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## Testing an Exercise Intervention to Improve Aerobic Conditioning and Autonomic Function after an Implantable Cardioverter Defibrillator (ICD)

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### Abstract

**Background**—Implantable cardioverter defibrillators (ICDs) are an increasingly common treatment for survivors of sudden cardiac arrest or others with life-threatening ventricular arrhythmias. Health-care providers are often reluctant to prescribe exercise for this group because of the belief that it will provoke ventricular arrhythmias and cardiac arrest; patients are often afraid to exercise because of concern over receiving an ICD shock. A social cognitive theory-driven exercise intervention aimed at stabilizing cardiac arrhythmias and reducing ICD shocks by increasing parasympathetic autonomic nervous system control is described.

**Methods**—The exercise intervention has two phases that include an 8-week aerobic conditioning component followed by a 16-week exercise maintenance component. The aerobic exercise intervention is expected to have significant impact on cardiopulmonary function, ventricular arrhythmias, cardiac autonomic function, and self-efficacy in persons who have an ICD. The exercise intervention is currently being tested using a randomized clinical trial format, the results of which will be available in 2012.

**Conclusion**—The exercise after ICD trial is one of the first clinical trials to test the effects of aerobic exercise on cardiopulmonary outcomes after receiving an ICD for primary or secondary prevention of sudden cardiac arrest.

### Keywords

exercise; aerobic conditioning; self-efficacy; implantable cardioverter defibrillator (ICD); intervention; walking; ICD shocks

## Introduction

Sudden cardiac arrest (SCA), also called sudden cardiac death, claims nearly 300,000 lives in the U.S. per year, representing 65% of the total deaths resulting from cardiovascular disease.<sup>1</sup> Most individuals who survive resuscitation from SCA or have life-threatening ventricular arrhythmias receive an implantable cardioverter defibrillator (ICD) to prevent death from recurrent arrhythmias. Because SCA accounts for approximately 50% of the mortality for patients with left ventricular (LV) dysfunction with reduced ejection fraction (EF), the use of the ICD for primary prevention has also been recently expanded to this population. The numbers of ICDs being implanted in the U.S. has grown significantly in the last few years, with estimates reaching in excess of 250,000 per year in 2006.<sup>2</sup> The results of several primary prevention trials in patients with heart failure (HF) demonstrate absolute reductions in mortality ranging from 4% to 7% with prophylactic implantation of the ICD.<sup>3-6</sup> Results of these clinical trials prompted the Center for Medicare and Medicaid Services to expand coverage for ICDs in 2003 to this high-risk population.

While the ICD represents a modern medical achievement with substantial life-saving benefits for patients at risk for life-threatening arrhythmias, recipients of an ICD find living with such a device often requires learning new skills and making lifestyle adjustments. Some of these changes include getting back to regular physical activities, managing the stress associated with ICD shocks, and adjusting to a diagnosis of heart disease. One of the biggest challenges in living with an ICD is becoming comfortable with a metal device implanted in the body that may deliver a shock to the heart at any time.<sup>7</sup>

The development of lethal ventricular arrhythmias has been attributed to multiple causes. Evidence points to the important role of the autonomic nervous system (ANS) in producing susceptibility to ventricular fibrillation (VF) in subsets of persons with heart disease.<sup>8,9</sup> Protection against SCA may be achieved through mechanisms that increase parasympathetic tone,<sup>10</sup> exercise being one of these therapies.<sup>11</sup>

Exercise interventions in those with an ICD have not been extensively studied. Health-care providers are often reluctant to prescribe exercise for this group because of the belief that it will provoke ventricular arrhythmias and cardiac arrest. Patients are often afraid to exercise because of concern over receiving an ICD shock. It is unclear if the amount of exercise required to improve cardiopulmonary function and parasympathetic nervous system activity can be achieved in this group. However, exercise offers the potential benefit of stabilization of autonomic function and protection against future arrhythmic occurrences in a population of cardiac patients who could potentially benefit the most.<sup>6</sup> Exercise interventions have the potential to reduce long-term costs of post-ICD care by reducing hospitalizations and office visits related to recurrent arrhythmias and ICD shocks, and by improving overall quality of life and function.<sup>12</sup>

