and high levels of confidence is indicated by a high score. The SEE is considered a reliable and valid tool for measuring exercise self-efficacy. Internal consistency scores for SEE are excellent with a Cronbach’s alpha ranging from .84 to .92 (Harnirattisai and Johnson, 2005; Resnick and Jenkins, 2000; Resnick, Luisi, Vogel and Junaleepa, 2004). The scale was validated with health status scores. Controlling for age and gender, the SEE scores significantly predicted exercise participation (F= 78.8; p < 0.05) (Resnick and Jenkins, 2000). The authors of the SEE have granted written permission to use in this study which is attached in Appendix F.
Health beliefs questionnaire. The perceived benefits and perceived barriers subscales of the Health Belief Questionnaire (HBQ), originally developed by Mirotznik, Feldman, and Stein (1995) was used for this study. The theoretical framework for the HBQ is the HBM. The HBQ’s internal consistency reliability has a mean Cronbach’s alpha of .80 with a range of .69-.89. The test-retest stability has a mean Pearson r correlation of .75. The perceived benefit subscale consists of nine Likert style items that measure beliefs about how helpful exercise is for heart disease and health. Answer selection choices have options that range from one to five with one being not at all helpful to five being extremely helpful. The subscale score is the average of the total item score which can range from one to five. Internal consistency scores for perceived benefits subscale range from .73-.92 (Mirotznik, Stein, Manfry, and Feldman, 1995; Mirotznik, Feldman, and Stein, 1995). In research using the HBQ to determine the effect of the HBM on exercise participation in Jordanian MI patients, Al-Ali and Haddad, (2004) reported low internal consistency scores (Cronbach’s alpha = .32) for the perceived benefits subscale. This might be explained by the fact that the researchers used fourteen questions instead of the nine original tested questions that measure perceived benefits. Perceived barriers subscale consists of five questions that focus on the individual’s perceived cost of PA in terms of time, money, pain and effort. The questions are Likert style items with scoring like that of perceived benefits. The subscale score is the average of the items (average total score = one to five). Internal consistency scores are good (Cronbach’s alpha = .86-.88) (Mirotznik, Stein, Manfry, and Feldman, 1995). The internal consistency score for the study on Jordanian MI patients was reported as Cronbach’s alpha = .41 which can be explained in part to the authors adding two additional, untested items to the subscale (Al-Ali and Haddad, 2004).
Perceived benefits and perceived barrier questions were developed for use in patients with previous heart attacks and chronic heart disease and thus are relevant to the ICD population. To keep the language consistent within the context of this study, the term exercise in the HBQ was replaced with PA participation. Additional terms have been added in several answer selections that are relevant to the ICD population. The changes were as follows; (a) the terms physical activity in place of the term exercise, (b) preventing recurrence of irregular heart rate or shock in place of preventing recurrence of heart disease, and (c) improving quality of life after having an ICD in place of improving quality of life after being diagnosed with heart disease. Verbal permission for modification was granted by the author of the questionnaire. Written permission was granted via email notification (Appendix G).

**Quality of life questionnaire.** The Medical Outcomes Study, 36-Item Short Form (MOS-SF36®) survey is an eight scale profile consisting of thirty six questions reflecting functional health and general well-being. Physical functioning (ten items), role-physical (four items), bodily pain (two items) and general health (five items) represent a person’s perception of their overall physical health. Vitality (four items), social functioning (two items), role-emotional (three items) and mental health (five items) represent a summary measure of an individual’s mental health. Raw scores of the items are converted to scale scores ranging from zero to 100 with the higher scores indicating a better level of functioning (Habibovic et al., 2011; Probst et al., 2011). Reliability and validity of the SF-36® has been extensively studied across many domains, in many chronic disease states and in many ICD intervention studies (Cheng, Cumber, Dumas, Winter, Nguyen, and Nieman, 2003; Dickerson, Kennedy, Wu, Underhill, and Othman, 2010; Thomas, Friedmann, Kelley, Obias-Manno, and Apple, 2001; Ware, 2004).
Internal consistency scores across all scales in adults range from Cronbach’s alpha .68-.93. Reliability and validity of the SF-36® has been well established in patients with heart disease (Beery, Baas, and Henthorn, 2007; Kao, Friedman, and Thomas, 2010). Internal consistency scores reported in research with adult ICD recipients ranged from a Cronbach’s alpha greater than .75 to .87 for each component and both summary scales (Hamilton and Carroll, 2003; Kao, Friedman, and Thomas, 2010; Probst et al., 2011). The survey is written on the sixth grade reading level and takes approximately five to ten minutes to complete. It is suitable for adults fourteen years of age or older (Ware, 2004). License for use of the SF36® was applied and granted (Appendix H).

**Physical activity questionnaire.** Selecting a questionnaire for individuals living with ICD’s is a complex task as this population has a range of co-morbid and cardiac conditions that vary in disease severity and symptom burden. There are no measures of PA or exercise that are specific to the varying needs of the ICD population (Dunbar et al., 2012). A review of self-report PA instruments used in cardiac patients showed that most of the measures were inadequate for assessing total PA participation (LeGrande, Elliott, Worcester, Murphy, and Goble, 2008). The measures (most being seven day PA recall) were shown to be inadequate in accounting for the variability of PA from day to day and week to week for cardiac patients. Of the measures reviewed, few were validated in elderly patients and most were difficult to administer (too long) or score (Le Grande, Elliott, Worcester, Murphy, and Goble, 2008).

The Incidental and Planned Exercise Questionnaire-Weekly Average (IPEQ-WA) is a measure developed for use in aging research which has been established as a valid and reliable measure of PA in older adults. The measure assesses physical activity/exercise in the average
week over the past three months and takes approximately ten minutes to complete. The IPEQ-WA has a high test-retest reliability (intraclass correlation = 0.84) and moderate internal consistency score (Cronbach’s alpha of 0.61) (Delbaere, Hauer, and Lord, 2010). Reasons this measure may more accurately reflect the level of PA in ICD recipients include: (a) the average age of individuals with an ICD is over sixty-eight years and (b) the variability of daily and weekly activities secondary to a range of physiologic and psychological sequelae that accompany diagnoses leading to ICD implantation and other co-morbidities (Delbaere, Hauer, and Lord, 2010; Fan, Lyon, Savage, Ozonoff, Ades, and Balady, 2009; Hammill et al., 2010; Sears et al., 2007; Tsiperfal, Ottoboni, Beheiry, Al-Ahmad, Natale, and Wang, 2011).

The IPEQ-WA is a self-report, PA measure with ten questions that include the type, frequency and duration of planned and incidental activities performed on average each week during the past three months. Questions focus on planned PA and incidental PA. Total activity time is obtained by first multiplying frequency and duration scores in each component. Next, add each of the component totals to give the total activity (hours per week) the individual spends. Sub scores for incidental activity, walking activity, planned activity, planned walking activities and planned sports activities may be obtained by multiplying the frequency and duration of each subscale. A high score indicates a more physically active individual and a lower score, less physically active (Delbaere, Hauer, and Lord, 2010). Permission for use of this scale was provided by the authors (Appendix I).

**Clinical data form.** The clinical data form (Appendix J) was a form designed by the PI to collect clinical data pertinent to this study. Data collected from the subject’s medical records included NYHA classification, diagnostic reason for ICD implantation (primary versus
secondary indication), date of implantation, type of ICD (biventricular, single chamber or dual chamber ICD), the number of shocks since ICD implant, the presence of atrial fibrillation and medical clearance for PA participation. The clinical data form served to validate the patient’s self-report and provided information that oftentimes patients cannot recall.

**Data Analysis Procedures**

Data was entered and analyzed by the researcher using the Statistical Package for the Social Sciences (IBM-SPSS Version 21© Graduate Pack for Windows). QOL data was entered and analyzed (scoring and internal consistency) using the SF36® QOL Scoring Software. Data was double checked prior to and after entry for completeness and accuracy. To assess for coding or data entry errors frequency distributions were analyzed. Significance level was at a p value of ≤ .05. To ensure internal consistency Cronbach’s alpha was analyzed for HBQ-subcales, SE-ICD, SEE, IPAQ-WA and QOL questionnaires. Interval and ratio level variables were assessed for normal distribution by evaluating P-P plots, histograms, skewness and kurtosis to determine parametric or non-parametric analysis. Parametric tests are based on normal distribution and non-parametric analyses are conducted to explore for differences in unequal groups.

Univariate descriptive statistics was used to describe the sociodemographic, health belief (benefits, barriers and self-efficacy), PA participation and QOL characteristics (Aim 1) of the population participating in this study. This included frequencies, distributions, percentages, means and standard deviations. Independent t-tests were conducted to assess for gender and/or racial differences in mean scores of health beliefs (perceived benefits, barriers and self-efficacy), PA and QOL questionnaires. Bivariate descriptive statistics were used to determine possible relationships (Aim 2) between the variables (Polit and Beck, 2012). Pearson’s Product-Moment
Correlation Coefficient was used to analyze study variables and to examine multicollinearity among potential predictors of PA participation. Spearman’s Rho Correlation Coefficient was used for variables that were not normally distributed.

Analyses assessing mediation (Aim 3) were conducted using Baron and Kenny’s (1986) meditational analyses model. Linear regression was used to analyze for partial or complete mediation of PA participation on health beliefs and QOL. Evidence for partial or complete mediation is found when the presence of the mediator variable attenuates or eliminates the association between the independent variable (IV) and the outcome in the setting where the IV was previously significantly associated with the outcome (or QOL in this study).

Non-parametric analysis (Mann-Whitney U test) was used to explore differences in subjects implanted for primary prevention versus secondary prevention (Aim 4). The reason a nonparametric analysis was used was because the data was not normally distributed. Multiple linear regression analysis was conducted to explore if PA participation is predicted by health beliefs (benefits, barriers and self-efficacy) and modifying variables significantly related to the outcome variable (Aim 5) while controlling for severity of heart disease (New York Heart Association Heart Failure Classification) and type of ICD (Single Chamber, Dual Chamber or Bi-ventricular ICD).
CHAPTER IV: RESULTS

The results of this descriptive, cross-sectional study provide a description of ICD recipients’ perceived benefits, barriers and self-efficacy beliefs related to PA and the association of these beliefs with PA participation and QOL in adult, ICD recipients. Research aims which include description of the sample characteristics and findings from the questionnaires are reported.

Between May 22, 2013 and July 18, 2013, 121 adult, ICD recipients seen for ICD and arrhythmia/heart failure follow-up in the private clinic setting were screened for eligibility and recruited to participate in this study. A total of 107 out of 121 recruited (88.5 percent) agreed to and consented to participate in this study. Of the 107 who agreed to participate, two (1.8 percent) formally withdrew and 81 (76 percent) completed study tasks. Over 88 percent (N=23) of the females and 71.6 percent of the males (N=58) completed the study tasks. Reasons given for not participating in the study included “I don’t have time for filling out questions”, “I don’t exercise and don’t think I can help”, and “I don’t take part in studies”. Reasons given for formal withdrawal from the study were “I am too busy to do this and don’t know why I agreed” and “I think the questions about me are too personal”. Reasons given for not completing study tasks ranged from “I just don’t do homework”, “I lost the package of questions”, “My wife just died” and from most, “I just don’t have the time”.

During the study explanation and consenting process subjects were allowed time for questions and discussion. A section in the demographic questionnaire solicited comments related to PA participation. Content from conversations and comments taken from the demographic questionnaire which may be pertinent to this study include common statements/questions
specific to PA participation. A majority of comments in the clinic session were related to type of physical activity. That is, subjects would state they felt comfortable doing basic activities of daily living but were unsure of what activities outside of walking were safe to perform. Three subjects stated they worked out at a gym regularly prior to having the ICD but had stopped because they were not sure what they could or could not do. Subjects recruited from rural settings commented on the lack of facilities to exercise and not having adequate transportation. Others stated they were not certain how safe they would feel if they exercised without medical professionals being present. Statements recorded in the demographic questionnaire were similar to those discussed in the clinic setting with regards to (a) not sure what type of physical activity they could perform, (b) no access and (c) not feeling safe to exercise/afraid of getting shocked. In fact, one subject stated they had been treated for post-traumatic stress disorder after having received multiple shocks from their defibrillator. “I am still afraid of what might happen if I exercise.”

Other statements were in the context of symptoms related to chronic illnesses. For example, one subject stated “I get so short of breath anytime I do anything. My medicine makes me feel tired all the time so I don’t do anything but sit in my chair.” Another stated “The only thing that has slowed me is having a stroke. I go to rehab for my stroke which is helping me know what is good for the defibrillator too”.

**Sample Sociodemographic Characteristics**

The first aim was to describe sociodemographic (age, gender, ethnicity, socio-economics, religion and knowledge) characteristics, health beliefs (benefits, barriers and self-efficacy), PA participation and QOL of the participants in this study. Descriptive, sociodemographic
characteristics of the study population ($N=81$) are presented in Table 5. Age ranged from 40-91 years, with a mean of 70.23 (SD=11.76) years. The majority of the subjects were male (71.6 percent, $N=58$). The majority of the subjects were Caucasian (77.8 percent, $N=63$) and all (100 percent, $N=81$) were of non-Hispanic ethnicity. Almost half of the subjects were married (49.4 percent, $N=40$) and lived with their spouse (48.1 percent, $N=39$). Nineteen subjects (23.5 percent) were widowed and the remaining 27.1 percent were single ($N=10$), separated/divorced ($N=11$) or lived with their domestic partner ($N=1$). Approximately one third of the subjects reported living alone (32.1 percent, $N=26$) and other living arrangements reported include living with a domestic partner (8.6 percent, $N=7$); living with their children (6.2 percent, $N=5$); or other living arrangements (4.9 percent, $N=4$). Most of the subjects reported living in rural areas (44.4 percent, $N=36$) or small towns (30.9 percent, $N=25$). In fact, a majority of the subjects who completed the study tasks were recruited from the practice’s rural clinics (78 percent, $N=63$). A majority of the study population reported protestant as a religious affiliation (49.4 percent, $N=40$) and that role of religion as being important (80.2 percent, $N=65$).

From an education level most individuals reported high school or equivalent as being their highest level of education (49.4 percent, $N=40$). Of the remaining forty-one, eleven (13.6 percent) reported grammar school as their highest level of education; 24.6 percent ($N=20$) had some vocational/technical or some college; 11.1 percent ($N=9$), a bachelor’s or master’s degree; and 1.2 percent (one) had their doctorate.

Economic characteristics reported included all subjects ($N=81$) reporting that they have medical insurance, the majority being Medicare (79 percent, $N=64$) and they were currently retired (50.6 percent, $N=41$). Income levels were varied among the subjects. The majority who
answered (19.8 percent, N=16) reported incomes of 10,000 to 19,999 dollars per year; 18.5 percent (N=15), 20,000-29,999 dollars/year; sixteen percent (N=13), 30,000-39,999 dollars/year; and 4.9 percent (four subjects), 40,000 to 49,999 dollars/year. Thirteen (16 percent) subjects reported incomes over 50,000 dollars/year and twelve (14.8 percent) reported having incomes less than 10,000 dollars/year. Seventy-nine (97.5 percent) reported their employment status and 90.1 percent (N=73) reported income.

