EXAMINATION OF TREADMILL STRESS TEST EXPOSURE THERAPY FOR PEDIATRIC CARDIAC DEVICE PATIENTS (TreadExpo)

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Pediatric patients with cardiac devices report fear and anxiety associated with exertion and activity resulting in high avoidance of activities, things, or places post-device implant. Extant pediatric cardiac literature is minimal, establishing the need for improved description of the sample. The field is in need of a better understanding of the role of anxiety in physical activity and self-limiting behaviors of the pediatric arrhythmia population. Examining the strength of relationship between patient estimations for duration of exercise capacity and general anxiety, as well as cardiac specific anxiety, may provide clinicians with information to guide intervention for re-engaging this population in exertive behavior.

The primary aims of the current project were: 1) to examine feasibility of using treadmill stress tests as a clinical intervention, 2) determine the effects of a treadmill test on anxiety, and 3) examine the strength of relationship between patient-predicted treadmill stress test duration and activity, psychosocial distress, and cardiac specific distress.

Participants were recruited from an outpatient electrophysiology (EP) clinic at Texas Children's Hospital in Houston, Texas, presenting for a standard of care (SOC) exercise treadmill test (ETT). Child report of general anxiety and device specific anxiety was collected, as well as predicted and

total ETT time for six cardiac device patients aged 12-17. Analyses included descriptives, paired *t*-tests, and correlations.

Results indicated moderate feasibility for the current study design, after multiple logistical adjustments to the recruiting process, the protocol, and the personnel necessary to complete the procedures. The use of ETT as an anxiety intervention was not statistically efficacious in this sample. Statistical results indicated strong relationships between predicted ETT duration and general anxiety ($r = 0.85$, $p = 0.033$), post-ETT state anxiety and device acceptance ($r = -0.82$, $p = 0.048$), general anxiety and report of normal daily functioning ($r = -0.84$, $p = 0.036$), body image and Total ETT duration ($r = 0.85$, $n = 6$, $p = 0.032$), and post-ETT state anxiety and report of device distress ($r = -0.84$, $p = 0.036$).

In conclusion, future projects could be feasible with increased research personnel, increased engagement of clinic EPs, expanded eligibility criteria, and funding to compensate families for parking or traveling expenses. Participants and families saw inherent value in researchers' improved understanding of fears of exertion via ETT. Future research should determine the impact of number of exposure sessions necessary to impact anxiety in patients who report marked anxiety or activity avoidance.

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Table of Contents

LIST OF TABLES ..... **vi**

LIST OF FIGURES ..... **vii**

Introduction **1**

Purpose of Current Study *3*

Review of the Literature **4**

Cardiac Devices and Psychological Distress *4*

Treatment *10*

Medical Based Therapies and Diagnostics for Cardiac Patients. *15*

Feasibility Research *18*

Current Study *19*

Methods **21**

Participants *21*

Sample size *21*

Sample *22*

Experimental Design *23*

Measures *24*

Data Collection *26*

Statistical Analyses *26*

Feasibility *28*

Experience *29*

Anxiety *30*

Device Specific Anxiety *32*

Correlations *34*

Discussion **36**

Recruitment *36*

Analyses *38*

Structure of Clinic Visits *42*

Research Involving Pediatric Patients *44*

Limitations *45*

References **47**

APPENDIX A: IRB Approval Letter **56**

APPENDIX B: Pre-Treadmill Questionnaire **57**

APPENDIX C: Post-Treadmill Questionnaire **64**

LIST OF TABLES

Table 1. Psychological distress in pediatric patients with cardiac devices 5

Table 2. Recent CBT trials for cardiac device patients 11

Table 3. Plan of statistical analysis 27

Table 4. Commentary on attributes of ETT 30

Table 5. STAI-C State norms and TreadExpo sample 31

Table 6. Descriptives for TreadExpo measures 32

Table 7. FPAS-P score interpretation guide 32

Table 8. Correlational analyses 34

Table 9. Study design amendments 37

LIST OF FIGURES

Figure 1. Feedback loop examples for ICD patients 7

Figure 2. Theory of planned behavior 13

Figure 3. Power analysis screen capture 22

Figure 4. TreadExpo study design 24

Figure 5. Primary and secondary variables 27

Figure 6. Correlation hypotheses 28

Figure 8. State anxiety total scores 31

Figure 9. Device acceptance total scores 33

Figure 10. Device acceptance subscale scaled scores 33

Introduction

The diagnosis and treatment of a child with significant cardiac disease and dysfunction represents a severe medical and family stressor. This scenario may change family dynamics, via reinforcing sick roles and eliciting protective behaviors from the parents. The child may experience decreased quality of life (QOL), secondary to the limitations and boundaries that are enforced. Coping with the disease state is one process, but coping with a new device and managing adherence to medications and physical restrictions is another way in which a child's psychological health may be impacted. Post-device implant is a particularly vulnerable time for increased psychological distress, particularly in a younger population. Young people are an active population as a whole, and the implantation of this device coupled with psychological distress, may be a recipe for avoidance and withdrawal from activity, creating a cycle of reinforced reduction of activity. The current study investigated the feasibility of a brief exposure paradigm (to exertion), initial efficacy of the paradigm to decrease general anxiety in pediatric cardiac device patients, as well as the strength of relationship between patient-predicted exercise treadmill tests (ETT) duration and psychosocial variables.