The purpose of this article is to outline an aerobic exercise intervention program for persons who have an ICD using rationale from aerobic exercise conditioning, cardiac autonomic function, and social cognitive theory.<sup>13</sup> The aerobic exercise intervention is currently being tested using a randomized clinical trial format, sponsored by the National Heart, Lung, and Blood Institute of the National Institutes of Health (5R01 HL084550).

## Methods

### Research Design

A stratified random two-group clinical trial is being conducted with ICD recipients to determine effects on cardiopulmonary function, ventricular arrhythmias and ICD shocks,

heart rate variability (HRV), and self-efficacy in those who participate in an aerobic exercise intervention compared to usual care. The stratifying variables are EF for either EF%  $\leq 35\%$  or  $>35\%$  and Charlson comorbidity scores  $\leq 2.0$  or  $>2.0$ .<sup>14</sup>

### Patient Selection

One hundred sixty ICD recipients (80/group) will participate in this study. Participants will be identified from 16 participating acute care institutions in the Pacific Northwest. Subjects are eligible for inclusion in the study if they meet the following criteria: (1) ICD implantation for either primary or secondary prevention of SCA; (2) able to read, speak, and write English; (3) taking  $\beta$ -blockers medication; and (4) willingness to complete the exercise program and all follow-ups. Patients are ineligible for participation in the study if one of the following exclusion criteria are present: (1) clinical comorbidities that severely impair cognitive and/or physical functioning at telephone screening; (2) short BLESSED score  $> 6$ <sup>15</sup>; (3) age less than 21 years; (4) AUDIT-C score  $\geq 4$  for alcohol use<sup>16</sup>; (5) unstable angina, myocardial infarction (MI), or heart surgery within the previous 3 months; (6) concurrent participation in a regular exercise program (30 minutes/5 days per week); or (7) presenting cardiac rhythm other than normal sinus rhythm that will prevent HRV calculations. Eligible patients are identified by site coordinators as they are admitted to the acute care agency implanting the ICD.

### Intervention Design

The exercise intervention being tested in this study is a home-based walking program that includes two phases: (1) an 8-week aerobic conditioning component followed by (2) a 16-week aerobic maintenance component, and is based on current guidelines for cardiac populations.<sup>17,18</sup>

**Aerobic Conditioning Phase (1 hr/day  $\times$  5 days/week  $\times$  8 weeks)**—The conditioning program uses the results of the preliminary supervised cardiopulmonary exercise test (CPET) to develop individualized heart rate (HR) targets for each week of the program as follows: weeks 1–2, 60% of heart rate reserve (HRR), weeks 3–4, 70% of HRR, and weeks 5–8, 80% of HRR. Karvonen's<sup>18</sup> HRR formula (maximum HR – resting HR = HRR; [HRR  $\times$  training%] + rest HR = target heart rate {THR}) for calculating THR is used. The THR is kept below the ischemic threshold and below the ICD detection HR for that individual. Wrist-worn Polar HR monitors (Polar Electro USA, Lake Success, NY, USA) are exchanged bimonthly with each intervention subject during the study. These HR monitors are programmed specifically for each subject with their THR and are used to guide the exercise intervention. Exercise sessions are recorded and saved in the Polar HR watch and downloaded every 2 weeks.

Exercise sessions are conducted at home and begin with 5 minutes of lower extremity stretching to enhance flexibility of the large muscle groups and to prevent injury. After stretching, subjects walk on a level surface at a pace until they reach their THR. After 1 hour of walking, each subject does a 5-minute cool-down consisting of lower extremity stretching exercises.