Table 5

*Study Population's Sociodemographic Characteristics (N=81)*

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<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
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<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
<td>58</td>
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<tr>
<td>Female</td>
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<tr>
<td><strong>Race</strong></td>
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<td><strong>Marital Status</strong></td>
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<tr>
<td>Married</td>
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<tr>
<td>Domestic Partner</td>
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</tr>
<tr>
<td>Single</td>
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<tr>
<td>Separated/Divorced</td>
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<tr>
<td>Live with Spouse</td>
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</tr>
<tr>
<td>Live with Domestic Partner</td>
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<td>8.6%</td>
</tr>
<tr>
<td>Live with Children</td>
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</tr>
<tr>
<td>Other</td>
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<td>Lives in Rural Area</td>
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<tr>
<td>Lives in Small Town</td>
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<td>Lives in the Suburbs</td>
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<td>4.9%</td>
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<tr>
<td>-------------------------------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Catholic</td>
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</tr>
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<td>Protestant</td>
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</tr>
<tr>
<td>None</td>
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<td>6.2%</td>
</tr>
<tr>
<td>Other</td>
<td>32</td>
<td>39.5%</td>
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<td>Important</td>
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<tr>
<td>Not Important</td>
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<tr>
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<table>
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<tr>
<td>Grammar School</td>
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<tr>
<td>High School or Equivalent</td>
<td>40</td>
<td>49.4%</td>
</tr>
<tr>
<td>Vocational or Tech. School</td>
<td>7</td>
<td>8.6%</td>
</tr>
<tr>
<td>Some College</td>
<td>13</td>
<td>16%</td>
</tr>
<tr>
<td>Bachelor’s Degree</td>
<td>6</td>
<td>7.4%</td>
</tr>
<tr>
<td>Master’s Degree</td>
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<td>3.7%</td>
</tr>
<tr>
<td>Doctorate/Professional Degree</td>
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<tr>
<td>Full-time</td>
<td>9</td>
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</tr>
<tr>
<td>Unemployed</td>
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</tr>
<tr>
<td>Retired</td>
<td>41</td>
<td>50.6%</td>
</tr>
<tr>
<td>Medical leave/disability</td>
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<td>22.2%</td>
</tr>
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<td>14.8%</td>
</tr>
<tr>
<td>$10,000-$19,999</td>
<td>16</td>
<td>19.8%</td>
</tr>
<tr>
<td>$20,000-$29,999</td>
<td>15</td>
<td>18.5%</td>
</tr>
<tr>
<td>$30,000-$39,999</td>
<td>13</td>
<td>16.0%</td>
</tr>
<tr>
<td>$40,000-$49,999</td>
<td>4</td>
<td>4.9%</td>
</tr>
<tr>
<td>$50,000-$74,999</td>
<td>10</td>
<td>12.3%</td>
</tr>
<tr>
<td>$75,000-$99,999</td>
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<td>1.2%</td>
</tr>
<tr>
<td>More than $100,000</td>
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<td>2.5%</td>
</tr>
<tr>
<td>Missing Data (Not answered)</td>
<td>8</td>
<td>9.9%</td>
</tr>
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<table>
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<tr>
<th>Health Insurance</th>
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<tbody>
<tr>
<td>Private Health Insurance</td>
<td>9</td>
<td>11.1%</td>
</tr>
<tr>
<td>Medicare</td>
<td>64</td>
<td>79%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>8</td>
<td>9.9%</td>
</tr>
</tbody>
</table>
Sample’s Knowledge and Social Support Characteristics

General knowledge and social support characteristics specifically concerning ICD and physical activity reported by the study population are described in Table 6. A majority of the study population responded no to the questions asking whether they had participated in (66.7 percent, \(N=54\)) or were told by their doctors or nurses that they need to participate (61.7 percent, \(N=50\)) in cardiac rehabilitation. Twenty-three (28.4 percent) reported participating in cardiac rehabilitation. Since having the ICD implanted 40.7 percent (\(N=33\)) of the subjects reported that their level of PA had remained the same; 38.7 percent (\(N=31\)), PA level decreased; Sixteen percent (\(N=13\)), PA level increased; and 4.9 percent (\(N=4\)) were unsure. Three (3.7 percent) did not answer the question. Knowledge regarding physical activity limitations was consistent except for knowledge of safe heart rate. Most of the subjects reported their doctors and nurses had discussed PA restrictions/instructions and felt they had enough information to safely participate in PA (58 percent, \(N=47\) and 64.2 percent \(N=52\), respectively). When asked whether they knew what heart rate they could safely achieve to avoid being shocked when physically active, only 12.3 percent (\(N=10\)) reported yes. Fifty-one (63 percent) reported no and twenty (24.7 percent) reported they were unsure of what heart rate was safe for PA related to their device. All of the study population completed the knowledge questions.

Social support characteristics included questions about ICD support group meetings; whether they had someone to call in times of need; and who supported/encouraged them to be physically active. The majority of respondents reported never attending an ICD support group (63 percent, \(N=51\)) and 25.9 percent (\(N=21\)) were unaware of an ICD support group. Most of the subjects reported having someone to call if they needed help (95.1 percent, \(N=77\)) and having
their spouse or significant other to help and encourage them to be physically active (43.2 percent, \( N=35 \)). Twenty-five (30.8 percent) reported other family members or close friends as helping/encouraging them to be physically active. One (1.2 percent) reported not having anyone to call if they needed help and twenty (24.7 percent) reported not having anyone to encourage or help them be physically active. Eighty (98.8 percent) of the study population completed the social support questions.

Table 6

*Study Population's ICD Knowledge and Social Support Characteristics*

<table>
<thead>
<tr>
<th>ICD and Physical Activity Knowledge</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you participated in any type of cardiac rehabilitation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>23</td>
<td>28.4%</td>
</tr>
<tr>
<td>- No</td>
<td>54</td>
<td>66.7%</td>
</tr>
<tr>
<td>- Not Sure</td>
<td>4</td>
<td>4.9%</td>
</tr>
<tr>
<td>Have you ever been told by your doctors or nurses that you need to participate in cardiac rehabilitation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>26</td>
<td>32.1%</td>
</tr>
<tr>
<td>- No</td>
<td>50</td>
<td>61.7%</td>
</tr>
<tr>
<td>- Not sure</td>
<td>5</td>
<td>6.2%</td>
</tr>
<tr>
<td>Have your doctors or nurses discussed physical activity restrictions or instructions regarding your implantable cardioverter defibrillator?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>47</td>
<td>58%</td>
</tr>
<tr>
<td>- No</td>
<td>28</td>
<td>34.6%</td>
</tr>
<tr>
<td>- Not Sure</td>
<td>6</td>
<td>7.4%</td>
</tr>
<tr>
<td>Since you had your defibrillator placed your level of physical activity has:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Remained the same</td>
<td>33</td>
<td>40.7%</td>
</tr>
<tr>
<td>- Has decreased</td>
<td>31</td>
<td>38.3%</td>
</tr>
<tr>
<td>- Has increased</td>
<td>13</td>
<td>16%</td>
</tr>
<tr>
<td>- Not sure</td>
<td>4</td>
<td>4.9%</td>
</tr>
</tbody>
</table>
Do you know what heart rate you can safely achieve when you are being physically active? That is, what your cut-off heart rate is before you will receive a shock from your defibrillator?

- Yes 10 12.3%
- No 51 63%
- Not sure 20 24.7%

Do you feel like you have enough information to safely participate in physical activities?

- Yes 52 64.2%
- No 12 14.8%
- Not sure 17 21%

<table>
<thead>
<tr>
<th>Social Support Characteristics</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you attend the support group meetings for implantable cardioverter defibrillator patients?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes, frequently (6 or more times a year)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- Yes, on occasion (less than 5 times a year)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- No, never</td>
<td>51</td>
<td>63%</td>
</tr>
<tr>
<td>- No, there is not one near where I live</td>
<td>5</td>
<td>6.2%</td>
</tr>
<tr>
<td>- I have in the past but do not now</td>
<td>3</td>
<td>3.7%</td>
</tr>
<tr>
<td>- I did not know there was a support group</td>
<td>21</td>
<td>25.9%</td>
</tr>
<tr>
<td>- Missing data</td>
<td>1</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

Do you have someone you can call if you need help?

- Yes 77 95.1%
- No 1 1.2%
- Not sure 2 2.5%
- Missing data 1 1.2%

What social support do you have to encourage and help you participate in physical activities?

- Spouse or significant other 35 43.2%
- Friend 7 8.6%
- Other family member 18 22.2%
- None 20 24.7%
- Missing data 1 1.2%

Medical Characteristics of Study Population

Medical characteristics of the study population include data collected from the medical record for the Clinical Data Form and self-report data contained in the Demographic Data
Questionnaire. Table 7 provides frequencies of the type of ICD implanted, time since implant, subject’s Body Mass Index (BMI), diagnostic indication, heart failure class, medication class, arrhythmia history and medical clearance to participate in PA. Self-reported and documented medical diagnoses are described in Table 8.

Type of ICD implanted includes single chamber (14.8 percent, \(N=12\)), dual chamber (46.9 percent, \(N=38\)) and bi-ventricular (38.3 percent, \(N=31\)) ICDs. Time since implant of the ICD ranged from one-half year to nineteen years with a mean of 5.6 ± 3.62 years. The majority of ICDs implanted were for primary prevention of sudden cardiac death (86.4 percent, \(N=70\)) and 13.6 percent (\(N=11\)) were for secondary prevention. Heart failure classification using NYHA Heart Failure Classification was reported by the physician or nurse practitioner after examination on each clinical visit. Five (6.2 percent) subjects were classified as having Class I heart failure; fifty-nine (72.8 percent) Class II; fifteen (18.5 percent) Class III; one (1.2 percent) Class IV; and one (1.2 percent) no heart failure. Paroxysmal and chronic atrial fibrillation account for 37 percent (\(N=30\)) and 17.3 percent (\(N=14\)) respectively. All of the subjects met the eligibility criteria of having medical clearance to participate in PA. Sixty (74.1 percent) had documented medical clearance and 25.9 percent (\(N=21\)) had verbal clearance by the medical doctor. Body Mass Index was calculated using self-reported height and weight using the formula: weight (kilograms) divided by [height (meters)]² (CDC, 2011). The mean BMI was 29.60 ± 6.79, ranging from 17.75 to 52.22. A majority of the subjects reported taking beta-blockers (84 percent, \(N=68\)) and less than half (35.8 percent, \(N=29\)) take anti-arrhythmia medications. Height, weight and medications were self-report items.
The Demographic Data Questionnaire contained a list of conditions common to ICD recipients. The subjects were asked to respond whether they had any of these conditions by placing a check-mark by each condition. To verify these clinical conditions, the Clinical Data Form contained the same checklist for the researcher to complete using the medical records. Side by side comparison of self-report and documented diagnoses is described in table 8.

Table 7

*Medical Characteristics of Study Population*

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of ICD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Chamber</td>
<td>12</td>
<td>14.8%</td>
</tr>
<tr>
<td>Dual Chamber</td>
<td>38</td>
<td>46.9%</td>
</tr>
<tr>
<td>Bi-ventricular</td>
<td>31</td>
<td>38.3%</td>
</tr>
<tr>
<td><strong>Time since implant, mean (SD) range</strong></td>
<td>5.6 years ± 3.62 years (0.5-19)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of Shocks Since Implant, mean (SD) range</strong></td>
<td>1.22 shocks ± 2.67 (0-14)</td>
<td></td>
</tr>
<tr>
<td><strong>BMI, mean (SD) range</strong></td>
<td>29.60 ± 6.79 (17.75-52.22)</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnostic Indication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Prevention</td>
<td>70</td>
<td>86.4%</td>
</tr>
<tr>
<td>Secondary Prevention</td>
<td>11</td>
<td>13.6%</td>
</tr>
<tr>
<td><strong>NYHA Heart Failure Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>5</td>
<td>6.2%</td>
</tr>
<tr>
<td>Class II</td>
<td>59</td>
<td>72.8%</td>
</tr>
<tr>
<td>Class III</td>
<td>15</td>
<td>18.5%</td>
</tr>
<tr>
<td>Class IV</td>
<td>1</td>
<td>1.2%</td>
</tr>
<tr>
<td>No Heart Failure</td>
<td>1</td>
<td>1.2%</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-Blockers</td>
<td>68</td>
<td>84%</td>
</tr>
<tr>
<td>Anti-Arrhythmics</td>
<td>29</td>
<td>35.8%</td>
</tr>
<tr>
<td><strong>History of Atrial Fibrillation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>37</td>
<td>45.7%</td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>30</td>
<td>37%</td>
</tr>
<tr>
<td>Chronic</td>
<td>14</td>
<td>17.3%</td>
</tr>
<tr>
<td><strong>Medical Clearance for Physical Activity</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 8

**Self-Reported and Clinically Documented Medical Diagnoses**

<table>
<thead>
<tr>
<th>Diagnosis/Condition</th>
<th>Documented (n=81)</th>
<th>Self-Report (n=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>Yes</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes Type I</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>81</td>
</tr>
<tr>
<td>Diabetes Type II</td>
<td>Yes</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>54</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Yes</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>13</td>
</tr>
<tr>
<td>Lung Disease</td>
<td>Yes</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>56</td>
</tr>
<tr>
<td>Cancer</td>
<td>Yes</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>64</td>
</tr>
<tr>
<td>Myocardial Infarction (Heart Attack)</td>
<td>Yes</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>22</td>
</tr>
<tr>
<td>Stroke</td>
<td>Yes</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>68</td>
</tr>
<tr>
<td>Heart Surgery</td>
<td>Yes</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>50</td>
</tr>
<tr>
<td>Angioplasty/Stent</td>
<td>Yes</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>39</td>
</tr>
<tr>
<td>Obstructive Sleep Apnea</td>
<td>Yes</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>61</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>Yes</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>65</td>
</tr>
</tbody>
</table>

Differences in self-report and documented diagnoses occurred for all conditions.

Documented frequency of HF in the study population was 98.8 percent (N=80) as compared to the self-reported frequency of HF of 49.4 percent (N=40). Over twice as many subjects (twenty-
seven, 33.3 percent) reported they did not have high blood pressure than were documented (thirteen, 16 percent). Over 80 percent of self-reported medications are used to treat hypertension.

**Descriptive Analysis of Major Study Variables**

The following is a discussion of perceived benefits, perceived barriers, SEICD, SEE, IPEQ-WA and QOL descriptive analyses (Table 9). The discussion includes results of gender and race differences in the mean scores (Table 10 and 11 respectively).

**Perceived Benefits**

The mean scores, SD and Cronbach’s alpha for perceived benefits subscale of the HBQ are presented in Table 9. Perceived benefits related to PA mean score is 3.729 with a SD of 0.80. The benefit with the highest mean was how helpful you think PA is with regard to improving QOL after having an ICD ($M = 4.074 \pm 0.8771$).