Pediatric cardiology patients require a unique care plan for managing the disease state. Specific considerations include a smaller body size, variance in vasculature, congenital heart defects, and arrhythmias (Baddour et al., 2010). Disease management and prevention may include implanting a cardiovascular implantable electronic device (CIED), such as a pacemaker and/or implantable cardioverter defibrillator (ICD). The CIEDs (1) reduce symptoms associated with cardiac disease and (2) reduce risk of cardiac death. PMs have the ability to (1) sense electrical activity in the ventricle or atria and (2) employ a pacing output if the subsequent heartbeat is too slow (Wren, 2011). The most common causes of sudden cardiac arrest (SCA) in pediatric patients are cardiomyopathies, primary electrical diseases, and corrected congenital cardiac defects (Sreeram, Trieschmann, & de Haan,

2008). The ICD detects abnormal heart rhythms and delivers a life-saving shock to terminate these arrhythmias (Bardy et al., 2005). Children may receive an ICD for primary or secondary prevention of SCA, significantly reducing mortality with a post-implant survival rate of 95.8% over 10 years (Gradaus et al., 2004).

Extant literature has primarily focused on the psychosocial adjustment of adult patients to cardiac devices, however minimal research exists with a focus on pediatric and young adult populations (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000; Salmoirago-Blotcher & Ockene, 2009; Sears & Conti, 2003; Sears et al., 2007). Pediatric cardiac patients and their families must cope with managing a disease state that involves symptoms associated with exertion, pacing, and risk for SCA, potential defibrillation (in ICD patients), possible physical activity limitations, and body image concerns. Risk factors for poor psychological outcomes in CIED patients include decreased premorbid functioning, both psychological and physical, having poor conceptualization of the disease state and the cardiac device, being young in age (< 50), being a woman, other medical comorbidities, and having been exposed to frequent ICD shocks (Sears & Conti, 2003). Latal and colleagues (2009) reviewed the literature on psychological and QOL parameters in children/adolescents with congenital heart defects and found that there was a larger proportion of children that experienced psychological distress in the contexts of *adjusting to the disease* and difficulties increase with greater disease severity (Latal et al., 2009).

Pediatric patients with cardiac devices report fear and anxiety associated with exertion and activity (DeMaso et al., 2004; Koopman et al., 2012; Sears et al., 2011). This anxiety is so pervasive that 84.7% of children with ICDs report avoiding activities, things, or places post-device implant (Sears et al., 2011). The effect that avoiding such activities, things, or places has on the child is unknown at this time. However, examining and establishing brief and practical treatments of

pediatric patients with psychological distress due to cardiac devices may reduce anxiety and re-establish a quality of life necessary for thriving with heart disease as a young person.

Purpose of Current Study

Currently, pediatric patients with cardiac devices report fear and anxiety associated with exertion (DeMaso et al., 2004; Koopman et al., 2012; Sears & Conti, 2002; Sears, Amant, & Zeigler, 2009; Sears et al., 2011). ETT is a clinic-based test to determine cardiac function under exertion, but may have broader potential benefits. The ETT could serve as a practical form of exposure therapy in pediatric patients with cardiac devices, where patients experience and master fear of exertion. Exposure therapy is an empirically based treatment for anxiety and has yet to be used in this population in the form of an exercise treadmill test. The primary aims of the new project were: 1) to examine feasibility of using treadmill stress tests as a clinical intervention, 2) determine the effects of a treadmill test on anxiety, and 3) to examine the strength of relationship between patient-predicted treadmill stress test duration and activity, psychosocial distress, and cardiac specific distress.

Review of the Literature

Cardiac Devices and Psychological Distress

Implantable cardiovascular devices are surgically implanted in a patient to identify and terminate, or pace, a heart out of life-threatening arrhythmias. The effect of ICD therapy has been shown to reduce mortality when compared to the effect of treatment as usual (antiarrhythmic drug therapy) (Kuck, Cappato, Siebels, & Ruppel, 2000; McAnulty et al., 1997). However, literature suggests that patients with cardiac devices have an increased risk for psychological distress, including anxiety, depression, panic attacks, anger, post-traumatic stress disorder (PTSD), and adjustment disorder, when compared to the general population (Lemon & Edelman, 2007; Sears et al., 2011; Sola & Bostwick, 2005).