Activity diaries and the data from the Polar HR monitors (i.e., actual duration of exercise session, amount of exercise time in various HR zones) are collected for each intervention subject during the program. Subjects are taught to collect preexercise, mid-exercise, and postexercise HRs from the Polar HR monitors. Adherence is monitored in weekly phone interventions and through analysis of the saved Polar HR data.

Social cognitive theory principles that were applied to the implementation of the exercise intervention were aimed at enhancing self-efficacy expectations by: (1) skills mastery (teaching individuals how to monitor exercise, take and record their pulse, keep a journal of exercise, determine physiological responses to walking, and adjust exercise to fit into their daily lives), (2) vicarious experience (mentoring subjects in normal and abnormal exercise responses, coaching during difficult periods, modeling of exercise behaviors over time), (3) verbal persuasion (providing validation and positive reinforcement), and (4) monitoring physiological state (recording HR, weight, and pedometer responses to exercise and providing interpretations, carefully monitoring of ICD function during the study, problem solving when medications affected HR, and implementing anxiety reducing strategies by reinforcing physiological responses to exercise).

**Aerobic Conditioning Rationale**—Exercise guidelines to improve cardiopulmonary function, health outcomes, and HRV in persons with an ICD have been sparsely published. We are seeking to determine if a home walking exercise program can enhance cardiopulmonary function and cardiac autonomic function. The intensity, duration, and frequency of exercise are designed to ensure a level of cardiopulmonary fitness and improvement in parasympathetic function. Compared to exercise programs performed using formal supervision, those that are at least in part carried out at home are more feasible, reduce transportation costs, improve adherence, and enhance long-term exercise maintenance.<sup>19</sup>

**Aerobic Maintenance Phase (minimum 30 min/day × 5 days/week × 16 weeks)**—After completing the 8-week aerobic conditioning phase, participants enter the maintenance phase and continue home walking at 80% of HRR for 150 minutes a week for 16 weeks. During this time, they receive bimonthly telephone calls from the exercise interventionist to support exercise maintenance, troubleshoot problems encountered with home walking, and to assist in monitoring HRs. Adherence during the maintenance phase is monitored in the same way as during the conditioning phase with phone calls, Polar HR monitor data, and diaries.

**Aerobic Maintenance Rationale**—The rationale for continuing a maintenance phase after the initial aerobic conditioning period includes: (1) traditional exercise programs in cardiac patients are not typically followed by an organized maintenance phase to give support while the person transitions from the more intensive training to the less intensive maintenance phase. Many exercise benefits may be lost if the person stops exercising completely; (2) we seek to determine if the benefits gained in outcomes after the initial aerobic training period at 8 weeks are sustained with maintenance type interventions; (3) guidelines for physical activity that are advocated for maintaining health (30 minutes of moderate level physical activity on all or most days of the week) are supported by several national organizations, including the Institute of Medicine, American College of Sports Medicine, and the American Heart Association<sup>20</sup>; and (4) evidence supports that an exercise maintenance phase that continues a similar level of exercise intensity (80% of HRR), but reduced duration and frequency, can sustain levels of fitness previously achieved in normal subjects.<sup>21</sup> If maintenance exercise helps to sustain benefits on outcomes at 6 months, this information will be extremely useful in designing future studies of exercise after an ICD, in making exercise prescriptions in clinical practice, and calculating costs of exercise programs.

## Outcomes

### Intervention Outcomes

The primary outcome for the study is peak cardiopulmonary function after 8 weeks of exercise using the CPET. The secondary outcomes are: (1) ventricular arrhythmias (ICD shocks, ventricular tachycardia [VT]/VF), (2) cardiac autonomic activity (HRV), and (3) self-efficacy (self-efficacy for walking, outcome expectations for walking). Measures are taken at three times: (1) baseline study entry, (2) 8 weeks later (completion of the aerobic training component), and (3) 24 weeks from baseline (completion of the aerobic maintenance component).