**Perceived Barriers**

Perceived barriers mean score was 2.496 ±0.722. There were only five items in the scale and item statistics showed that Cronbach’s alpha was not improved by deleting any items from the scale. The perceived barrier with the highest mean score (3.2469 ± 1.1568) was it’s hard to find the time to participate in physical activity on a regular basis.

**Self-Efficacy Implantable Cardioverter Defibrillator Scale**

The SEICD scale had a mean score of 7.814 ± 1.848. The lowest mean scores occurred with statements of one’s self-confidence to eventually get back to normal activities and work since the ICD was implanted ($M = 6.864$); the ability to resume normal housework, yard work
and other physical activities since the ICD (\(M = 6.666\)); and that they have been able to deal satisfactorily with shocks or other treatments for fast/irregular heart rhythms (\(M = 6.8519\)).

**Self-Efficacy for Exercise**

The SEE scale had a mean score of 4.573 ± 3.205. The SEE items with the highest means included how confident are you right now that you could exercise three times per week for twenty minutes if you had to exercise alone (\(M = 5.235 \pm 4.078\)); and how confident are you right now that you could exercise three times per week for twenty minutes if the weather was bothering you (\(M = 5.161 \pm 4.042\)). The item with the lowest mean was how confident are you right now that you could exercise three times per week for twenty minutes if you felt pain when exercising (\(M = 3.914 \pm 3.762\)). On average Whites (\(M = 4.718 \pm 3.453\)) had higher SEE than AAs (\(M = 4.068 \pm 2.122\)). This difference was significant \(t(45.332) = .980, p < .05\).

**Incidental and Planned Exercise Questionnaire Weekly Average**

The average time the ICD recipient spends each week participating in incidental and planned exercise was 25.708 ± 19.790 hours. That is, on average ICD recipients spent 3.67± 2.83 hours per day engaging in incidental or planned physical activity. The lowest mean score for incidental and planned PA was 0.16204 ± .40622 hours (less than 3 ± 5 minutes per day). The majority of total PA was incidental activity (\(M = 22.921 \pm 18.872\) hours per week). Incidental activities included how many hours in the past three months you spent each day out of the house doing other PA such as house maintenance and gardening (\(M = 1.15 \pm 1.371\)); and in the past three months how many hours did you spend on your feet each day indoors doing tasks like housework, self-care or care for another person (\(M = 1.8611 \pm 1.615\)). Thirty percent of subjects
reported on average they participated in zero planned PA and greater than 75 percent reported less than 20 minutes of planned PA per day over the past three months.

**Quality of Life**

The following are subscales of the SF36® QOL questionnaire. Scoring and internal consistency were analyzed using the licensed, registered scoring software specifically designed for this scale and are included in Table 9.

**Physical Function**

Mean score of the PF subscale was 43.33 ± 28.48. There are ten items in the PF subscale. Response value frequencies show that 62 percent of ICD recipients report their health limits them a lot in vigorous activities such as running, lifting heavy objects, participating in strenuous sports; 48 percent walking more than a mile; and 45 percent climbing several flights of stairs. A majority of subjects (63 percent) report being limited a lot and a third (31 percent) limited a little with moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf. Fifty-seven percent are limited in climbing one flight of stairs and over half (52 percent) were limited in walking one hundred yards. Four percent were limited a lot in bathing or dressing, 24 percent limited a little and 53 percent reported no limitation.

**Role Physical**

Mean score for RP was 52.31 ± 30.64. There are four items in the subscale. The highest response value frequencies include; 41 percent report during the past four weeks as a result of their health had to cut down most or some of the time on work and other activities; 37 percent were limited most or all of time in the kind of work or activities; and 36 percent had difficulty performing work or other activities most or all of the time. African Americans on average scored
lower than Whites on the RP subscale of the QOL questionnaire. This difference was significant \( t(42.112) = 1.002, p < .05. \)

**Bodily Pain**

Mean BP scores were 55.93 ± 28.95. There are two items in this subscale. Response value frequencies include 40 percent reported moderate to very severe pain during the past four weeks and 25 percent report in the past four weeks pain interfered moderately to extremely in normal work (outside and inside the home).

**General Health**

Mean GH scores were 50.63 ± 20.38. There are five items in this subscale. Ten percent of the study population reported their health was poor; 22 percent, fair; and 49 percent, good to very good.

**Vitality**

Mean VT score was 48.15 ± 20.90. This subscale contains four items. Over half of study subjects report feeling worn out or feeling tired some to all of the time during the past four weeks (59 percent and 67 percent respectively).

**Social Function**

Mean SF score was 71.76 ± 26.79. There are two items in this scale. Most subjects reported during the past four weeks their physical health or emotional problems had interfered slightly to not at all (13 percent to 37 percent respectively) with their social activities.

**Role Emotional**

Mean RE score was 73.75 ± 26.79. Three items represent RE. A majority of subjects report during the past four weeks they cut down on the amount of time spent on work or other
activities; accomplishing less than they would like; and performing work or other activities less carefully than usual a little of the time (39 percent, 31 percent and 36 percent respectively).

**Mental Health**

Mean MH score was $71.54 \pm 20.196$. There were five items in the MH subscale. A majority of subjects reported feeling calm and peaceful or happy most of the time in the past four weeks (44 percent and 34 percent respectively).

Table 9

Descriptives and Cronbach’s Alpha for Major Study Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Observed Range</th>
<th>Possible Range</th>
<th>Cronbach’s Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived Benefits Subscale</td>
<td>3.729 (0.801)</td>
<td>1.888-5</td>
<td>0-5</td>
<td>.912</td>
</tr>
<tr>
<td>Perceived Barriers Subscale</td>
<td>2.496 (0.722)</td>
<td>1-4.2</td>
<td>0-5</td>
<td>.690</td>
</tr>
<tr>
<td>Self-Efficacy- Implantable Cardioverter Defibrillator (SE-ICD)</td>
<td>7.814 (1.848)</td>
<td>2.397-10</td>
<td>0-10</td>
<td>.921</td>
</tr>
<tr>
<td>Self-Efficacy for Exercise (SEE)</td>
<td>4.573 (3.205)</td>
<td>0-10</td>
<td>0-10</td>
<td>.934</td>
</tr>
<tr>
<td>Incidental and Planned Exercise Questionnaire-Weekly Average (IPEQ-WA)</td>
<td>25.708 (19.790)</td>
<td>.875-80.50</td>
<td>0-182</td>
<td>.495</td>
</tr>
</tbody>
</table>
SF-36® Quality of Life (QOL)*

- **PF**
  - Mean: 43.335 (28.482)
  - Range: 00-95
  - 0-100: .933

- **RP**
  - Mean: 52.314 (30.641)
  - Range: .00-100
  - 0-100: .945

- **BP**
  - Mean: 55.925 (28.949)
  - Range: .00-100
  - 0-100: .875

- **GH**
  - Mean: 50.629 (20.379)
  - Range: 15-100
  - 0-100: .776

- **VT**
  - Mean: 48.148 (20.905)
  - Range: 0-93.75
  - 0-100: .844

- **SF**
  - Mean: 71.759 (26.793)
  - Range: 0-100
  - 0-100: .802

- **RE**
  - Mean: 73.354 (25.699)
  - Range: 0-100
  - 0-100: .874

- **MH**
  - Mean: 71.543 (20.196)
  - Range: 20-100
  - 0-100: .519

Note: SD=Standard Deviation; *Cronbach’s Alpha calculated using SF-36® Licensed Scoring Software. PF=Physical Functioning; RP=Role Physical; BP=Bodily Pain; GH=General Health; VT=Vitality; SF=Social Functioning; RE=Role Emotional; MH=Mental Health.

### Table 10

**Gender Differences in Questionnaire Scores**

<table>
<thead>
<tr>
<th></th>
<th>Gender</th>
<th>N</th>
<th>Mean</th>
<th>(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Perceived Benefits Total Score</td>
<td>Male</td>
<td>58</td>
<td>3.724130</td>
<td>(.7659127)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>3.743970</td>
<td>(.9023293)</td>
</tr>
<tr>
<td>*Perceived Barriers Total Score</td>
<td>Male</td>
<td>58</td>
<td>2.548276</td>
<td>(.7441565)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>2.365217</td>
<td>(.6596202)</td>
</tr>
<tr>
<td>*Incidental and Planned Exercise</td>
<td>Male</td>
<td>58</td>
<td>28.055388</td>
<td>(20.8149270)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>19.790761</td>
<td>(15.8299020)</td>
</tr>
<tr>
<td>*SEICD Score</td>
<td>Male</td>
<td>58</td>
<td>7.677112</td>
<td>(1.9904743)</td>
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<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>8.160326</td>
<td>(1.4094126)</td>
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<tr>
<td>*Self-Efficacy for Exercise Score</td>
<td>Male</td>
<td>58</td>
<td>4.81995</td>
<td>(3.2735807)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>3.951648</td>
<td>(3.0061381)</td>
</tr>
<tr>
<td>*Physical Functioning</td>
<td>Male</td>
<td>58</td>
<td>46.8969</td>
<td>(28.48253)</td>
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<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>34.3474</td>
<td>(27.02213)</td>
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<tr>
<td>*Role Physical</td>
<td>Male</td>
<td>58</td>
<td>53.2328</td>
<td>(30.80253)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>50.0000</td>
<td>(30.79210)</td>
</tr>
<tr>
<td>*Bodily Pain</td>
<td>Male</td>
<td>58</td>
<td>55.6724</td>
<td>(28.24976)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>56.5652</td>
<td>(31.29453)</td>
</tr>
<tr>
<td>*General Health</td>
<td>Male</td>
<td>58</td>
<td>49.5345</td>
<td>(20.84127)</td>
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<tr>
<td></td>
<td>Female</td>
<td>23</td>
<td>53.3913</td>
<td>(19.33141)</td>
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<tr>
<td>Variables</td>
<td>Race</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
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<td>-----------</td>
<td>-------------------</td>
<td>-----</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Perceived Benefits Total Score</td>
<td>White</td>
<td>63</td>
<td>3.682534</td>
<td>.8191385</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>18</td>
<td>3.895067</td>
<td>.7325492</td>
</tr>
<tr>
<td>Perceived Barriers Total Score</td>
<td>White</td>
<td>63</td>
<td>2.511111</td>
<td>.7550072</td>
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Note: SD = Standard Deviation. *Differences in gender scores by independent t tests not significant, p < .05.

Table 11

Racial Differences in Questionnaire Scores
### Relationships among Major Study Variables and Descriptive Characteristics

The objective of Aim 2 of this study was to examine the relationships between the theoretical study variables (perceived benefits, perceived barriers and self-efficacy beliefs), outcome variables (PA and QOL), ICD type, HF Class and modifying variables (age, gender, race, socioeconomics, religion and knowledge).

Prior to statistical analysis of study variables data were screened for entry errors, missing data, outliers, multicollinearity and normal distribution. (Field, 2005) recommends analyzing skewness, kurtosis, histograms and P-P plots to assess for normally distribution of interval and ratio data. According to Cameron, (2004) if data are normally distributed skewness and kurtosis should fall between a value positive two and negative two. All study variables were normally distributed except for planned PA subscale of the IPEQ-WA which was skewed to the right (3.508) and kurtosis was excessive at (16.647). It was for this reason and subjects’ reports of this section being very difficult (subsequent discussion) that the total PA score was used for data analyses.
Relationships among theoretical variables outcomes (PA-total and QOL) were analyzed using bivariate correlation (Pearson’s Product-Moment Coefficients) (Table 13). Relationships among the modifying factors (age, gender, socio-economics, religion, knowledge, NYHF Class and ICD type) and theoretical variables/outcomes are reported in Table 14. Modifying variables which did not reach a level of statistical significance included gender, NYHA Class and religion ($p > .05$).

Physical activity participation was positively associated with higher levels of self-efficacy related to having an ICD, self-efficacy for exercise and QOL subscales, PF and RP. Higher household incomes were correlated with increased PA participation. Age was inversely correlated with PA participation. That is, as age increased PA participation decreased.

Higher perceived benefits were related to higher SEICD beliefs and overall general health. Perceived benefits were positively correlated with type of ICD which indicates that the more complex the device the higher their perceived benefits. Perceived barriers were also correlated with SEICD scores. This relationship was such that the more barriers the less self-efficacy to deal with issues related to having an ICD. This was also true of all QOL subscales. The more perceived barriers, the lower the QOL scores.

Higher SEICD scores were related to perceived benefits and all QOL scores except physical function. Higher incomes were correlated with higher SEICD scores. In addition to association with higher levels of PA participation, higher SEE was also positively correlated with overall QOL (all subscales) and higher income levels. The presence of atrial fibrillation was negatively associated with PA participation ($r = -.222, p < .05$); that is, subjects with atrial fibrillation participated in PA less than those who were not diagnosed with atrial fibrillation.
Mediation Analyses

Aim three was to test PA participation as a mediator between health beliefs (perceived benefits, perceived barriers and self-efficacy) and quality of life. Mediation analyses tests if there is a means through which belief affects QOL. Results from correlational analyses suggest PA may have a mediating effect on the relationship between SEE beliefs and two QOL subscales (physical function and role performance). In addition, PA participation may have a mediating effect on the relationship between SEICD beliefs and QOL subscale, role performance. Three separate regression analyses were done to test for the mediator effect for, (a) SEE and PF, (b) SEE and RP, and (c) SEICD and RP. Each analysis requires three equations to test for mediation using the Baron and Kenny procedures (Baron and Kenny, 1986, p. 1177). Figure 3 depicts the model guiding each of the three tests of mediation. Table 14 presents the regression equation steps for SEE and PF (the only test where mediation was found).

The first mediation analysis was to test if PA acts as a mediator between SEE and the QOL subscale, physical function. Step one results indicate the independent variable (IV) SEE is a significant predictor of PA participation $\beta = .481, p = .001$. The second step results demonstrate the IV, SEE as a significant predictor of physical function $\beta = .568, p = .000$. The third step of mediation analysis contains the IV, SEE and mediator variable (PA participation) entered simultaneously with the DV (physical function). The results indicate PA participation significantly predicts physical function $\beta = .264, p = .011$. With the mediator (PA participation) added to the equation $\beta$ value for SEE changed from .568 to .440 indicating a small reduction in the relationship between SEE and physical function.
Table 12

Significant Theoretical and Outcome Variable Relationships

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Note: PAQ = Incidental and Planned Physical Activity Questionnaire; Ben = Benefits; Bar = Barriers; SE1 = Self-Efficacy after Implantable Cardioverter Defibrillator; SEE = Self Efficacy for Exercise; PF = Physical Performance; RP = Role Performance; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Function; RE = Role Emotional; MH = Mental Health; ICD = Type of Implantable Cardioverter Defibrillator; HF = New York Heart Association Heart Failure Class.