Two of the most common psychological disorders experienced within the cardiac population are anxiety and depression, with over a quarter of all ICD patients presenting with symptoms consistent with anxiety or depressive disorders (Dunbar et al., 2012b). The presence of both anxiety and depression in the cardiac population may be associated with patient QOL, education, and familial situation, particularly when examining younger patients (DeMaso et al., 2004; Dunbar et al., 2012a). Extant literature highlights significant anxiety in device patients, compared to a reference group (Koopman et al., 2012) including device specific worries of "receiving shocks" and being "able to do less" (DeMaso et al., 2004). Depression findings vary in pediatric cardiac device literature (DeMaso et al., 2004; Koopman et al., 2012; Webster et al., 2014). Table 1 presents the most recent studies (past 10 years) of pediatric patients with cardiac devices and the respective psychosocial findings. In general, these studies indicate that pediatric device patients, when compared with normative groups, report greater psychological distress and lower QOL.

Table 1. Psychological distress in pediatric patients with cardiac devices

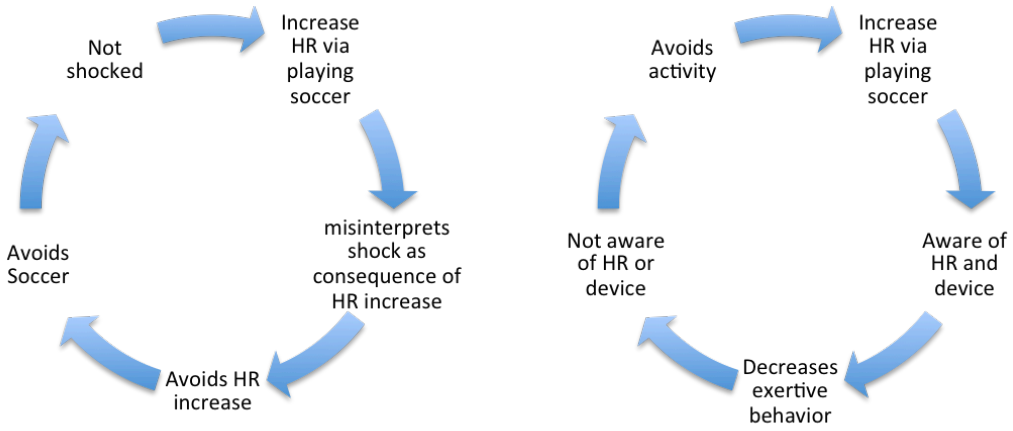
Study	*N*	Age range (Mean)	Selected Measures	Findings Summary
Webster and Colleagues (2014)	166	6-20	*Schedule for Affective Disorders and Schizophrenia in School Aged Children and Adolescents-Present and Lifetime Version (K-SADS-PL)* *Child Health Questionnaire-50*	• ICD patients reported higher rates of anxiety diagnoses (Current = 27% and Lifetime = 52%) than did PM patients (Current = 11% and Lifetime = 32%). • Depression rates did not differ between groups. • Device patients reported lower physical QOL than healthy counterparts.
Cheng and Colleagues (2013)	27	8-18 (M = 13.59)	*PedsQL- Child* *PedsQL-Parent* *Survey of Children's Social Support (SOCSS)*	• Patients reported lower QOL than normative sample across PedsQL domains (psychosocial, school, social, emotional, physical functioning). • Parents reported lower QOL than healthy normative sample across domains of QOL, except physical health (p = 0.059). • Social support was positively correlated with physical, social, psychosocial, and Total QOL scores.
Koopman and Colleagues (2012)	30	9 – 23 (M = 16.3)	*Symptom Check List -90 Revised (SCL-90-R)* *Worries About ICDs – Short Form (WAICD - SF)*	• Patients 13+ years reported higher anxiety, depression, and sleep disturbance than normative sample. • No differences between male and female patients. Greatest worries included: • *"I am afraid of being alone if the ICD fires and I need help"* (66%) • *"I worry about how I will feel when the ICD fires"* (59%) • *"I am nervous that if I exercise my heart might start beating faster and make the ICD fire"* (55%)
Czosek and Colleagues (2012)	173	8-18 (PM M = 12.9; ICD M = 13.8)	*PedsQL* *Pediatric Quality of Life Inventory (PCQLI)*	• Cardiac device patients reported lower QOL than healthy peers. • PM and ICD patients reported lower QOL than bicuspid aortic valve patients.
Sears and Colleagues (2011)	58	8 -18	*Pediatric Quality of Life Inventory-Child Version (PedsQL)* *PedsQL-Parent Version* *The ICD and Avoidance Survey*	• Device patients reported lower QOL (psychosocial and physical health domains) compared to healthy norms. • Device patients reported lower psychosocial health compared to a chronic health condition population. • Parents reported lower QOL (psychosocial and physical health domains) compared to a

				healthy sample. • Parents reported lower QOL (psychosocial and physical health domains) compared to a chronic health condition population. • Female patients were more likely to avoid places than male device patients.
DeMaso and Colleagues (2004)	20	9 – 19 (M = 14.8)	*Child Health Questionnaire-50 (CHQ-50)* *Child Health Questionnair-87 (CHQ-87)* *Impact on Family Scale (IFS)* *Revised Children's Manifest Anxiety Scale (RCMAS)* *Reynolds's adolescent Depression Scale (RADS)* *WAICD*	• Illness severity was not associated with psychosocial functioning • QOL report was associated with psychological distress • Caregivers reported lower perceived QOL across domains (i.e. physical, social-physical, and general health) compared to normative group. • Device patients reported depression at lower levels than clinically depressed group. • Global worry items: • *Receiving shocks* (50%) • *No worries (20%)* • *ICD will break* (10%) • *Able to do less* (10%)