**Primary Outcome**—Cardiopulmonary function (peak  $\dot{V}O_2$ ) is measured using peak oxygen utilization in a CPET session conducted in the exercise laboratory (Viasys VMax series 229, Sensor Medics, San Diego, CA, USA). The treadmill exercise test protocol is the modified Balke protocol.<sup>22</sup> This is a symptom-limited exercise protocol, where the subject stops the test voluntarily when they feel they have exercised to exhaustion. In order to enter the trial, a respiratory exchange ratio (RER) of  $>1.0$  must be reached on the baseline exercise test. After the exercise test is completed, the patient continues to walk on the treadmill at 1.5 mph at 0% grade for 5 minutes. During the CPET a 12-lead electrocardiogram (ECG) is continuously recorded. Blood pressure is measured every minute by automated exercise sphygmomanometer. Expired gases are analyzed breath-by-breath using a metabolic exercise system. Inspiratory flow, expiratory oxygen and carbon dioxide concentrations, and oxygen consumption and  $\text{CO}_2$  production are calculated using standard formulas. Peak oxygen utilization (peak  $\dot{V}O_2$ ) is determined as the average value observed over the last 10 seconds of exercise. Anaerobic threshold is determined by computerized algorithms using the V-slope method (separation in  $\text{VC}_{\text{O}_2}$ - $\dot{V}O_2$  L/min slopes)<sup>23</sup> and is independently verified by two investigators. Maximum HR, anaerobic threshold HR, end-tidal  $\text{CO}_2$ , power output, and HR where arrhythmias may be observed are used for making exercise prescriptions and to determine the physiological benefits of exercise. The ICD has VT detection temporarily suspended during the exercise test, though VF detection and therapies remain active during the test. The original ICD programming is resumed immediately after the exercise test is completed. This technique is used in order to ascertain the HR response to exercise without subjecting the person to the risk of being inadvertently treated by the ICD for sinus tachycardia falling within a programmed VT zone while performing the test.

Special considerations need to be taken into account when performing maximal exercise testing in patients with an ICD. First, the staff needs to be aware of the ICD programming information including the HR detection threshold at which therapies will be delivered, and the sequence of therapies programmed for arrhythmias: antitachycardia pacing (ATP) and shock. Second, it is mandatory that a person who has specialized training in the care of patients with an ICD be present to deactivate and reactivate the ICD.<sup>24</sup> Third, the ICD should be programmed in such a manner as to avoid administering antitachycardia therapies during exercise should the HR exceed the prescribed limits during the exercise test. Typically, this means inactivating VT detection. Conversely, VF detection is typically preprogrammed at a HR that is unlikely to be achieved with exercise. This HR is noted, but VF detection and therapies are kept active to expedite treatment of exercise-precipitated VF. In the event of a ventricular arrhythmia, detection can be immediately reactivated or emergency equipment can be used that is available in the exercise laboratory. Fourth, anterior-posterior defibrillation pads (RT-2) that can be attached directly to the external defibrillator are placed on the chest to enhance rapid defibrillation in the event they are needed.

**Secondary Outcomes**—(1) Ventricular arrhythmias and ICD therapies are assessed using ICD interrogations performed at baseline, 8 weeks, and 24 weeks, and any time a subject receives an ICD shock or ATP therapy. All ICD therapies, including ATP and ICD shocks during the study, are noted and reported. Non-sustained arrhythmias are monitored. ICD interrogations are printed, saved to disk, and reviewed by two investigators. These data include the date and time of any arrhythmias; a sample of a cardiac electrogram of the arrhythmia that resulted in ICD therapy; the rate, regularity, and abruptness of onset of the tachycardia; and the response to therapy. From these data, the arrhythmia classification (VT, VF, atrial fibrillation, supraventricular tachycardia) is determined. Any temporal association between the occurrence of ventricular arrhythmias and the exercise intervention is noted.