*Correlation is significant at the 0.05 level (2-tailed). $\times$Correlation is significant at the 0.01 level (2-tailed).
Table 13

Correlation Coefficients for Modifying Variables

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Note: IPEQ-WA= Incidental and Planned Exercise Questionnaire-Weekly Average; SEICD= Self-Efficacy ICD Scale; SEE= Self-Efficacy for Exercise; PF= Physical Function; RP= Role Physical; BP= Bodily Pain; GH= General Health; VT= Vitality; SF= Social Function; RE= Role Emotional; MH= Mental Health; Knowledge Question = Do you feel you have enough information to safely participate in physical activity? Social Question = Do you have someone you can call if you need help? ICD Type = Single Chamber, Dual Chamber or Biventricular. **rpb** = point-biserial correlation. * Correlation is significant at the 0.05 level (2-tail). ** Correlation is significant at the 0.01 level (2-tail).
The last equation coefficient for SEE was significant \((p < .05)\) indicating a partial mediating effect of PA participation on the relationship between SEE and the QOL subscale, physical function. An insignificant equation coefficient for SEE in the last step of the mediation analysis would indicate PA has a significant mediating effect between SEE and physical function (Baron and Kenny, 1986).

The second mediation analysis was to test if PA acts as a mediator between SEE and role physical. Step one results are the same as the first mediation analysis (SEE is a significant predictor of PA, \(\beta = .481, p = .001\)). Second step results indicate SEE is a significant predictor of the QOL subscale, RP, \(\beta = .346, p = .002\). The third step results indicate PA is not a significant predictor of role physical \(\beta = .127, p = .296\). The IV, SEE remained a significant predictor of role physical \(\beta = .285, p = .020\). The final regression violates an assumption of the mediation model which requires the mediator (PA) to cause a significant effect in the outcome variable (RP). Thus, according to Baron and Kenny (1986), PA participation does not act as a mediator between SEE and RP.

The third mediation analysis was to test if PA acts as a mediator between SEICD and RP. The first step equation results indicate the IV (SEICD) is a significant predictor of PA participation \(\beta = .244, p = .028\). The second step results indicate SEICD is a significant predictor of role physical \(\beta = .268, p = .015\). The third step results indicate PA participation does not significantly predict the outcome variable (RP) \(\beta = .211, p = .059\); and, IV (SEICD) is not a significant predictor of role physical \(\beta = .217, p = .052\). Thus, the final analysis indicates that PA participation does not mediate the relationship between SEICD and role physical.
Table 14

**Mediating Effect of Physical Activity on Self-Efficacy for Exercise and Physical Function**

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<td>• Regress DV (PF) on Mediator (PA) and IV (SEE).</td>
<td>PA=.380</td>
<td>.147</td>
<td>.264</td>
</tr>
<tr>
<td></td>
<td>SEE= 3.914</td>
<td>.906</td>
<td>.440</td>
</tr>
</tbody>
</table>

Note: Step One $R^2 = .231, p = .001$; Step Two $R^2 = .322, p = .000$; Step Three $R^2 = .376, p = .011$. PA = physical activity; IV = independent variable; DV = Dependent Variable; SEE = Self-Efficacy for Exercise; PF = Physical Function.

**Figure 2. Mediation Model.**
Implant Indication Comparison

Aim four of this study was to determine if there were any differences in health beliefs and PA participation between ICD recipients who were implanted for primary or secondary prevention of sudden cardiac death. The Mann-Whitney U test is a nonparametric analysis used to test for differences in continuous measures between two independent groups. It is the alternative to parametric t-test which could not be used with these two groups as they are not normally distributed (skewness and kurtosis > 2.0). The frequency of ICD implants for primary indication was 86.4 percent (N=70) and secondary indication was 13.6 percent (N=11). Results of the Mann-Whitney U test are presented in Figure 3, 4, 5, 6 and 7.

Mann-Whitney U Test compares median scores instead of comparing mean scores of the questionnaires. The median scores on the questionnaires are converted to ranks and compared across the two groups to determine if the groups differ significantly. Z scores are reported in the analysis thus allowing for calculation of effect size using the formula \( r = Z / \text{square root of } N \) (Field, 2009).

The Mann-Whitney U Test revealed no significant differences in the PA participation levels of subjects implanted for primary prevention (N=70) and subjects implanted for secondary prevention (N=11), Grand Median (Md) = 22.875, U = 294, \( z = -1.255 \), \( p = .605 \), \( r = -.14 \).

There was no significant differences in perceived benefits in primary prevention (N=70) and secondary prevention (N=11), Grand Md = 4.000, U = 307.5, \( z = -1.071 \), \( p = .775 \), \( r = -.12 \); no significant difference in perceived barriers, Grand Md = 2.600, U = 334.5, \( z = -.699 \), \( p = .636 \), \( r = -.08 \); no significant difference in SEE scores, Grand Md = 4.222, U = 358, \( z = -.373 \), \( p = .965 \),
$r = -.04$; and no significant difference in SE-ICD scores, $Grand \ Md = 8.125$, $U = 428.5$, $z = .600$, $p = .435$, $r .07$.

Figure 3. Mann-Whitney U Test: Primary vs. Secondary and Physical Activity Participation Scores.
Figure 4. Mann-Whitney U Test: Self-Efficacy for Exercise.

Figure 5. Mann-Whitney U Test: Self-Efficacy ICD Scores
Figure 6. Mann-Whitney U Test: Perceived Benefits.

Figure 7. Mann-Whitney U Test: Perceived Barriers.

1. Multiple comparisons are not performed because the overall test does not show significant differences across samples.
Predictors of Physical Activity Participation

The fifth aim of this research was to predict PA participation using health belief constructs and modifying variables while controlling for severity of heart disease (NYHA HF Class) and type of ICD (single chamber, dual chamber or bi-ventricular). Multiple linear regression analyses were conducted to explore possible predictors of PA participation in ICD recipients.

In the first regression analysis HBM constructs and modifying variables (age and income) were simultaneously entered to explore possible contributions they may have on PA participation while controlling for NYHA Class and type of ICD (entered in first step)(Table 15).

The second linear regression analysis excluded variables not significantly contributing to the first analysis (perceived barriers, perceived benefits and income) while continuing to control for NYHA Class and type of ICD implanted. NYHA Class and ICD type were entered in the first step of the analysis. The remaining variables (SEE, SEICD and Age) were entered in the second step. The results of the second analysis are listed in Table 16. Statistical diagnostics were analyzed with each of the regression analyses. Multicollinearity (two or more variables are closely linearly related) was assessed by examining the correlation coefficients in the output. None of the correlation coefficients were strongly correlated. Tolerance and VIF statistics were very close to one for all factors which indicates collinearity is not an issue. Cook’s distance which is a measure of the overall influence of a case on the model was less than one. Any values greater than one would suggest the regression model is biased by influential cases making the model unstable. The Durbin-Watson analysis (analyzes adjacent residuals for relatedness) result was 1.759 in the first analysis and 1.731 in the second. Values less than 2.0 indicate a positive
correlation. Values less than one or over three indicates that the residuals in the model are not independent (Field, 2009).

Table 15

**Exploring Possible Predictors of Physical Activity Participation in ICD Recipients**

<table>
<thead>
<tr>
<th>Coefficients * DV = Incidental and Planned Exercise Questionnaire-Weekly Average</th>
<th>b</th>
<th>SE</th>
<th>β</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step One</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>46.311*</td>
<td>18.827</td>
<td>-.177</td>
<td>2.460</td>
</tr>
<tr>
<td>NYHA Class</td>
<td>-5.651</td>
<td>3.403</td>
<td>-.177</td>
<td>-1.661</td>
</tr>
<tr>
<td>ICD Type</td>
<td>2.678</td>
<td>3.091</td>
<td>-.092</td>
<td>.866</td>
</tr>
<tr>
<td><strong>Step Two</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Benefits</td>
<td>-4.039</td>
<td>3.015</td>
<td>-.162</td>
<td>-1.340</td>
</tr>
<tr>
<td>Perceived Barriers</td>
<td>-1.248</td>
<td>2.843</td>
<td>-.046</td>
<td>-.439</td>
</tr>
<tr>
<td>SEICD</td>
<td>2.888</td>
<td>1.344</td>
<td>.267*</td>
<td>2.149</td>
</tr>
<tr>
<td>SEE</td>
<td>2.317</td>
<td>.699</td>
<td>.362**</td>
<td>3.312</td>
</tr>
<tr>
<td>Age</td>
<td>-.465</td>
<td>.184</td>
<td>-.270*</td>
<td>-2.525</td>
</tr>
<tr>
<td>Income</td>
<td>1.310</td>
<td>1.209</td>
<td>.119</td>
<td>1.083</td>
</tr>
</tbody>
</table>

Note: Model Coefficients and Summary. * Indicates p < .05; ** Indicates p < .01

Model Summary

<table>
<thead>
<tr>
<th>Variable</th>
<th>$R^2$</th>
<th>$F$ Change</th>
<th>Degree of Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA &amp; ICD Type</td>
<td>.030</td>
<td>1.080</td>
<td>2.70</td>
</tr>
<tr>
<td>Perceived Benefits</td>
<td>.033</td>
<td>.224</td>
<td>1.69</td>
</tr>
<tr>
<td>Perceived Barriers</td>
<td>.073</td>
<td>2.940</td>
<td>1.68</td>
</tr>
<tr>
<td>SEICD</td>
<td>.139*</td>
<td>5.099</td>
<td>1.67</td>
</tr>
<tr>
<td>SEE</td>
<td>.324**</td>
<td>18.093</td>
<td>1.66</td>
</tr>
<tr>
<td>Age</td>
<td>.387*</td>
<td>6.681</td>
<td>1.65</td>
</tr>
<tr>
<td>Income</td>
<td>.398</td>
<td>1.173</td>
<td>1.64</td>
</tr>
</tbody>
</table>

Note: NYHA = New York Heart Association; ICD = Implantable Cardioverter Defibrillator; SEICD = Self-Efficacy ICD; SEE = Self-Efficacy for Exercise. * Indicates p < .05; ** Indicates p < .01
Table 16

Predictors of Physical Activity Participation in ICD Recipients

Coefficients * DV = Incidental and Planned Exercise Questionnaire-Weekly Average

<table>
<thead>
<tr>
<th>Step One</th>
<th>b</th>
<th>SE</th>
<th>β</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>37.368</td>
<td>15.880</td>
<td>2.353</td>
<td></td>
</tr>
<tr>
<td>NYHA Class</td>
<td>-6.373</td>
<td>3.190</td>
<td>-.198*</td>
<td>-1.998</td>
</tr>
<tr>
<td>ICD Type</td>
<td>.405</td>
<td>2.847</td>
<td>.014</td>
<td>.142</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step Two</th>
<th>b</th>
<th>SE</th>
<th>β</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEE</td>
<td>2.407</td>
<td>.616</td>
<td>.390**</td>
<td>3.911</td>
</tr>
<tr>
<td>SEICD</td>
<td>2.304</td>
<td>1.072</td>
<td>.215*</td>
<td>2.149</td>
</tr>
<tr>
<td>Age</td>
<td>-.394</td>
<td>.173</td>
<td>-.234**</td>
<td>-2.277</td>
</tr>
</tbody>
</table>

Note: Model Coefficients and Summary. b = Unstandardized Coefficient; SE= Standard Error; SEE = Self-Efficacy for Exercise; SEICD= Self-Efficacy after Implantable Cardioverter Defibrillator. * Indicates p < .05; ** Indicates p < .01

Model Summary

<table>
<thead>
<tr>
<th>Variable</th>
<th>R²</th>
<th>F Change</th>
<th>Degree of Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class &amp; ICD Type</td>
<td>.029</td>
<td>1.170</td>
<td>2.78</td>
</tr>
<tr>
<td>SEE</td>
<td>.257**</td>
<td>23.564</td>
<td>1.77</td>
</tr>
<tr>
<td>SEICD</td>
<td>.282</td>
<td>2.657</td>
<td>1.76</td>
</tr>
<tr>
<td>Age</td>
<td>.328*</td>
<td>5.186</td>
<td>1.75</td>
</tr>
</tbody>
</table>

Note: ∆ R² = .029 for Step One; ∆ R² for SEE = .227; ∆ R² for SEICD = .025; ∆ R² for Age = .046. * Indicates p < .05; ** Indicates p < .01

Results from each linear regression analyses indicate while controlling for type of ICD and NYHA Class, SEE is the strongest significant predictor of PA participation. In the final regression analysis (Table 16) SEE accounts for 22.7 percent of variance in PA participation. Age accounts for 4.6 percent and SEICD, 2.5 percent (although not statistically significant p > .05). Overall almost 33 percent of the variance in PA participation can be explained by Type of
ICD/NYHA Class, SEE, SEICD and age. The coefficient results (Table 16) indicate on average with each point increase in SEE scores there is a 0.390 point increase in PA participation scores; each point increase in SEICD scores there is a 0.215 increase in PA; and for each year a person ages, a 0.234 decrease in PA participation scores. Also with each increase in NYHA Class there is a subsequent decrease in PA participation score by 0.198 (p < .05 for each).
CHAPTER V: DISCUSSION

Discussion of study findings and conclusion of study results will be presented in this chapter. Initial discussions will focus on the sample characteristics followed by discussion of major study variables, mediation findings, differences in primary and secondary prevention and predictors of PA participation. Remaining discussion includes study limitations, implications for nursing practice, use of the HBM and future research.

Characteristics of the Sample

ICD recipients who took part in this study had characteristics representative of the national ICD population. The sample in this study was a little older ($M = 70.23 \pm 11.76$ years compared to $67.3 \pm 13$ years). Of course the sample was individuals who had been living with an ICD for an average of almost six years. The national ICD registry population consists of new implants. Mean age at implant in this study was $64.59 \pm 11.672$ years which is slightly younger than the national average. The most frequent age of this study sample was sixty-eight years; over half of the sample was over seventy years; and nearly 25 percent were over eighty years of age.

Over 75 percent of the sample reported living in a small town or rural farming areas. The sample recruited were mainly from rural clinics ($N=63$). Rurality of the sample is important to consider when there may be access issues with regards to exercise facilities; especially those catering to the needs of elderly clients with heart disease and other co-morbidities. In fact, one subject stated that she did not have a place to exercise. She stated that even if there was such a place, she did not have transportation. In each of the rural areas there was a rural health center affiliated with the small hospitals. The centers had rehabilitation and exercise facilities. One of the health centers had a free senior walking program. This program allowed free access every
day at noon to a climate controlled, indoor track. Two of the subjects stated they met a group of seniors from their church at least two to three times a week to walk around the track. They said they felt reassured knowing that there were nurses available to check their blood pressure or help them if they had a fast heart beat. Many subjects participating in this study stated they did not know there was a rural health center with exercise programs. When asked if they thought they would use these centers for exercise subjects stated they would and would feel safer due to health professionals being present in the facility. Cost of exercise facilities is another important consideration, especially when most of the subjects were retired/disabled (72 percent) and reported incomes less than 30,000 dollars/year (70 percent).