Anxiety. Many theorists have postulated how anxiety is initiated and maintained in humans. For example, Skinner suggested that the majority of human behaviors develop due to avoidance of unpleasant events (Skinner, 1957). Accordingly, the link between avoidance and anxiety is established, whereby avoidance decreases anxiety and thus avoidance is reinforced. Another model, Mowrer's two-factor model (Mowrer, 1947) of anxiety, may provide greater insight to the fear-inducing pathway for cardiac device patients. Mowrer presents fear and anxiety as a conditioning phenomenon where emotional symptoms are maintained with avoidance. Fears are learned when a signal is presented adjacent in time to a punishment (Mowrer, 1956). The logic that follows the supposition of these theories is that avoidance decreases anxiety and thus avoidance is reinforced. For example, if an individual with an ICD engages in avoidance of increasing heart rate and simultaneously does not receive an ICD shock, he/she is reinforced for their avoidant behavior. Thus, anxiety and avoidance exist in a positive feedback loop, where avoidance of increasingly exertive

behaviors is possible and probable in the pediatric cardiac device population. Figure 1 details examples of heart rate and avoidance mechanisms.

Figure 1. Feedback loop examples for ICD patients



Research supports a cognitive model for the presentation of psychological distress and anxiety (Clark, 1986; Lemon, Edelman, & Kirkness, 2004), which incorporates activity avoidance. Men and women reported avoiding activities at the same rate, with studies showing 39% of patients avoiding exertion (Lemon et al., 2004). Patients reported fear of heart rate increase, with the potential threat of leading to pacing or ICD shock, being the most prominent reason for avoiding activities. The cognitive model would state that once the individual is aware of the cardiac device, he is likely to misinterpret somatic symptoms (i.e. heart beat, dizziness, shortness of breath), also cardiac symptoms, as dangerous. This common behavioral cycle of anxiety is reinforced each time a patient avoids strenuous activity.

Anxiety is prevalent in the cardiac population, affecting roughly half of patients with a cardiac device (Bilge et al., 2006; Dunbar et al., 2012b). Anxiety that persists beyond one year occurs in just over half (54%) of the population (Dunbar et al., 2012b). This distress may include decreased social interactions, worry and avoidance of physical activity and sexual activity, body image concerns with

regard to scarring and device profile, or the way the device projects from the chest (Dubin, Batsford, Lewis, & Rosenfeld, 1996). These negative internal factors serve to maintain the young patient's maladjustment.

A major differentiating factor of psychological distress in ICD patients from pacemaker patients is the presence of shock, and the anticipatory anxiety that may develop. Sears et al. (2008) define shock anxiety as "the fear or anticipation of an ICD shock that often results in increased heart-focused anxiety symptoms, as well as the development and maintenance of avoidance behaviors to minimize patients' perceived risk of shock" (p. 242). Shock anxiety can specifically be targeted in treatment with protocols aimed toward stress reduction and management (Sears et al., 2007). These chronic and perpetuating cycles of misinterpreted somatic symptoms, emotional distress, and anxiety may also serve a precipitating factor for depressive symptoms (Nemeroff et al., 2006).

Depression. Clinical depression rates in the cardiac population are consistent with that of other chronic disease populations in adult literature. The symptoms associated with congenital heart disease, including fatigue and shortness of breath (SOB), may mimic symptoms of depression or anxiety. Medications that the patient may be prescribed can also have an effect on lethargy and heart rate. The patient's perception of these effects determines the reaction and risk for psychological distress. It is possible for symptoms to be subclinical, but persistent.

Depression rates in the cardiac population range from 34% to 41%, and subsequently affect patient outcomes (Sears & Kirian, 2010). Patients with previous shock history and/or congenital heart disease are at greater risk for depressive symptoms and significant decrease in QOL (Jacq et al., 2009). Currently, there is a dearth of literature examining the prevalence of psychological distress in children and adolescents with cardiac devices. Pediatric patients report clinical depression cutoff scores at rates of 15%, with minimal patients meeting clinically significant anxiety (DeMaso et al.,

2004). However, overall study results that indicate age as a risk factor for depression in general cardiac populations have been mixed. Increased understanding of anxiety in this population may enable better prediction of those who are more likely to develop depressive symptoms.

Quality of Life (QOL). Pediatric cardiovascular disease patients are at greater risk for decreased QOL compared to a normative healthy data (Cheng et al., 2013). Overall, the general ICD population report avoiding "strenuous sports" and "running a short distance" at rates of 80.4% and 74.3%, respectively (Cutitta et al., 2014). When questioned further about reasoning for avoiding these activities, up to 16% reported increase in heart rate, dependent on level of exertion. The sensation of increased heart rate during activity as well as increased SOB may affect the experience of physical activity, diminishing pleasure derived from activity.