(2) Cardiac autonomic activity is assessed using HRV with a 5-lead ECG recording over a 24-hour period using a digital Holter monitor. Standards of measurement set forth by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology are used when computing HRV.<sup>25</sup> Both time and frequency domains of HRV are calculated, including the power in spectral bands. Both the sympathetic and parasympathetic frequencies of HRV are calculated.

(3) Self-efficacy is measured by two instruments: (i) self-efficacy expectations for exercise and (ii) outcome expectations for walking. The self-efficacy for exercise scale is a 9-item scale that measures self-efficacy expectations related to one's ability to walk in the face of barriers to exercise. This measure was developed initially for sedentary adults in the community. Validity of the instrument using construct methods has been completed using hypothesis testing with patients completing versus not completing the exercise programs.<sup>26</sup> The outcomes expectations for exercise scale is a 9-item scale that assesses the perceived consequences of exercise for adults.<sup>27</sup> Both scales are formulated based on Bandura's Social Cognitive Theory and have been tested in older adult populations.<sup>28</sup>

## Discussion

One small randomized study of exercise in ICD recipients (N = 16) has been reported.<sup>29</sup> After a 12-week (1 hour/2×/week) cardiac rehabilitation program at 60%–75% of maximum age adjusted HR, significant improvements in exercise time (9:55–11:11 minutes), with reductions in anxiety and depression, were demonstrated. The change in exercise time was maintained for up to 12 weeks after the program was completed. There were no reported ICD shocks in any patient during any phase of exercise testing, supervised exercise, or home exercise. The dropout rate during exercise was 19% due to transportation challenges and forgetting appointments, and failure to complete posttest measures was 32% due to infection or worsening HF.

Exercise training has been shown to reduce the incidence of coronary artery disease (CAD) and, in persons with known heart disease, to prevent the development of future cardiac events and sudden cardiac death in persons with known heart disease.<sup>11</sup> However, little is known about the type, intensity, duration, and frequency of exercise that will aid adaptation, improve cardiac autonomic function, reduce the number of ICD shocks, and prevent recurrent arrhythmias. Evidence suggests that the intensity of exercise required to improve cardiopulmonary function and parasympathetic activity must exceed 30 minutes 3×/week.<sup>30-32</sup> The exercise intervention being tested in the current study is designed to be safe and feasible, have positive benefits on health outcomes, and yet not be too strenuous or risky to complete.



## Aerobic Exercise Conditioning

Cardiopulmonary fitness describes maximal aerobic capacity adjusted for body size and composition, and is an integrated measure of cardiorespiratory and neuromusculoskeletal function, oxygen transport and delivery, and psychological drive. Regular physical activity using large muscle groups such as walking, running, or swimming produce cardiovascular adaptations that increase exercise capacity, endurance, and skeletal muscle strength.<sup>6</sup> A number of studies have shown inverse gradients for all-cause and cardiovascular disease mortality across levels of physical activity which favors high-fitness groups, such that mortality is reduced the most in those who achieve higher levels of cardiopulmonary fitness.<sup>33,34</sup> Cardiopulmonary fitness is also associated with reduced risk of fatal and nonfatal MI as well as recurrent coronary events.<sup>35</sup> Evidence is further strengthened by the observation that physical inactivity poses a major public health risk for many diseases, including CAD.<sup>36</sup> This has prompted national organizations to recommend at least 30 minutes of moderate intensity physical activity each day (or most days).<sup>6,20</sup>

Exercise can be performed in most populations with careful management of risks, and reductions in mortality can be achieved through modest improvements in fitness.<sup>37</sup> Vigorous physical exertion has been shown to trigger sudden death or MI in persons who are the least physically active and not accustomed to regular exercise.<sup>38</sup> The general principle that the volume of exercise should be increased gradually over time is widely regarded as critical for reducing injury risk. The mechanisms for triggering sudden death or MI are thought to be related to activation of the sympathetic nervous system with vigorous exertion, rupture of vulnerable plaque, or triggering VF in susceptible myocardium.<sup>39</sup> Conversely, physical fitness would be expected to enhance electrical stability of the myocardium and protect against VF, as well as favorably modify risk factors associated with the development of atherosclerotic lesions.<sup>40</sup>