Racial characteristics were different from the ICD registry in that the only two races represented in this study were white, non-Hispanics (77.8 percent) and African Americans (22.2 percent). According to North Carolina population health facts the majority of people living in the state are white, non-Hispanic and AA (65.8 percent and 22 percent respectively) (North Carolina DHHS, 2012). Hispanic patients that were seen in the clinic during the recruitment time (N=6) were unable to read, write or speak English.

**Social Support, Knowledge and Medical Characteristics**

Social support characteristics were good for the ICD sample. Most reported they had someone to call for assistance and had someone to encourage them to exercise. ICD support group attendance was extremely low to absent in the study sample. Most had never attended and over 25 percent did not know there was an ICD support group. Of course this could be explained by the rurality of the majority of the sample. The only ICD support group available to this study population meets once a month in a large city (over an hour drive from each of the rural clinic
locations). Social support is an important factor that can influence quality of life in ICD recipients (Carroll and Hamilton, 2008). ICD support groups are venues in which ICD patients can share concerns and help one another cope with different facets of living with an ICD. Research over the years (although few) on ICD support groups have mixed results; that is, some say they are effective at improving QOL and others not. One suggestion to help improve the effectiveness of support groups is that they be facilitated by healthcare professionals and meetings be structured with psychoeducational sessions with the aim of improving knowledge, coping skills and QOL in ICD recipients (Sears and Conti, 2002). Support groups could also be structured to provide cues to action (PA education, prevention education, etc.) from health care professionals. Cues to action, a construct of the HBM not measured in this study, are strategies such as informational sessions that promote awareness or provide how-to instructions which may be useful in increasing PA engagement (Champion and Skinner, 2008).

Knowledge of the ICD related to PA was assessed with three questions. Most of the sample stated the healthcare professionals had provided instructions on PA restrictions. Most felt that they had enough information to safely engage in physical activities. However, almost 90 percent were unaware of their device settings. That is, what their tachycardia treatment rates were. How fast could they safely get their heart rate while exercising? One subject stated “I just don’t want to get my heart rate so fast that I get shocked so I just don’t really do too much”. Another, “I want to know all I can about my device so I can be safe. I did not even consider this. This will help me know if I am doing too much at work or the gym”. It is the opinion of the researcher that in most instances these individuals may not be able to attain their tachycardia detection rates during physical activity because of the cardiac medications (beta-blockers and/or
other heart rate lowering medications). Implantable cardioverter defibrillators have sophisticated detection algorithms which discriminate true arrhythmias versus sinus tachycardia (Hayes and Friedman, 2008). Being aware of this information and providing a means (heart rate monitor) of tracking the heart rate may allow the individual more confidence to participate in physical activity. Knowledge of how the ICD works may allow more confidence; alleviate any misconceptions that may be barriers to engaging in PA; thus, improving levels of PA participation.

It is not enough to tell a patient they need to be more physically active. They need instructions on what types of PA are safe and other ways to be physically active when exercise facilities are not available. Time restrictions on visits to the ICD clinic don’t allow for such explanations. One subject, while expressing their desire to go back to the gym and work out as they did prior to the ICD being implanted stated “I have not worked out for over three years because I don’t know what I can do. I know what I can’t do which is lift heavy weights so I don’t hurt my defibrillator.” Instructions for physical activities take time and need be individually tailored to the physical capabilities and medical restrictions of each patient.

Medical characteristics of this sample were consistent with the ICD registry. Primary prevention implants were higher in this cohort (86 percent compared to 74 percent). This is important to consider especially for those individuals who have experienced sudden death versus those who have not. The effects of surviving sudden cardiac death and receiving an ICD include changes in physical, social and psychological function especially during the first year (Dougherty and Thompson, 2012). Most of the sample who were implanted for secondary prevention had their devices in for 11.09 ± 4.4 years. Research indicates that over the period of a
year ICD recipients adjust to living with their defibrillator (Carroll and Hamilton, 2008). This is most likely the case as there were no significant differences in primary and secondary prevention study participants which will be discussed later.

The co-morbidities that ICD recipients most often are diagnosed may confound the results of PA participation. Worsening heart disease and cardiac function associated with HF is known to decrease physical function over time (Duncan, Pozehl, Norman and Hertzog, 2009). Almost 93 percent of this sample had NYHA class II-IV which is associated with diminished capacity for physical exertion. Decreases in pulmonary function for those diagnosed with COPD and emphysema can greatly diminish physical activities (DePew, Garofoli, Novotny and Benzo, 2012). The sequelae associated with diabetes (neuropathies) and PVD (diminished blood flow to extremities) may diminish physical function (Abbatecola, et al., 2012; Calderaro-Bentley and Andrews, 2013). Residual weakness and/or balance issues associated with stroke decreases PA participation (Schmid, et al., 2012). The presence of atrial fibrillation serves as an additional risk factor for decreasing PA participation (Mozaffarian, Furberg, Psaty and Siscovick, 2008). Atrial fibrillation was present in 54.3 percent of the study sample and was correlated with lower PA participation.

A finding that bears mentioning was the difference in self-reported conditions and actual diagnoses. Although this was not an objective of this study and is beyond the scope of this discussion it has implications for future inquiry.

Analysis of Major Study Variables

A major finding in this study was that there were no relationships between two of the HBM variables (perceived benefits and perceived barriers) and PA participation. There was a
significant relationship between self-efficacy beliefs and PA participation. Each of the HBM variables was associated with QOL subscales. The subsequent discussion will focus on findings specific to major study variables and aims of this study.

**Perceived Benefits**

Perceived benefits scores of the study population indicate they understood physical exercise as being beneficial to a person with heart disease. The question with the highest score indicated the benefits PA has on QOL after an ICD. Perceived benefits were not significantly related to PA participation in this sample which is similar to the findings of Al-Ali and Haddad (2004) except in this sample the scores on the questionnaire indicated an understanding of the benefits of exercise. In their research on PA participation in Jordanian MI patients Al-Ali and Haddad (2004) concluded results indicated a lack of knowledge of benefits. Overall, PA participation was low in this study which despite not reaching statistical significance, is similar to the inverse relationship between benefits and PA participation that Mirotznik, Feldman and Stein (1995) found in their study looking at exercise attendance in a community based heart disease exercise program. They found that despite the high knowledge of the benefits of exercise in preventing heart disease exercise participation levels were lower than those who did not have high levels of perceived benefits. Their results were significant. Most of the patients in their study did not have heart disease. According to Shanks (2009) the HBQ questions may not be appropriate for predicting health behavior in patients with heart disease.

Understanding the benefits of taking part in a healthy behavior in context of heart disease may not be enough to motivate this population to be physically active. Understanding the benefits of PA in patients living with ICDs may hold more promise in motivating behavior.
ICD recipients in this study were older, lived in areas with low access to physical activity facilities and often had multiple other chronic illnesses. The HBQ may not have been appropriate for this population. Beliefs in the face of other formidable obstacles are often not enough to be successful in healthy behavior adoption without some intervening variable.

**Perceived Barriers**

Mean scores of perceived barriers indicate the study population perceived relatively few barriers to participation in physical activity. The barrier with the highest score involved cost in the context of time to be physically active on a regular basis. The questionnaire did not score well with regards to internal consistency. Perceived barriers did not significantly affect PA participation. The five perceived barrier questions likely were not adequate to address the barriers that might impact an ICD recipient’s willingness to increase physical activity. Perceived barriers might be perceived limitations related to the device. For example, one subject stated “I don’t get on those exercise machines because they might interfere with my defibrillator.” And another refused to walk on a treadmill because he was afraid the electronics would cause his defibrillator to “miss-fire”. Although the exercise equipment will not affect the device, this perceived barrier is real to the ICD recipient and begs to be addressed with education (Hayes and Friedman, 2008). Another barrier to ICD recipients is device malfunction. Many of the subjects in this study indicated they had a device or component of their device that was under advisory for possible malfunction. Malfunction as a perceived barrier to PA participation is a barrier that can be addressed with education. Understanding the barriers to PA participation that are applicable to the ICD recipient is one key component in developing strategies to overcome them.
This study was focused on total physical activity participation in ICD recipients. When exploring possible relationships with planned PA, perceived barriers were significantly correlated with planned PA \( (r_s = -.339, p < .01) \) which indicates that higher perceived barriers are related to lower planned physical activities; however, these results should be viewed with caution due to problems with the subscale (subject confusion, distribution issues and low internal consistency scores).

**Self-Efficacy**

Both SEICD and SEE were significantly related to PA participation. The SEICD scores indicated that most of the ICD recipients in the study felt confident in dealing with issues related to living with a defibrillator. Mean scores of the SEE indicate a low-level confidence in PA participation. The influence of self-efficacy beliefs after ICD and SEE significantly affected PA participation. The correlation for SEICD was not as strong as SEE; however, both results serve to validate the importance of self-efficacy beliefs (even at low levels) in healthy behavior adoption. Both the SEICD and SEE results are consistent with results by Allison and Keller (1999), Blanchard et al., (2006), Oka, Gortner, Stotts and Haskell (1996) and Sol, van der Graaf, van Petersen and Visseren (2011). Their research indicates that in cardiac patients higher self-efficacy beliefs are significantly correlated with increased levels of PA participation and adherence.

The lowest scoring item in the SEICD scale was related to dealing with shocks or other treatments for fast/irregular heart rhythms. The lower scoring items in the SEICD scale reflect the difference in the population answering the questionnaire than for which it was designed. The scale was first designed for patients who had survived sudden cardiac death and received an ICD.
for secondary prevention (Dougherty, Johnston and Thompson, 2007). Over 80 percent of this study population was for primary prevention, thus they did not experience sudden death so may have been uncertain how to answer questions related to having confidence to deal with shock from the defibrillator or irregular heart rhythms requiring treatment. Over 68 percent have never received a shock from their ICD.

Despite the SEE and SEICD scores being significantly correlated with IPEQ-WA total scores PA participation was still low. With incidental activity (activities of daily living, returning to work, chores around the house and going to the store) both SEE and SEICD were significantly correlated ($p < .05$). Most ICD recipients taking part in this study have lived with their devices for longer than five years which has allowed them time to gain confidence in living with an ICD to return to normal activities. This is most reflected in the high SEICD scores.

The focus of this study was total PA participation which will be discussed in the subsequent section on PA participation scores.

**Physical Activity Participation**

Physical activity participation in this ICD population on average was well below the American Heart Association (AHA) Physical Activity guidelines for adults. The AHA recommends at least thirty minutes of moderate intensity aerobic activity at least five days a week for a total of 150 minutes per week (AHA, 2013). The average score for this sample consisted of incidental and planned PA which was a mean of twenty-six hours per week or approximately four hours a day. When subtracting time for sleep (eight hours), individuals on average may be spending approximately twelve hours a day being inactive. Planned aerobic physical activity scores were very low with a mean of 2.7 hours per week (less than 20 minutes a
day) and mode of zero; that is, most frequently subjects reported zero planned aerobic activity. This means that most ICD recipients do not meet AHA recommendations for moderate intensity aerobic activity. Most of the ICD recipients in this study indicated their level of PA had remained the same since their ICD was implanted. This leads the researcher to believe that most were not physically active prior to ICD implantation. An adult’s previous PA behavior is associated with PA participation as an older adult (Hall, et al., 2011). One third of subjects reported their physical activity has decreased since ICD implantation. This fact could be confounded by increasing age, disease burden (worsening HF and/or pulmonary disease) and access to physical activity sites. The symptoms associated with HF have an overwhelming impact on a patient’s ability to participate in even low to moderate physical activity (Tung, Jan, Lin, Chen and Huang, 2012).

Age is another factor in PA participation. Research has shown that as patients age they tend to exercise less especially when dealing with chronic illnesses (Chen, 2009). Age was significantly correlated with PA in this study. The relationship was such that the older the patient the lower the PA participation. This is similar to results in research conducted to determine the effects of age on quality of life in ICD recipients. Results indicated the elderly ICD recipient was less physically active and had lower physical function (Hamilton and Carroll, 2004).

The scale used for this study did not have a good Cronbach’s alpha (.410-.495). This may be due to the confusion about the first section of the questionnaire (planned PA). This section asked if in the past three months, how much time they spent on the following aerobic activities. Most subjects left this section blank. When the researcher called to inquire and offer
assistance the subjects stated “I just did not understand what to put in these blanks” or “I don’t do any of those things so I left it blank”. Most overlooked the sentence instructing them to select “never” and move on to question five. Because of the confusion with this section, low internal consistency score and uneven distribution, the planned PA subscale was not considered for further exploration in this population. The findings in this research indicate the IPEQ-WA may not be a valid tool to measure PA participation in adults with ICDs. Findings further validate the need for research/interventions aimed at investigating and increasing planned PA levels in the ICD population.

Quality of Life

The SF36® QOL questionnaire was administered for the ICD recipient to answer in the context of living with their ICD and physical activity participation. Quality of life in ICD recipients is an important outcome which has been assessed in previous research (although using different QOL surveys with mixed results). Findings from research indicates QOL is diminished in the first six months to a year after ICD implantation but then is thought to return to normal or better levels after one year (Dickerson, Kennedy, Wu, Underhill and Othman, 2010; Sears, Todaro, Lewis, Sotile and Conti, 1999). Other study results indicate QOL measures are affected temporally; that is, the longer the individual has the ICD, the poorer their QOL, specifically physical functioning, role physical and social functioning (Friedman, et al., 2006). One study concluded QOL measures increase after living with an ICD for four years. There were two exceptions to the increase; physical function and role physical (Carroll and Hamilton, 2008).

Overall measures in this study indicate QOL scores were on average lower than the general population across all subscales. The lowest subscales in this sample were physical
function, role physical, bodily pain and general health. Social functioning, vitality, role emotional and mental health scores were at or slightly below the general norm. These results are consistent with other studies measuring QOL in ICD recipients. The lower scores in physical function, role physical, bodily pain and general health are thought to be a result of continued progression of heart disease (worsening HF, e.g.), other disease processes and lack of PA participation (Carroll and Hamilton, 2008). PA participation scores were significantly correlated with physical function and role physical in subjects participating in this study.

There is substantial evidence of the significant positive effect PA participation has on QOL in adults. In fact, a systematic review of research investigating the effects of PA on QOL indicates there are consistent positive associations between PA levels and QOL (Bize, Johnson and Platkinoff, 2007). One might infer that if PA is low then associations might be either negatively associated or not associated at all. The PA participation levels in this study were low which may explain why PA participation scores were not correlated with all or most of the QOL subscales in this study.

Theoretical variables in this study were significantly correlated with many of the QOL subscales, which may indicate the power of one’s beliefs on perceived quality of life. The variables that significantly correlated with most all QOL subscales were perceived barriers, SEE and SEICD beliefs. Perceived barriers were significantly negatively correlated with all QOL subscales ($p < .001$), which means as barrier scores were higher (indicating more perceived barriers) QOL scores were significantly lower. As previously stated, barriers to PA participation specific to ICD recipients need to be considered. Fear and uncertainty related to physical activity participation is common in ICD recipients and has been correlated with decreased activity and
QOL (Dickerson, Kennedy, Wu, Underhill and Othman, 2010; van Ittersum, et al., 2003; Groeneveld, Matta, Suh, Yang and Shea, 2007).