Pediatric device patients may be at a greater risk for decreased QOL due to their premorbid activity-filled lives. Patients may be more likely to decrease or avoid activity due to physiological symptom presentation. Koopman and colleagues (2012) questioned their study participants to examine the issue of activity avoidance and found that 55% of participants were concerned about receiving an ICD shock if they exercised, or generally increased heart rate.

The concern that the ICD will fire is rated a top concern among pediatric ICD patients (DeMaso et al., 2004), resulting in high levels of activity avoidance. Sears et al. (2011) found that 84.7% of children with an ICD reported avoiding activities, things, or places post-implant. However, the extent to which pediatric pacemaker patients are affected and avoid activity, places, or things is unknown at this time. In sum, pediatric patients are at great risk for avoiding activity and experiencing a decrease in QOL and may also exhibit decreased adjustment and acceptance of device.

Device Acceptance. Patient device acceptance is an amalgam of "perception of the device, the perception of possible discharge, changing body image, changes in lifestyle, patient and family

perceptions, home going concerns, and fear of complications" (Lüderitz, Jung, Deister, & Manz, 1994). The American Heart Association (AHA) recently (Dunbar et al., 2012b) released a statement of psychosocial concerns for which to target in pediatric clinical cardiology. Among the treatment concerns were rejection by peers, activity restrictions, *low to non-acceptance of the medical device*, thoughts of device removal, and possible suicidal ideation (Dunbar et al., 2012b).

Device acceptance has been operationalized by The Florida Patient Acceptance Survey (FPAS) and entails four factors to obtain a global picture of acceptance (Burns, Serber, Keim, & Sears, 2005). The four empirically derived factors are: return to function, device-related distress, positive appraisal, and body image concerns. Recently, psychological factors were strongly related to device acceptance, whereas clinical and medical factors were found to be significantly less indicative of patient reported acceptance (Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008).

Initial research with the FPAS indicated that patients with pacemakers indicated higher levels of device acceptance than did their ICD counterparts (Burns et al., 2005). This finding brings into question the differentiating factors associated with these two device categories. Experience and threat of ICD shock is an essential difference between the two groups. In an ICD specific population, repeated shock exposure also has a significant effect on the acceptance of the device and QOL of the patient (Irvine et al., 2002; Passman et al., 2007; Sears & Conti, 2003). The FPAS has not been used in pediatric populations, but likely has value to evaluate device-specific QOL outcomes. Device acceptance in pediatric patients may be even more important because of the longer duration of device use by pediatric patients.

Treatment

Different approaches to treatment of psychological distress and medical programs have been studied among patients with implantable medical devices. However, extant research of psychological

treatments is not exhaustive with regard to specific populations. In particular, there are no studies examining treatment of psychological distress among pediatric cardiology patients. Table 2 introduces recent interventions developed for the cardiac device population.

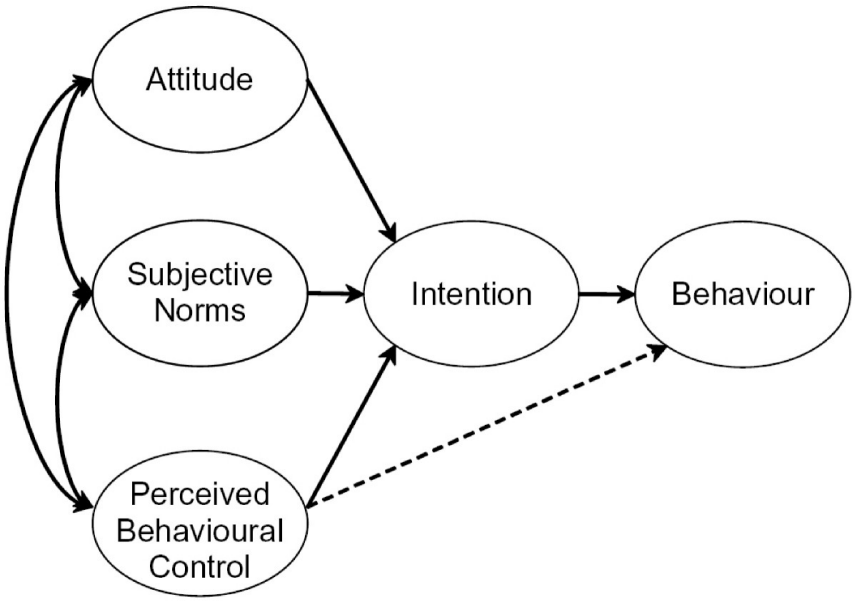
Table 2. Recent CBT trials for cardiac device patients