Special considerations need to be taken into account when prescribing exercise for patients with an ICD.<sup>41</sup> Implantable defibrillator patients are a heterogeneous group, some of who have LV dysfunction. It may benefit persons with an ICD to undergo a CPET before beginning a new exercise program in order to establish parameters for an individualized program, to detect exercise-induced arrhythmias, and to provide reassurance to the patient that exercise is safe.<sup>42</sup> Patients with an ICD may benefit from exercising but often are apprehensive and avoid even mild physical activity for fear of triggering an arrhythmic event, which could result in syncope and/or an ICD shock.<sup>43</sup> Sixty-three percent of patients less than age 40 with an ICD report being worried about engaging in exercise.<sup>44</sup> Learning how to monitor one's peripheral pulse will help patients determine if they are achieving and staying within a safe THR zone when exercising outside a supervised setting.<sup>45</sup>

## Therapeutic Role of Exercise in Altering Cardiac Autonomic Function

The etiological factors responsible for the development of SCA in the highest risk individuals include inherited channelopathies or structural heart disease, prior ventricular arrhythmias in the setting of moderate to severe LV dysfunction and HF, and after a MI.<sup>46</sup> The risk of SCA is associated with alterations in ANS tone in both healthy and ill individuals.<sup>47</sup> The current theories that explain the occurrence of SCA link predisposing risk factors of CAD with trigger mechanisms that result in electrical instability of the myocardium, subsequently producing VF in victims. Many of the trigger mechanisms of VF are thought to be mediated through the ANS, with sympathetic stimulation increasing and parasympathetic stimulation decreasing the occurrence of ventricular arrhythmias.<sup>48</sup>

Scientific evidence suggests a role for exercise training in altering autonomic outflow by enhancing HRV. HRV is defined as the variation in R-R intervals over a defined time

period. Quantification of parasympathetic and sympathetic nervous system activity using HRV can play an important role in understanding the pathophysiological development of SCA, and be useful clinically in prognosis, evaluation, and management.

There are no published reports that describe the exercise effects on HRV in patients with an ICD. There are few studies that examine the effects of exercise on HRV in cardiac patients; most demonstrate that exercise improves HRV as noted below. In several randomized clinical trials of aerobic conditioning in post-MI survivors, HRV has been noted to improve with exercise programs that included: (1) 5 hours of walking/week for 8 weeks<sup>49</sup>; (2) 1 hour of cycling/day, 6 times/week for 2 weeks<sup>30</sup>; and (3) 3 hours/week for 12 weeks of walking and cycling.<sup>31,32</sup> However, HRV was not found to significantly differ in one study between a 6-week supervised exercise program and a 6-week home walking program begun immediately after acute MI. Rather, HRV was found to improve in both groups regardless of type of exercise, presumably because of training effects in the home walking group and no available control group.<sup>50,51</sup>

Physical exercise has been found to improve HRV in persons with chronic HF (average EF = 24%) who exercised on a bicycle for 30 min/3 times/week for 3 months. The exercise group (N = 8) experienced a 71% increase in exercise capacity, an increase in the high-frequency power by 22%–55%, and a reduction in the low-frequency/high-frequency ratio, while the low-frequency HRV increased in both groups.<sup>51</sup> The main effect of the exercise was an increase in the parasympathetically mediated high-frequency component of HRV during daytime hours. In HF, it has been shown that the functional gains of exercising are positively influenced by the duration of the program, such that functional gains are higher after 12 weeks versus 6 weeks<sup>52</sup> and also higher after 24 weeks versus 12 weeks.<sup>53</sup>