Self-Efficacy for exercise and Self-Efficacy beliefs after having an ICD were significantly correlated with most QOL subscales. Having confidence to take part in healthy behaviors has been shown to improve physical activity participation in cardiac patients. Enhanced self-efficacy is thought to improve physical and mental health function and is considered a factor in adapting to multiple chronic illnesses (Warner, Schwarzer, Schuz, Wurm and Tesch-Romer, 2011). Based on this study’s results indicating the affects of self-efficacy beliefs and perceived barriers on QOL, designing interventions tailored to address PA barriers specific to this population while simultaneously fostering self-efficacy for PA may significantly improve QOL.

**Mediation**

Mediation analyses indicate partial mediation between SEE and PA participation which produces the outcome, physical function. Perfect mediation, which is met when the IV (SEE) has no effect when the mediator (PA) is controlled, was not present in this analysis. However, perfect mediation may not be attainable when measuring self-report or psychological measures due to the presence of measurement error. The internal consistency of the IPEQ-WA was low, indicating it may not be measuring what it is intended to measure; physical activity participation. Subjects participating in this study expressed some confusion with the instrument which may have altered the results. And, as with any self-report instrument, there may be under or over reporting. Measurement error may also cause overestimation of the effect of the IV (SEE) on the
outcome (physical function) which may in turn cause other possible mediators to be disregarded (Baron and Kenny, 1986).

The results of this study indicate the power of a person’s beliefs in helping them engage in PA. Perceived beliefs were also significantly correlated with quality of life measures. Physical activity participation was low in this study which may have affected its mediating role. The ICD recipients in this study had many other conditions that may have affected their self-report of physical function and other QOL subscales. Results from a study to determine if disease specific symptoms in older adults mediate relationships between medical conditions and self-reported physical function, indicate pain and fatigue are strongly associated with lower levels of self-reported physical function (Bennett, Stewart, Kayser-Jones and Glaser, 2002). Therefore it is important to consider disease specific symptoms (fatigue, dyspnea, angina and other pain) that may be mediating the relationship between beliefs and QOL in this study population.

**Implant Indication**

Most of the subjects in this study were implanted for primary prevention of sudden cardiac death. The eleven who were implanted for secondary prevention on average had their ICDs longer than their counterparts ($M = 11.10 \pm 4.4$ years compared to $M = 4.79 \pm 2.6$ years). The objective for aim four was to determine if there were any differences in health beliefs and PA participation. In addition, differences were assessed in QOL scores between these two groups. There were no significant differences in perceived health beliefs, PA participation or QOL scores. This is the first study to measure differences in PA participation and health beliefs in primary versus secondary prevention ICD recipients.
Results indicate there are no significant differences in QOL scores which are consistent with prior research measuring QOL among primary and secondary prevention ICD recipients (Dunbar, et al., 2012). One such study, conducted by Groeneveld, Matta, Suh, Yang and Shea, (2007), had different frequencies of primary and secondary prevention patients. They had 45 primary and 75 secondary prevention patients. Most likely this was due to the year (2006) they recruited for their study. Implantation of an ICD for primary prevention was not approved by the Centers for Medicare and Medicaid Services (CMS) until the end of January, 2005 (CMS, 2005). In addition to their findings regarding QOL, there were no significant differences in clinical comorbidity or number of prescription medications taken. Important, significant similarities between primary and secondary prevention ICD recipients were concerns about physical activities such as lifting, driving and sexual activity (p.463). An important aspect of these similar concerns was that time living with the device did not alter their concerns. That is, concerns were similar in newly implanted ICD recipients and those who had lived with their ICD for years. Concerns were measured using two survey instruments specifically designed to measure fears/concerns of ICD recipients. Unfortunately concerns were not measured in this study population. Both groups (primary and secondary) scored low on PA participation, thus one could postulate there may be the same physical activity concerns in this study sample.

Predictors of Physical Activity Participation

The results of regression analyses indicating self-efficacy for exercise is the most significant predictor of physical activity in this population further validates the preponderance of studies which have similar findings in adult populations with and without heart disease. In fact, in patients with HF self-efficacy beliefs were found to be the most significant predictor of
physical activity levels and physical functioning. Self-efficacy was more predictive than physical measures (fitness levels and ratings of perceived exertion) (Oka, Gortner, Stotts and Haskell, 1997). In research to determine PA participation in stroke patients results indicate self-efficacy factors (balance self-efficacy) was independently correlated with activity and participation; even more so than physical components of gait (Schmid et al., 2012).

Self-efficacy-ICD may not have been as strong a predictor of PA as it is not a measure of PA participation; that is, it is a measure of self-confidence in facing situations common to ICD recipients (Dougherty, Johnston and Thompson, 2007). Age has been well documented in the literature to be a predictor of physical activity levels/functional status in adults (Chen, 2010), so it was not a surprise to find age as a predictor of PA participation in this study population.

Type of ICD implanted and NYHA class were not significantly correlated with PA participation scores. Type of ICD was not predictive of PA participation; however, NYHA class was. Moving from one lower NYHA class to a higher class (I-II, II-III, III-IV, e.g.) indicates worsening cardiac function which translates to increased symptom burden and decreased physical activity (HFSA, 2011).

Perceived benefits, perceived barriers and income were not significant predictors of total PA participation in this ICD population. Benefits and barrier beliefs were not significantly correlated with PA participation and results from various studies are mixed with regards to their ability to predict PA participation as seen in previous (p. 28) discussion. Income was significantly correlated with PA participation but did not significantly predict PA participation. Income is positively correlated with PA engagement in older adults (Lee and Laffrey, 2006).
Results support the view that income level is not sufficient for engagement in healthy behaviors in ICD recipients. Self-efficacy is the stronger determinant in participation in physical activity.

**Strengths and Limitations**

The strength of this study is the addition of new and supporting information to guide practice and future research in the ICD population. Very little research has been conducted with regards to PA participation in the ICD population and until this study no research has explored health beliefs related to PA. Although conclusive evidence may not be drawn from this proposed study, patterns found in the data may help illuminate causal processes (Polit and Beck, 2012; Stommel and Wills, 2004). The major goal of this type of study is to describe relationships among variables (Polit and Beck, 2012; Wood and Brink, 1998). This design was not concerned with causation; however, according to Kazdin (2003) strong inferences can be drawn about variables that may influence an outcome even though the research does not involve experimental manipulation.

Strengths associated with the study design include the practicality of a cross-sectional study. This design involved a one-time administration of questionnaires which was more economical, took less time to complete versus a longitudinal design, and one has less worry of subject drop-out as in a repeated-measures or longitudinal study. This one-time snapshot of information, while beneficial, does have the limitation of temporality. That is, one cannot determine the time sequence between predictor and outcome variables (Polit and Beck, 2012). Cross-sectional studies lack the ability to provide information about phenomena over time and disease progression. The sample population for this study may vary in their disease progression and time since ICD implantation. The ICD population in this study has on average lived with
their devices for almost six years. Since diagnosis and implantation of an ICD individual disease progression, physical limitations and quality of life may have changed. In fact, subjects participating in this study reported changes in their PA levels since implant. Multiple observations over time may help to determine if changes in behavior are correlated with disease progression and/or time since ICD implantation (Polit and Beck, 2012; Stommel and Wills, 2004).

Longitudinal studies are warranted especially when examining health behaviors using HBM variables. It is suggested that not having the ability to measure health beliefs before adoption of a healthy behavior could inaccurately represent the ability of the HBM constructs to predict behavior (Carpenter, 2010). This also holds true for estimating the effect of health behaviors on quality of life. One can only report a correlation between the two but not be assured of causation.

Although the sampling method (convenience) was practical in this study design, it has weaknesses. Those that chose to participate may not be representative of the population of ICD recipients. There may be a potential bias in responders versus non-responders as well as selection bias by the physicians and nurse practitioners identifying subjects eligible for recruitment. The ICD recipients who participated may have characteristics/beliefs different from the non-responders thus biasing the outcome measures. Most of the ICD recipients taking part in this study were from rural farming communities thus may not reflect the views of ICD recipients in more urban/metropolitan areas. Access to exercise facilities may be greater in these areas so PA participation may have been greater. Sample size in this study was not large enough to appreciate significant differences in scores between and among gender, race and age groups. The sample
size may not have been large enough to really appreciate the effects HBM variables may have on predicted behavior.

There may also be weaknesses associated with the questionnaires. Mailed questionnaires are cost-effective when compared with face-to-face interviews (time and personnel), are anonymous thus increasing the chance that the responder will answer honestly, and eliminate interviewer bias. Drawbacks of mailed questionnaires include missing data, low response rates and inability to determine if the participant answered the questions versus a family member. This study used both mailed questionnaires and in office administration of paper-pencil questionnaires as a data collection method. In office (in person) administration of questionnaires have better response rates (in this study 100 percent completed their in office questionnaires versus 75 percent for mailed questionnaires), are more inclusive to audiences with low literacy or vision problems (interviewer can ask the questions), allow for clarity, decreases chance of missing information and assures the participant is actually answering the questionnaire (Polit and Beck, 2012).

Questionnaires that are not designed specifically for the study population may not accurately measure the intended construct. Perceived barrier items in this study may not accurately reflect the actual perceived barriers that have a true effect on behavior, thus causing a misrepresentation of results. The same holds true for questionnaires designed specifically for the ICD recipient. In this study, the SEICD questionnaire was designed to measure self-efficacy beliefs related to having an ICD. Although scores were significantly correlated with PA participation these beliefs were not intended to measure this behavior, thus lacked significance in its predictive power.
An additional problem which can occur with self-report questionnaires is the potential for subjects to over or under report. This was the case when subjects under-reported the frequency of clinical diagnoses. Without clinical documentation to verify the diagnoses the results may have been misinterpreted, especially if this were the focus of the study. The possibility of under or over-reporting of PA participation or other measures is of concern with respect to interpreting findings.

**Implications for Nursing Practice and Future Research**

Results from this study indicate PA participation in ICD recipients is not influenced entirely by an individual’s health beliefs. Future research using other theoretical frameworks may more accurately reflect predictors not identified in this study.

Self-efficacy for exercise explained almost 23 percent of variance in predicting PA participation; however, there are other factors nurses must consider. Living with an ICD has many physical and psychological implications that nurses much take into account. Not only do individuals with ICDs have heart disease that has either placed them at risk for SCD or has caused SCD, they have competing chronic illnesses that have potential to impact PA participation and affect overall quality of life. For example, the diagnosis of HF entails a trajectory that may leave an individual incapable of participating in any PA without debilitating symptoms. Pharmacologic therapy for HF patients often involves the use of diuretics which may inhibit individuals from leaving home to participate in PA for fear of not getting to the bathroom in a timely fashion. Other chronic illnesses have their own sets of symptoms and medications that may affect PA participation and quality of life. Individuals are living longer with their ICDs and with age physical function declines and disease burden increases causing a myriad of issues.
Nurses caring for ICD recipients have the responsibility to continue efforts aimed at building our understanding of effects this technology has on patients and family members/significant others. Nurses caring for ICD recipients need be well versed on the technology so they can help educate the ICD community (patients, family/significant others and other healthcare professionals). Knowledge of the device may help allay patient/family fears that are often associated with living with an ICD. Nurses should continue research and facilitate dissemination of tested interventions to facilitate increased PA participation and increase quality of life. Nurses have the responsibility to collaborate with multiple disciplines (physical therapy, rehabilitation experts, psychologists, etc.) and an array of clinical experts (HF, Pulmonary, Diabetes, PVD, CVD specialists and others) in designing studies/trials aimed at improving PA participation and QOL in ICD recipients. Nurses should take initiative in introducing/facilitating policies aimed at promotion and reimbursement for cardiac rehabilitation for ICD recipients; and promoting/increasing the use of rural health centers for cardiac rehabilitation/exercise programs to reach underserved populations.

Qualitative research using phenomenology or grounded theory may guide an understanding of living with this technology. Such an approach might illuminate barriers to adoption of healthy behaviors and/or develop theory which can guide future research for these patients. Qualitative studies designed to determine what PA means to ICD recipients would be valuable as there may be generational, gender, cultural differences in beliefs of what PA is or is not. Qualitative research may facilitate development of surveys/questionnaires specific to the needs of ICD patients.
An unexpected finding in this study indicates a need for research involving the validity of self-report questionnaires. Were the recipients under-reporting their documented clinical diagnoses in error? Do they understand their clinical diagnosis? Have they been told they have HF or a weak heart, thus in a self-report the term “heart failure” may not have meaning? Does this imply they do not know what their medications are treating? Do they feel they have the condition only while being treated for acute exacerbations related to the condition? This may have implications for research in preventing readmissions for various clinical conditions (HF, HTN, Diabetes and COPD).

The ICDs have technology that allows for validating the success of interventions aimed at increasing PA in ICD recipients. That is, the devices store heart rate histograms that allow the clinician to assess heart rate variability over time (Hayes and Freidman, 2008). This information is already being used in the clinical setting to assess for possible HF exacerbation or other problems. This is a valuable tool which can help validate self-report PA questionnaires and validate the success or failure of PA interventions.

This study did not have adequate sample size to examine for significant racial or gender differences in QOL or PA participation. Further research needs to be conducted to assess for gender differences; and to determine needs of multi-ethnic, multi-racial ICD recipients. Are there cultural beliefs that impact an ICD recipient? Further examination of age differences is imperative to caring for geriatric ICD recipients whose needs may be much different than the pediatric, young adult or middle aged adult ICD recipient.

Social support is integral to quality of life. Further research is needed to evaluate the effect of ICD support groups on behavior change.
Conclusion

Findings in this study indicate health beliefs may not be enough to motivate an ICD recipient to engage in physical activity. Having the confidence to overcome obstacles and/or fears related to living with an ICD and other co-morbid health conditions is important (although not the only key) to improving adoption of healthy behaviors. Physical activity is vital to secondary prevention in ICD recipients. This study highlights a need for continued effort in the promotion of PA in patients living with life-saving technology. Increasing levels of PA engagement in this population will require a multifaceted, multidisciplinary approach if we are to address the complex needs of these patients who often are dealing with multiple chronic conditions.
APPENDIX A

RECRUITMENT FLYER
ICD Volunteers Needed

➢ If you have an Implantable Cardiac Defibrillator (ICD)

➢ Would like to participate in a study by answering brief questionnaires about your health and physical activity

➢ Please let your doctor or nurse know today during your visit.

If interested in hearing more:

Name: ____________________________

Contact information: ____________________________

Best time to contact: ____________________________

Your help is greatly appreciated!