Author	Sample	Intervention	Findings
Irvine and Colleagues (2011)	*N* = 193 ICD general patients Mean age = 63.2	**Tx group:** CBT x 8 telephone, psychoeducation, mindfulness, and PMR **Control:** usual care	• Avoidance symptoms reduced in treatment group. • Women in treatment group reported greater decrease in psychological distress.
Vazquez and Colleagues (2010)	*N* = 29 female ICD patients Mean age = 55.6	**Tx group:** 1-4 hour female-specific psychosocial tx **Control:** wait-list control	• Shock anxiety scores (FSAS) decreased in intervention group. • Device acceptance scores (FPAS) increased in intervention group.
Kuhl and Colleagues (2009)	*N* = 30 Mean age = 57.44	**Tx group:** Patient-Assisted Computerized Education for Recipients (PACER) - patient-paced educational tool **Control:** usual care	• No differences in knowledge between groups. • Patients with recent implantation (< 3 months) reported greater knowledge (p = .01), greater shock anxiety (p = .02), and decreased patient acceptance (p = .04).
Sears and Colleagues (2007)	*N* = 20 ICD pts with $\geq$ 1 shock Mean age = 59.8	**Tx group:** ICD Shock and Stress Management Program (SSMP) - 90 min CBT x 6 weeks for stress management **Control:** one-4 hour stress management workshop	• Treatment group reported reduction in State Trait Anxiety Inventory (STAI) scores at 2 month follow-up, compared to control group (p = .03). • Patient acceptance scores did not differ between groups.
Fitchet and Colleagues (2003)	*N* = 16 Mean age = 58	**Tx group:** 12 weeks of individually tailored cardiac rehabilitation therapy **Control:** usual care	• Cardiac rehab group exhibited increased exercise time after 12-week treatment (p = 0.001). • Treatment group reported lower Hospital Anxiety and Depression Scale (HADS) scores (p = 0.001). • ICD group did not experience shock during therapeutic exercise.

Cognitive behavioral therapy (CBT). CBT based treatment has been utilized for children with chronic illness to aid in the adjustment and maintenance of psychological well-being (Thompson, Delaney, Flores, & Szigethy, 2011). Sears and colleagues (2007) and Fitchet and colleagues (2003) conducted studies most similar to an exposure treatment. The ICD Shock and Stress Management Program (SSMP; (Sears et al., 2007)) was developed for the ICD population as a standardized way to optimize ICD patient QOL in adults. This protocol was developed as a 6-week treatment session to reduce anxiety and depression, with secondary aims to increase QOL and device acceptance. The study showed a significant decrease in anxiety and cortisol levels with an increase in patient device acceptance. This treatment relies on a cognitive behavioral therapy (CBT) based approach, incorporating education and strategies to reduce psychosocial distress. Overarching goals of the treatment are to provide relaxation and stress management techniques, increase patient acceptance, and re-engage the patient in pleasurable activity. The primary aim of this treatment was to reduce distress and avoidance, with the patient engaging in relaxation techniques in a safe environment, somewhat similar to exposure treatment.

Cognitive conceptualizations of patients' ability to complete exertion activities are likely affected by fear. Functional cardiac anxiety may be similar to functional pain patients, whereby quality of life, therefore daily activities and relationships, are affected by the presence of this symptom (Youssef, Murphy, Langseder, & Rosh, 2006). The Theory of Planned Behavior (TPB) model (Figure 2) establishes a link between perceived behavioral control, or self-efficacy, intentions of an individual, and lastly, the behavioral outcome (Ajzen, 1991). Self-limiting behaviors and psychological symptomology are established in the cognitive construction of self-efficacy. Self-limiting and avoidance of exertive activities appears common, however very little is known about these behaviors in this population.

Figure 2. Theory of planned behavior



Note: Graphic reprinted from (Ajzen, 1991)

Fitchet et al. (2003) conducted an intervention trial consisting of 12 weekly, individually tailored cardiac rehabilitation sessions for adult ICD patients. This research highlights the benefits of exercise training with significant findings that exercise time increases after completion of an exercise program (Fitchet et al., 2003). Depression ($p = 0.001$) and anxiety ($p = 0.001$) scores also improved compared to the control group (Fitchet et al., 2003). Lastly, no incidents of ICD shock were reported during actual exercise training, providing further evidence that exertive behaviors do not put patients at increased risk for device discharge. The value of these studies in a pediatric population is unknown, but is the next logical step to increase patient care of pediatric patients.

Exposure therapy. Exposure therapy was developed with the methodology of "patients intentionally confront[ing] feared, but otherwise safe, objects, situations, thoughts, sensations, and memories with the goal of reducing fear" (Marks, 2002). All exposure therapies are based on the theory of learning and extinguishing behavior. The pediatric literature tends to focus on behavioral therapies as a method of engaging the patient in overt behaviors that can be reinforced, a facet of

learning theory. Learning theory would purport that if an individual were continuously exposed to a perceived threat or feared situation, eventually the reactionary behavior (i.e. avoidance and anxiety) will extinguish, or cease. Therefore, exposure can assist in the reduction of the amount or degree of avoidance behavior. This causes a reduction in anxiety and therefore avoidance via extinction. With this rationale, all forms of exposure therapy would prove to have a psychological benefit, via reducing avoidance, the very behavior that maintains anxiety.