### **Social Cognitive Theory's Application to Increasing Physical Activity in Patients with ICDs**

Bandura's Social Cognitive Theory provides two related constructs, self-efficacy and self-regulation, which structure the intervention. Self-efficacy is a person's sense of competency to perform specific behaviors, the strength of which helps determine whether activities will be attempted, the duration/magnitude of effort to overcome obstacles to successful performance, and associated anxiety and distress.<sup>13</sup> Efficacy expectations are increased through four mechanisms: (1) performance attainment (learning by doing), (2) vicarious experiences (observing others or role models), (3) verbal persuasion from expert sources, and (4) minimizing emotional arousal (reducing anxiety). Self-regulation is the incorporation of self-management strategies of self-monitoring, self-evaluation, and self-reinforcement employed to control an aspect of behavior over time.<sup>54</sup>

The roles of self-efficacy beliefs and self-regulation have been studied extensively in cardiac illness. Self-efficacy has been shown to impact performance in cardiac-related lifestyle changes, motivational level, and emotional reactions to stressful situations.<sup>13</sup> Changes in self-efficacy scores have predicted both duration and intensity of subsequent home activity and correlated with performance on treadmill tests.<sup>55</sup> Interventions aimed at enhancing self-efficacy expectations include skills mastery (e.g., walking endurance, strength training), vicarious experience (e.g., mentoring, group activities, modeling of exercise behaviors), monitoring physiological state (e.g., cognitive restructuring of experience, uncoupling of anxiety-inducing dyspnea), and verbal persuasion (e.g., peer support, validation, and reinforcement). Interventions to promote self-management/self-regulation over time include education for collaborative self-management, self-monitoring skills, self-evaluation, and self-reinforcement. In the setting of chronic cardiac disease, self-regulatory coaching from health-care providers improved self-efficacy for walking and running in patients after MI<sup>56</sup> and decreased read-missions and health-care costs in patients with HF.<sup>57</sup> Self-regulation



interventions in cardiac rehabilitation have been shown to improve exercise adherence in cardiac patients and in older adults with chronic disease.<sup>56</sup>

Self-efficacy concepts are especially relevant for individuals who have an ICD and are beginning or attempting to exercise. Knowledge about ICD functions, the parameter settings of the ICD, and one's cardiac response to exercise will inform the individual about the safety of exercising at certain levels of exertion. Confidence in one's ability to exercise without receiving an ICD shock, monitoring exercise so that it is performed safely, and benchmarking progress is particularly applicable to this population.

## Study Progress

Enrollment for the study began on 12/1/2007. We are at the mid-point of the trial with enrollment rates meeting targets. Final follow-up for the study will be completed in December 2011.

## Study Innovation

This study is the first large randomized clinical trial of aerobic exercise in patients who have an ICD for the prevention of SCA. There has been no other systematic testing of aerobic exercise known to improve cardiorespiratory fitness and parasympathetic function in this population. This exercise intervention is being implemented at home using careful monitoring techniques not currently used in clinical practice. The exercise intervention contains an aerobic training component followed by an exercise maintenance component, allowing the determination of the effects of two types of exercise training on study outcomes. The study offers the potential to make a significant change in the clinical care of patients with ICDs, where exercise is not often prescribed or encouraged. Future studies will test the effects of exercise to reduce cardiac morbidity and mortality, this study being the first step in that effort.

## Conclusions

A social cognitive theory-driven exercise intervention aimed at improving cardiopulmonary function, stabilizing cardiac arrhythmias, and reducing ICD shocks by increasing parasympathetic ANS control is described. Providing a systematic approach to the development and testing of interventions that promote better health and reduce the risk of recurrent arrhythmias are needed. If the exercise intervention is successful, it holds promise for impacting important outcomes among future ICD recipients. The study procedures will also assist clinicians in prescribing exercise, performing exercise tests, and monitoring safe exercise in patients who have ICDs. Such information is currently not available in everyday clinical practice. The exercise intervention is currently being tested using a randomized clinical trial format, results of which will be available in 2012.

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