An Institutional Review Board responsible for human participant research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies.
APPENDIX B

IRB APPROVAL LETTER AND CONSENT FORMS
IRB APPROVAL LETTER

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**HSPP Correspondence Form**

**Investigator:** Rebecca Susan Crawford, Ph.D. Candidate

**Advisor:** Kathleen Insel, Ph.D., RN

**Project No./Title:** 13-0303 Health Beliefs Related to Physical Activity in Patients with Implantable Cardioverter Defibrillators

**Expiration Date:** No Expiration

**Department:** Nursing

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**Administrative Action**

**Administrative Review – New Project**

**FWA Number:** FWA00004218

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**Documents Reviewed Concurrently**

- F200 (signed 2013-04-04; revised 2013-05-01)

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**Consenting Instruments:**

- ICF (version 2013-04-30)
- PHI (version 2013-04-30)
- F107 (version 2013-04-18)

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**Site Authorizations:**

- WHV

---

**Recruitment Materials:**

- Flyer
- Script

---

**Data Collection Instruments:**

- Clinical Data Form
- Demographic Questionnaire
- Perceived Benefits and Barriers Questionnaire
- Physical Activity Questionnaire
- Self Efficacy Questionnaires
- SF-36 Questionnaire

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**Participant Materials:**

- Cover Letter

---

**Grant:**

- Application
- Beta Mu Award
- OGSR

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**Other (define):**

- CV Crawford

---

**Reminders:** No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.

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*The University of Arizona* - *Human Subjects Protection Program*
Approved as submitted effective as of the signature date below.

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<th>Regulatory Determination(s)</th>
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<tr>
<td>Exempt Approval 45 CFR 46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.</td>
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Digitally signed by Elaine Jones
DN: cn=Elaine Jones, o=HSPR, ou=HSPR, email=ejones@nursing.arizona.edu, c=US
Date: 2013.05.01 17:04:30 -07'00'

Elaine G. Jones, PhD, RN
Chair, University of Arizona IRB
EGI:ace

cc: Scientific/Scholarly Reviewer

* No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.
The University of Arizona Consent to Participate in Research

Study Title: Health Beliefs Related to Physical Activity in Patients with Implantable Cardioverter Defibrillators

Principal Investigator: Rebecca Susan Crawford

Sponsor: Beta Mu Chapter, Sigma Theta Tau International

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done? To understand health beliefs about taking part in physical activity among people living with Implantable Cardioverter Defibrillators.

2. How many people will take part in this study? 107 people will take part in this study.

3. What will happen if I take part in this study? You will be asked to complete six paper and pencil questionnaires about yourself, your beliefs about physical activity, your confidence in participating in physical activity and in your defibrillator, your physical activity participation and how you are feeling. The total time to complete the questions is about 1 and ½ hours. You can choose to answer these questions at home and mail them back to the principal investigator, Rebecca Susan Crawford, in a postage paid envelope that will be provided; or, you may choose to schedule an appointment with the principal investigator to answer the questionnaires in person at the clinic.

4. How long will I be in the study? It will take approximately one and one-half hour to complete the questionnaires. This is a one-time session. No further participation is required after the completion of the questionnaires.
5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona or your health care at the clinic. If you choose to participate or not to participate it will have no effect on your care. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

Some individuals may be bothered answering questions concerning their own risk for coronary heart disease and concerns about shocks from their heart device. If those concerns arise, the principal investigator will notify your doctor, nurse practitioner or nurse of the concerns so they may address them with you.

7. What benefits can I expect from being in the study?

There are no direct benefits to participating in this study. Knowledge generated from this research may benefit people who have ICDs by helping health care providers understand why people are or are not physically active.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):
- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study, their agents or study monitors
10. What are the costs of taking part in this study?
There are no costs other than the time to complete the surveys associated with taking part in this study.

11. Will I be paid for taking part in this study?
There are no payments for taking part in this study.

12. What happens if I am injured because I took part in this study?
You may be bothered by answering questions about your own risk for coronary heart disease and shocks from your heart device.
If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?
If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.
You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.
You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.
An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact Rebecca Susan Crawford at 904-451-1032 or online at rcrawford@nursing.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://ocr.arizona.edu/hssp.
Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject ___________________________ Signature of subject ___________________________ AM/PM

Date and time ___________________________

Printed name of person authorized to consent for subject (when applicable) ___________________________ Signature of person authorized to consent for subject (when applicable) ___________________________ AM/PM

Date and time ___________________________

Relationship to the subject ___________________________ Date and time ___________________________

Investigator/Research Staff

I have explained the research to the participant or the participant’s representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant’s representative.

Printed name of person obtaining consent ___________________________ Signature of person obtaining consent ___________________________ AM/PM

Date and time ___________________________
AUTHORIZATION FORM FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH (HIPAA Authorization)

Project Title: Health Beliefs Related to Physical Activity in Patients with Implantable Cardioverter Defibrillators

Principal Investigator: Rebecca Susan Crawford
Principal Investigator Contact Information: 2705 Dolphin Street, Unit 2A Fernandina Beach, Florida 32034, 904-451-1032

This permission from you allows the researchers in this research project to get information from your medical records or health insurance records for use in the research. This permission is required by the “Health Insurance Portability and Accountability Act” (HIPAA) and is called a “HIPAA authorization.”

PURPOSE
You are being invited to participate voluntarily in the research project titled at the top of the page. The purpose of collecting Protected Health Information (PHI) for this study is help researchers answer the questions that are being asked in this research study.

WHAT INFORMATION MAY BE USED AND GIVEN TO OTHERS?
Information that will be collected about you includes:
• Your type of heart device.
• The date you had your heart device surgically implanted.
• The medical reason you have a heart device.
• The type and degree of heart problem that you have.
• If you have had any heart rhythm problems or shocks from your heart device.
• If you have any other medical problems.
• Your doctor’s medical okay for you to take part in physical activity.

WHO MAY USE AND RECEIVE INFORMATION ABOUT ME?
Information about you may be given out by the Principal Investigator and researchers in the project to:
• Representatives of regulatory agencies (including the University of Arizona Human Subjects Protection Program) to ensure quality of data and study conduct.

WHY WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?
This information will be used to help understand if there are any differences in health beliefs related to your medical information provided. The information is needed to make sure that we consider all aspects of having a heart device and participating in physical activity

The results of this research may be published in scientific journals or presented at professional meetings, but your identity will not be disclosed.

HOW LONG WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?
Your PHI will be linked to your identifying information for 3 months and one day. After this
time, all links will be destroyed and your identity will not be able to be determined.

This authorization will expire on the date the research study ends.

MAY I REVIEW OR COPY THE INFORMATION OBTAINED FROM ME OR CREATED ABOUT ME?
You have the right to access your PHI that may be created during this study as it relates to your
treatment or payment. Your access to this information will become available only after the study
analyses are complete.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?
If you do cancel your authorization, any information previously disclosed cannot be withdrawn
and may continue to be used. Information sharing that has already happened cannot be changed.
You may cancel this authorization at any time by notifying the Principal Investigator in writing.
The address for the Principal Investigator is 2707 Dolphin Street Unit 2A, Fernandina Beach, FL
32034.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY
HEALTH INFORMATION?
You may refuse to sign this authorization form. If you choose not to sign this form, you cannot
participate in the research study. Refusing to sign will not affect your present or future medical
care and will not cause any loss of benefits to which you are otherwise entitled.

IS MY HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO
OTHERS?
Once information about you is disclosed in accordance with this authorization, the individual or
organization that receives this may redisclose it and your information may no longer be protected
by Federal Privacy Regulations.

CONTACTS
You can obtain further information from the Principal Investigator, Rebecca Susan Crawford,
RN, MSN, Ph.D. Candidate at 904-451-1032. If you have questions concerning your rights as a
research subject, you may call the Human Subjects Protection Program office at (520) 626-6721.
If you would like to contact the Human Subjects Protection Program via the web (this can be
anonymous), please visit http://orcr.arizona.edu hspp.

AUTHORIZATION
I hereby authorize the use or disclosure of my individually identifiable health information. I will
be given a copy of this signed authorization form.

_________________________________________________________________________

Subject’s Signature                        Date

_________________________________________________________________________

Version 04-30-2013                       Page 2 of 3                        Form date: 01/01/2013
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APPENDIX C
SITE APPROVAL LETTER
March 19, 2013

Human Subjects Protection Program
1618 E. Helen Street
The University of Arizona
PO Box 245137
Tucson, AZ 85724

Dear Human Subjects Committee:

This letter is to inform you that Rebecca Susan Crawford, MSN, RN, a PhD nursing student at the University of Arizona College of Nursing has permission to conduct her dissertation study titled "Health Beliefs Related to Physical Activity in Patients with Implantable Cardiowter Defibrillators" in the clinical offices of Wake Heart & Vascular Group.

Ms. Crawford has informed me of the study design and target population and she has my full support in her efforts to successfully implement her study. She will be allowed to recruit patients and review their medical records upon participant consent for the duration of the study. I understand we will receive a copy of the IRB-approved, stamped consent document.

Sincerely,

[Signature]

Randolph Cooper, MD, FACC
APPENDIX D

DEMOGRAPHIC DATA QUESTIONNAIRE
DEMOGRAPHIC DATA QUESTIONNAIRE

The following form is a list of questions about your personal and health information. In order to make sure that this form stays private, please do not put your name on the form. Please answer all of the questions. There are no wrong answers.

If you need assistance or have any questions please notify Susan Crawford. If you are answering the questions at home you can contact Susan Crawford by email:

rcrawford@nursing.arizona.edu or phone: 904-451-1032.
Some Questions About You:

Part One-Personal Information: These questions concern your personal information. This information is important to help get an idea of how personal issues may affect your health beliefs and physical activity participation. Please put a check or X in the blank next to your answer. You have the right to not answer some questions if you choose.

Gender: _______Male   Age: ___________   Date of Birth (Year Only):_______
                  _______Female

Race: _____American Indian/Alaska Native   Ethnicity: ___Hispanic/Latino
       _____Asian                                      _____Not Hispanic/Latino
       _____Black/African American
       -------Native Hawaiian or Other Pacific Islander
       _____White

Marital Status:                           Living Arrangements:
       _____Married                                 _____Live Alone
       _____Domestic Partner                        _____Live with Spouse
       _____Single                                  _____Live with Domestic Partner
       _____Separated/Divorced                      _____Live with Children
       _____Widowed                                 _____Other, please specify______

Religious Affiliation:                    Role of Religion:
       _____Catholic                                _____Important
       _____Protestant                              _____Not important
       _____None                                    _____Other
       _____Other

Which of the following best describes where you live?
       _____Rural area or countryside       _____City
       _____Small Town                            _____Suburb

The highest level of school you have completed.          Employment Status:
       _____Grammar School                        _____Homemaker
       _____High School or Equivalent             _____Part-time
       _____Vocational or Technical School (2year)_____Full-time
       _____Some College                          _____Unemployed
       _____Bachelor’s Degree                     _____Retired
       _____Master’s Degree                       _____Medical leave or
tenability
       _____Doctorate Degree/Professional Degree

Household Income:       Health Insurance Status:
       _____Less than $10,000                        _____Private Health Insurance
       _____$10,000 to $19,999                      _____Medicare
Some Questions About You:

**Part Two - Health Information** The second part of the questions is related to your health, your implantable cardioverter defibrillator and physical activity. This is very important information to help get an idea of how your individual health issues and what you know about your defibrillator may affect your health beliefs and physical activity participation. Please put a check or X in the blank next to your answer. You have the right to not answer some questions if you choose.

How long have you had your implantable cardioverter defibrillator? This is from the time you received your very first implant.

- Greater than 6 months but less than a year
- 1 year to 3 years
- 3 years to 5 years
- 6 years to 8 years
- 9 years to 11 years
- Greater than 12 years

How many times is your implantable cardioverter defibrillator checked every year (includes remote monitoring and office checks)?

- 1 time a year
- 2 times a year
- 3 times a year
- 4 times a year
- 5 times a year
- Greater than 6 times a year

Have you ever received a shock from your implantable cardioverter defibrillator?

- Yes
- No
- Don’t recall

If yes, how many shocks do you recall receiving since you got your defibrillator?

- 1-3
- 4-6
- 7-10
- More than 10
- Don’t recall
Please select any of the following conditions below that you have been treated for.

- Heart Failure
- Type I Diabetes
- Type II Diabetes
- High Blood Pressure
- Lung Disease
- Cancer

- Heart Attack
- Stroke
- Heart Surgery
- Angioplasty and/or Stenting
- Sleep Apnea
- Vascular problems in legs

What is your current Height? ______________

What is your current Weight? ______________

Please list the names (only the name) of your current medications in the space provided below. (If you have a list already made you may attach it or have the nurse make a copy to attach as long as your name or any identifying numbers are not on the list.)

<table>
<thead>
<tr>
<th>Medications</th>
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The remaining questions are concerning your implantable cardioverter defibrillator and physical activity. This information is extremely important to get an idea of what you know about your defibrillator and physical activity. This information is very valuable to your doctors and nurses. It helps us understand your individual needs so that we can help you.

Have you participated in any type of cardiac rehabilitation?
- [ ] Yes
- [ ] No
- [ ] Not Sure

Have you ever been told by your doctors or nurses that you need to participate in cardiac rehabilitation?
- [ ] Yes
- [ ] No
- [ ] Not Sure

Have your doctors or nurses discussed Physical Activity restrictions or instructions regarding your implantable cardioverter defibrillator?
- [ ] Yes
- [ ] No
- [ ] Not Sure

Since you had your defibrillator placed your level of physical activity has:
- [ ] Remained the same
- [ ] Has decreased
- [ ] Has increased
- [ ] Not sure

Do you know what heart rate you can safely achieve when you are being physically active? That is, what your cut-off heart rate is before you will receive a shock from your defibrillator?
- [ ] Yes
- [ ] No
- [ ] Not sure

Do you feel like you have enough information to safely participate in physical activities?
- [ ] Yes
- [ ] No
- [ ] Not sure
Do you attend the support group meetings for implantable cardioverter defibrillator patients?

- Yes, frequently (6 or more times per year)
- Yes, on occasion (less than 5 times per year)
- No, never
- No, there is not one near where I live
- I have in the past but do not now
- I did not know there was a support group

Do you have someone you can call if you need help?

- Yes
- No
- Not sure

What social support do you have to encourage and help you participate in physical activities?

- Spouse or significant other
- Neighbor
- Friend
- Other family member
- None

Is there anything else you would like to share that you think may help us to help you and other patients with implantable defibrillators?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Please feel free to write on the back of this if you run out of space.
APPENDIX E

PERMISSION FOR SELF-EFFICACY ICD SCALE USE AND REVISION
PERMISSION FOR SELF-EFFICACY FOR ICD SCALE USE AND REVISION

Re: PhD Dissertation SE-ICD Scale Permission Request

Rebecca: If you want to use the tool, that is fine. But, the tool is not going to tell you much about self-efficacy for engaging in physical activity. It is not designed for this.

Resnick has a self-efficacy for walking and outcome expectations for walking scales. You might find these more relevant to your work.