Traditionally, anxiety therapy would incorporate a hierarchy of stimuli producing an anxiety response, which are tested via interoceptive exposure (Foa, 2011). The overarching treatment goals for anxiety therapy via exposure are to "reduce pathological fear and related emotions" (Foa, 2011). The *in vivo*, or in person, exposures simultaneously activate a fear response in a safe environment which "disconfirms" the patient's predicted, catastrophic outcome. A new learning experience is formed that denies the original pathological response (e.g. fear and avoidance).

Exposure therapy has shown large effects when compared to control conditions (i.e. psychotherapy placebos relying on therapeutic factors) on both primary (i.e. PTSD symptoms) and secondary (i.e. general measures of anxiety and depression) measures (Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010). Due to the widespread findings of positive outcomes post-exposure therapy and the efficacy of treatment, the Veteran's Administration Office of Mental Health Services has indicated exposure to be the gold standard in trauma therapy (Nemeroff et al., 2006; Rauch, Sheila, Eftekhari, & Ruzek, 2012). Traditional exposure therapy incorporates psychoeducation, in vivo exposure, imaginal exposure, and emotional processing into a 9-12 session package (Powers et al., 2010). The patient is literally exposed to anxiety provoking ideas, things, or actions to reduce overall arousal. Rauch and colleagues (2012) report that exposure therapy is readily adaptable to any

environment or population and call for exposure practice to be more widely available for a range of trauma and anxiety patients.

Single-session exposure treatment has been examined with pediatric patients aged 7-17 (N = 60, (Mean age = 11.7, SD = 2.8) (Öst, Svensson, Hellström, & Lindwall, 2001). Exposure was utilized as the treatment package due to avoidance behaviors in children with phobias. Chronic avoidance develops as a result of negligible opportunities to learn that engagement in specific behaviors is safe. Participants were randomized to either (1) 1-3hour session exposure treatment alone, (2) 1-3 hour session exposure treatment with caregiver present, or (3) wait-list control group for 4 weeks. Exposure was conducted using a traditional hierarchy of situations and eliciting subjective units of distress (SUDs) throughout each individual exposure, until SUDs had decreased by at least 50% (Öst et al., 2001).

Pre and post-intervention anxiety, depression, phobias, and anxiety sensitivity assessment indicated that treatment group reported significantly improved outcomes than did the wait list control (WLC). However, once treated, the WLC did not differ significantly from the original treatment groups and data were collapsed across groups for further examination. The single-treatment session effects were robust at one-year follow up, with 90% of patients indicating significant reduction of symptom and functional impairment (Öst et al., 2001). With this evidence for an efficacious single-session exposure treatment, it would follow that similar benefits may be captured by exposing pediatric patients with cardiac devices to an ETT.

Medical Based Therapies and Diagnostics for Cardiac Patients.

Opportunities for exposure treatment in clinics exist as part of a standard medical therapy. Several treatment and diagnostic options for adult cardiovascular patients are in current practice, but

few of these are available or appropriate for pediatric patients. Below is a review of the predominately adult programs.

Cardiac rehabilitation. Cardiovascular rehabilitation is a multi-disciplinary program, including psychologists, nutrition, and exercise physiologists, offered by many heart institutes after major cardiac events. Major cardiac events can include myocardial infarction, SCA, device implantation, or a diagnosis of chronic obstructive pulmonary disorder (COPD). The program is designed to be weekly and brief, allowing the patient to engage in approximate successions of physical activity in a safe, responsive environment. Cardiac rehab programs support patients through their recovery and re-conditioning, with support for increase in psychological wellbeing (Fitchet et al., 2003). The downside to most cardiac rehab programs is the lack of patient diversity, with a majority of participants being older (Cooper, Jackson, Weinman, & Horne, 2002). Due to the makeup of the classes, this option is not preferable, or possible foremost, for pediatric patients. The model is valuable, but the environment and social groups are an incongruent fit for the young, and seemingly healthy pediatric patient.

Exercise training. Exercise training is a form of reconditioning the body during which multiple body systems, including cardiovascular, autonomic, and skeletal systems benefit (Movahed, Cao, Pitzalis, & Movahed, 2013). Research has also found benefits relating to pulmonary functioning and reversal of the inflammatory response (Movahed et al., 2013). The overall physiological impact of exercise training may increase QOL and exercise tolerance (Lloyd-Williams, Mair, & Leitner, 2002).

Exercise training has been hypothesized to have an effect on survival of patients with heart failure (Piepoli, Davos, Francis, Coats, & ExTraMATCH Collaborative, 2004). Exercise training reduces the disabling symptoms associated with heart failure (i.e. SOB, dyspnea), but is often

underutilized because morbidity outcomes are often not as provocative as mortality outcomes. This simple form of clinical therapy may also reduce hospital readmission in patients across disease states (Piepoli et al., 2004). Once again, this type of therapy may benefit pediatric patients, but it has never been studied.