Cynthia M. Dougherty ARNP, PhD, FAAN (206) 221-7927 phone
1959 NE Pacific Street, Room T615A (206) 543-4771 FAX
Biobehavioral Nursing & Health Systems (206) 416-1556 pager
University of Washington, Box 357266
Seattle, WA 98195-7266
cindyd@uw.edu

On Wed, 12 Dec 2012, Crawford, Rebecca wrote:

Good Day Dr. Dougherty,

My name is Rebecca Susan Crawford. I am a PhD Candidate at the University of Arizona, College of Nursing. I emailed you last year regarding your SE-ICD and OE-ICD scales for a transcultural assignment (translation of the scales from English to Chinese). It was quite interesting to see how the terms were interpreted in Chinese.
My request at this point of my PhD pursuit has to do with my dissertation. My dissertation proposal is to examine the health beliefs (perceived benefits, perceived barriers and self-efficacy beliefs) related to physical activity participation in implantable cardioverter defibrillator recipients. There are so few questionnaires/scales that are specific to the ICD population so I thought it would be beneficial to use the SE-ICD scale for this research. I also think it would be interesting to see the difference (if any) between individuals who are implanted for primary versus secondary indications.

I would like very much to have your permission to use the SE-ICD scale. I also appreciate any comments or suggestions you may have.

I look forward to your reply.

Warmest Regards,
Rebecca Susan Crawford, RN, PhD Candidate
Cell 707-239-9275
Home 904-432-8485

---

Cindy Dougherty <cindyd@u.washington.edu> Feb 20
to Rebecca

This change sounds fine.

sent from my iphone
excuse typos

On Feb 20, 2013, at 10:19, "Crawford, Rebecca" <rcrawford@nursing.arizona.edu> wrote:

Hello Dr. Dougherty,

Thank you so very much for allowing me to use your scale for my dissertation. I like the Resnick scale but really am looking at a general self-efficacy in this population and am really interested to see how your scale performs in patients who were implanted for primary versus secondary prevention of sudden cardiac death.

I would like to respectfully request your permission for a very minor change in the wording of the scale to make it relevant to primary prevention patients (since they have not experienced cardiac arrest). That is, on questions 2-3 of the SE-ICD scale, the questions use the term cardiac arrest and defibrillator. With your permission, I would like to change it to read as follows:
2. Original: I can successfully deal with limits placed on my driving since the cardiac arrest and defibrillator. New: I can successfully deal with limits placed on my driving since the defibrillator.
3. Original: I can manage my own nervousness since the cardiac arrest and defibrillator. New: I can manage my own nervousness since the defibrillator.

Again, thank you for allowing me to use your SE-ICD scale and also for your time.

Warmest Regards,
R. Susan Crawford, MSN, RN, PhD-candidate.

From: Cynthia Dougherty [cindyd@u.washington.edu]
Sent: Wednesday, December 12, 2012 5:39 PM
To: Crawford, Rebecca
Cc: cindyd@washington.edu; Insel, Kathleen
Subject: Re: PhD Dissertation SE-ICD Scale Permission Request
APPENDIX F

PERMISSION FOR USE OF SELF-EFFICACY FOR EXERCISE SCALE
PERMISSION FOR USE OF SELF-EFFICACY FOR EXERCISE SCALE

Resnick, Barbara M. <Resnick@son.umaryland.edu> Mar 9

to Rebecca, Kathleen

feel free to use this and revised as you would like or do whatever to it you would like! Barb

From: Crawford, Rebecca [rcrawford@nursing.arizona.edu]
Sent: Saturday, March 09, 2013 1:57 PM
To: Resnick, Barbara M.
Cc: Insel, Kathleen
Subject: Self-Efficacy Exercise Scale-Phd Student Permission to Use

Good Afternoon Dr. Resnick,

I am a Nursing PhD candidate at the University of Arizona College of Nursing. I am in the Dissertation phase of my PhD. My research is focused on health beliefs (perceived benefits, barriers and self-efficacy beliefs) related to physical activity participation in adult implantable cardioverter defibrillator patients. The average age of ICD patients is > 67 years so the SEE scale you developed and tested in older adults may be a valuable measurement tool for my patient population.

I would like to request your permission to use the SEE scale for my study. I will be citing two of your publications for this study:


I thank you so much for your time and consideration.

Warmest Regards,
Rebecca Susan Crawford, MSN, RN, PhD-candidate
APPENDIX G

PERMISSION FOR USE OF HEALTH BELIEF QUESTIONNAIRE
PERMISSION FOR USE OF HEALTH BELIEF QUESTIONNAIRE

Jerry Mirotznik <JerryM@brooklyn.cuny.edu> 11/1/11

to Rebecca

You're very welcome Susan.

Best,

Jerry

-----Original Message-----
From: Crawford, Rebecca [mailto:rcrawford@nursing.arizona.edu]
Sent: Tuesday, November 01, 2011 6:10 PM
To: Jerry Mirotznik
Subject: Re: Health Belief Questionnaire

Thank you so very much! I will keep you posted on my progress. Warmest Regards, Susan

Sent from my iPhone

On Oct 31, 2011, at 7:07 AM, "Jerry Mirotznik" JerryM@brooklyn.cuny.edu wrote:

-----Original Message-----
From: Jerry Mirotznik
Sent: Monday, October 31, 2011 10:05 AM
To: 'Crawford, Rebecca'
Cc: 'buddybetty@hotmail.com'
Subject: RE: Health Belief Questionnaire

Hi Susan,

I think the problem was on my end. My new Ipad was having some trouble sending these attachments. Hopefully this will work. And yes you may make the minor revisions we spoke about.

I've attached a copy of the revised HBM Questionnaire and some material regarding our attempts to assess the questionnaire's psychometric...
properties. I hope these are helpful.

Best of luck with your dissertation research. Please let me know how things are going for you.

Sincerely,

Jerry

-----Original Message-----
From: Crawford, Rebecca [mailto:rcrawford@nursing.arizona.edu]
Sent: Sunday, October 30, 2011 5:02 PM
To: Jerry Mirotznik
Subject: RE: Health Belief Questionnaire

Hi Dr. Mirotznik,

I am not certain what the trouble may be unless I have limited capacity for large documents on the college website. My home email is buddybetty@hotmail.com or scrawford8485@gmail.com. These should be able to receive large files.

Thanks again,
Susan

________________________________
From: Jerry Mirotznik [JerryM@brooklyn.cuny.edu]
Sent: Sunday, October 30, 2011 10:02 AM
To: Crawford, Rebecca
Cc: Jones, Elaine
Subject: RE: Health Belief Questionnaire

Dear Susan,

I'm having some trouble sending the questionnaire and additional material as attachments to your email address. Have you received either of my two emails? If not, might you have an alternate address I can use?

Best,
Jerry

______________________________
From: Crawford, Rebecca
(mailto:rcrawford@nursing.arizona.edu)
Sent: Thu 10/27/2011 5:04 PM
To: Jerry Mirotznik
Cc: Jones, Elaine
Subject: Health Belief Questionnaire
Hello Dr. Mirotznik,

It was a pleasure to speak with you today regarding the Health Belief Questionnaire developed by you and your colleagues. I really appreciate the time and your offer to be of assistance during my dissertation phase of my PhD work. I also appreciate your offer to send me the updated version that you have developed and refined over the years.

I am really curious to see how perceived barriers predict exercise adoption/adherence in these patients, especially related to their diagnosis/reason for undergoing implantation of an implantable cardioverter defibrillator. Will there be a difference in those patients who have not had an event or those implanted for primary prevention (ventricular arrhythmia or sudden cardiac death) versus those who were implanted for secondary prevention (experienced ventricular arrhythmia or sudden cardiac death)? Will these patients exhibit prediction in the opposite direction of the model as in your research?

I have copied the Chair of my Dissertation committee on this email.

Once again, thank you. I look forward to our future correspondence!

Warmest Regards,

R. Susan Crawford, MSN, RN
PhD Student
Jerry's Paper (Chronic Disease Prevention and Control).pdf
APPENDIX H

MEDICAL OUTCOME SURVEY-SF-36® LICENSE
Dear Rebecca Crawford,

Thank you for purchasing QualityMetric Health Outcomes(tm) Scoring Software 4.5. Please use the Activation Key provided below to unlock the application for the licensed survey(s) and scoring features. This key will install a pre-determined quantity of scoring credits (as per the license agreement) which will be decremented each time a record is entered/scored. Once the credits are exhausted, you will need to contact OptumInsight Life Sciences to obtain more credits and resume scoring.

ACTIVATION KEY:
829AE-DCC17-98436-58153

LICENSED PRODUCTS AND SCORING FEATURES:
PRODUCT NAME: QualityMetric Health Outcomes(tm) Scoring Software 4.5
PURCHASE DATE: 04/05/13
SF36v2 Credit Count: 110
SF36v2 MDE Enabled: Yes
SF36v2 Utility Index: No
SF36v2 RCI Score: Yes
SF36v2 DQE Report: Yes
DOWNLOAD AND INSTALLATION:
You may download QualityMetric Health Outcomes(tm) Scoring Software 4.5 installer from the following location:
http://www.qualitymetric.com/download/SFScoreSoftwareV45Setup.msi

IMPORTANT NOTES - PLEASE READ
Important installation notes are provided below. More detailed instructions are included in the attached. If you are prohibited from installing software or do not feel comfortable doing so, please consult your IT support and bring the items below to their attention:

1) Activation Keys are SINGLE-USE and can only be applied to one computer.
2) WINDOWS ADMINISTRATIVE ACCESS is required to install the software.
3) Subsequent use of the Scoring Software requires the ability to read/write to a specific path in the computer's registry (see documentation for more detail). [If the user is not an Administrator, this will need to be explicitly granted via REGEDIT]

4) You will be prompted to enter the activation key upon first launch. If you miss this opportunity, you can subsequently add keys via the "Tools" menu.

5) An active Internet connection is required for registration of Activation Keys. A workaround for offline activation is available in some cases.

SUPPORT:
- For installation help or system/software requirements, please consult the Installation Guide:
- For help on the use of the software, please review the User’s Guide within the application itself (by clicking on Help -> Contents and Index).

- For additional technical support, please send an email to scoringsoftware@qualitymetric.com.
- For all other questions (such as licensure, billing, or scientific support), please contact your account representative.

---------- Forwarded message ----------
From: NAV Auto-fullfillment <navapi@qualitymetric.com>
To: "rcrawford@nursing.arizona.edu" <rcrawford@nursing.arizona.edu>, "Pam Bartley" <pbartley@qualitymetric.com>
Cc: 
Date: Thu, 11 Apr 2013 10:03:12 -0400
Subject: QualityMetric Files

You have received 1 secure file from navapi@qualitymetric.com.
Use the secure link below to download.
Dear Rebecca Susan Crawford,
Below is a link to a compressed (zipped) archive file that contains your survey files. Click on the link to download your file.

NOTE 1: Please verify that the survey forms, versions and languages that you receive are all correct. If there is any problem, contact your OptumInsight Life Sciences representative immediately.

NOTE 2: If you receive Microsoft Word versions of the surveys, in addition to the Adobe Acrobat version, please print a hard copy of both the Adobe Acrobat and Microsoft Word files for each translation and compare them carefully before administering the surveys to your patients to verify that they are identical. Your computer may not have all the fonts installed to display and print the Microsoft Word document correctly. If you do not have Adobe Acrobat Reader installed on your computer, you can download a FREE copy at http://get.adobe.com/reader/

Secure File Downloads:
Available until: 10 July 2013
OptumInsightLifeSciences-QM018464-20130411-100301.zip
3,554.06 KB
You have received attachment link(s) within this email sent via Accellion Secure File Transfer. To retrieve the attachment(s), please click on the link(s).
APPENDIX I
INCIDENTAL AND PLANNED EXERCISE QUESTIONNAIRE-WEEKLY AVERAGE
PERMISSION FOR USE
Dear Rebecca,

Thank you very much for your interest in our research. The IPEQ is free to be used.

We have also developed an iPad app (search for NeuRA on the app store, and then you will see the ipeq app) to make assessment easier.

Best of luck with your research. Feel free to contact me if you would have any questions regarding the questionnaire.

Best regards,

Kim

Kim Delbaere, PhD
Research Fellow and Group Leader

Conjoint lecturer, University New South Wales

www.NeuRA.edu.au

Barker Street Randwick Sydney NSW 2031 Australia
PO Box 1165 Randwick Sydney NSW 2031 Australia
T +61 2 9399 1066 F +61 2 9399 1204

http://www.neura.edu.au/research/themes/delbaere-group
Affiliation with the Falls and Balance Research Group


-----Original Message-----
From: Crawford, Rebecca [mailto:rcrawford@nursing.arizona.edu]
Sent: Thursday, 13 December 2012 2:17 AM
To: k.delbaere@neura.edu.au
Subject: IPEQ WA Permission to Use

Good Day Dr. Delbaere,

My name is Rebecca Susan Crawford and I am a registered nurse pursuing a PhD in nursing at the University of Arizona, Tucson. I am at the dissertation phase of my PhD work and would like to obtain permission to use the Incidental and Planned Exercise Questionnaire, version WA.

My research is focused on benefits, barriers and self-efficacy beliefs related to physical activity in recipients of implantable cardioverter-defibrillators (ICD). Very little research has focused on physical activity in this population. Intervention research has determined that physical activity is safe in this population however very few participate. It is hypothesized that they avoid activity due to fear of shock and uncertainty, yet no studies to date have explored individual beliefs and their possible effects on behavior.

I have reviewed many different questionnaires/scales regarding physical activity participation and believe the IPEQ-WA would be a good instrument to measure physical activity in this population given that over 70% are over 65 years of age.

I am requesting your permission to use the questionnaire in my dissertation and of course I will make appropriate citations of your work with this measure.

I look forward to your reply and any comments.

Warmest Regards,

Rebecca Susan Crawford, RN, PhD Candidate

The University of Arizona, College of Nursing
APPENDIX J
CLINICAL DATA FORM
CLINICAL DATA FORM

Subject Number __________

Type of ICD: __________________________
  Bi-ventricular _____
  Single Chamber _____
  Dual Chamber _____

Date of ICD (Month/Year): __________________________

Diagnostic Indication:
  Primary Prevention _____
  Secondary Prevention _____

Clinical Diagnoses:

- Heart Failure
- Type I Diabetes
- Type II Diabetes
- HTN
- COPD
- Emphysema
- Cancer
- MI
- CVA
- Cardiac Surgery: Type _____
- PTCA/Stent
- Sleep Apnea
- PVD

NYHA HF Classification (if diagnosed with HF)

- Class I
- Class II
- Class III
- Class IV

ICD Therapy History:

Number of shocks since implant: ________

History of Atrial Fibrillation: No ( ), Paroxysmal ( ), Chronic ( )

Medical Clearance to engage in PA: ____Documented
  ____Undocumented, verbal clearance by MD
  ____Undocumented
REFERENCES


Cameron, A. C. (2004). Kurtosis. In M. S. Lewis-Beck, A. Bryman, & T. F. Lao (Eds.), *The Sage encyclopedia of social science research methods* doi:http://dx.doi.org/10.4135/9781412950589


Psychometric assessment of the Health Belief Model questionnaire presented at the Tenth National Conference on Chronic Disease Prevention and Control, Atlanta, GA.