Exercise stress testing or exercise treadmill tests (ETT). Exercise stress tests were developed to identify coronary insufficiency and exertion in patients with possible heart disease (Bruce, Blackmon, Jones, & Strait, 1963; Bruce, Blackmon, Jones, & Strait, 2004). The Bruce protocol consists of 7 stages of testing, increasing in speed and platform grade, with each stage lasting 3 minutes. Throughout the testing, heart rate and perceived exertion are sampled, as well as blood pressure at the end of each stage. The test score is total time spent exercise testing, in minutes. Exercise stress testing is considered safe for the pediatric population, even if the patient carries a high-risk category diagnosis (Freed, 1981). This is largely in part due to the emergency equipment (i.e. defibrillator, oxygen) and medical professionals that are present during the diagnostic session. Few contraindications for high-risk patients exist. Much of the exercise stress testing data indicates that the benefits of the testing outweigh the risks. For instance, a child has the ability to experience physical exertion in a safe environment, and test physical limits before physicians recommend possible physical restrictions. Currently, there are no recommendations for frequency of scheduling diagnostic ETTs in the pediatric population.

There are several stress test termination guidelines, not specific to pediatrics. These include: (1) decrease in ventricular rate with increasing workload. This is evidenced by fatigue, dizziness, or other symptoms indicating insufficient cardiac output, (2) failure for heart rate to increase with exertion, (3) persistent decrease in systolic blood pressure with increased exertion (4) severe hypertension, (5) intolerable dyspnea, (6) intolerable symptomatic tachycardia, (7) progressive drop

in oxygen saturation (from resting saturation), (8) presence of flat or downward sloping ST-segment depression in electrocardiogram (EKG), and (9) increase in ventricular ectopy (premature ventricular contractions or premature atrial contractions) with increasing workload (Paridon et al., 2006). These guidelines provide for cardiovascular diagnostics to be completed with vigilance.

Given the results from the Sears group (2011) and the Koopman group (2012), along with evidence supporting cardiovascular rehabilitation for cardiac patients, it would follow that exposure treatment could reduce anxiety and increase QOL. Being that exercise treadmill testing would increase a patient's heart rate (exposure), the patient would need to become comfortable (habituate) with heart rate increase at each speed/incline escalation. The individual treadmill test would allow for the subject to experience anxiety elevation and stabilization in a safe, controlled environment, contributing to extinction of the anxiety response. Over time this anxiety elevation will reduce (extinction) when the heart rate increase is not followed by an adverse event (i.e. being shocked, syncope, dyspnea, etc.) or escape from exertion.

Feasibility Research

Meta-research among feasibility and pilot studies is a relatively novel area of literature. Literature points toward the National Institute of Health Research in the United Kingdom to provide an operational definition of feasibility studies (Arain, Campbell, Cooper, & Lancaster, 2010). Feasibility studies are designed to answer the primary question of "Can this study be done?' (NIHR, 2016). Feasibility studies are often the precursor to pilot studies; trialing pieces of the gestalt in order to problem solve any foreseen challenges (NIHR, 2016). Feasibility studies are not expected to have large sample sizes or to produce sufficient power for hypothesis testing (Bowen et al., 2009; NIHR, 2016; Tickle-Degnen, 2013); the goal is to provide descriptives and basic understanding of the research flow to produce the future studies. Arain and colleagues (2010) identify several key findings

which are typically reported in feasibility research, (1) standard deviation of the outcome variable, (2) participant agreeableness to randomization process (if study is a randomized control trial), (3) clinician agreeableness to recruit participants, (4) a report of eligible patients, (5) characteristics of the proposed outcome variable, and (6) response rates to questionnaires. Arain and colleague (2010) propose a sample large enough to "estimate the critical parameters (e.g. recruitment rate)" in lieu of traditional power analysis.

Current Study

There are currently no evidence-based psychological treatments to improve anxiety in children with cardiac devices, and few opportunities for exposure via standard medical treatment exist for this population. This project aimed to examine the feasibility of utilizing a standard of care (SOC) diagnostic tool as a psychological intervention in the future. The current study incorporated an evidence-based approach as a patient is exposed to cardiac symptomatology (i.e. increased heart rate and pulmonary functioning) in a safe environment, furnished with medical personnel and emergency equipment (i.e. defibrillator and oxygen). Essentially, this study utilized PE techniques, replacing the conventional "trauma memory," thoughts, feelings, and emotions surrounding the anxiety provoking stimuli, with cardiac device fear as the exposure target (Foa, 2011). The current project utilized pediatric psychology, anxiety intervention literature, and adult cardiac device intervention literature to develop a cardiac exposure-based intervention.

Specific aims. The purpose of this feasibility study was to examine the use of SOC ETT as a means of exposure therapy to reduce anxiety for pediatric cardiac device patients. Young patients with implanted cardiac devices are at the greater risk for psychological distress more than any other group (Sears & Conti, 2002). This study was based on a commonly used intervention (exposure therapy) for anxiety disorders and provided insight to use of a brief, single-session intervention to

reduce anxiety among a pediatric cardiac device population. The primary aims of the project were 1) to examine the feasibility of using the treadmill stress test as a clinical intervention, 2) to determine the effects of a treadmill test on anxiety, and 3) to examine the strength of relationship between patient-predicted treadmill stress test duration and activity, psychosocial distress, and cardiac specific distress.

Methods

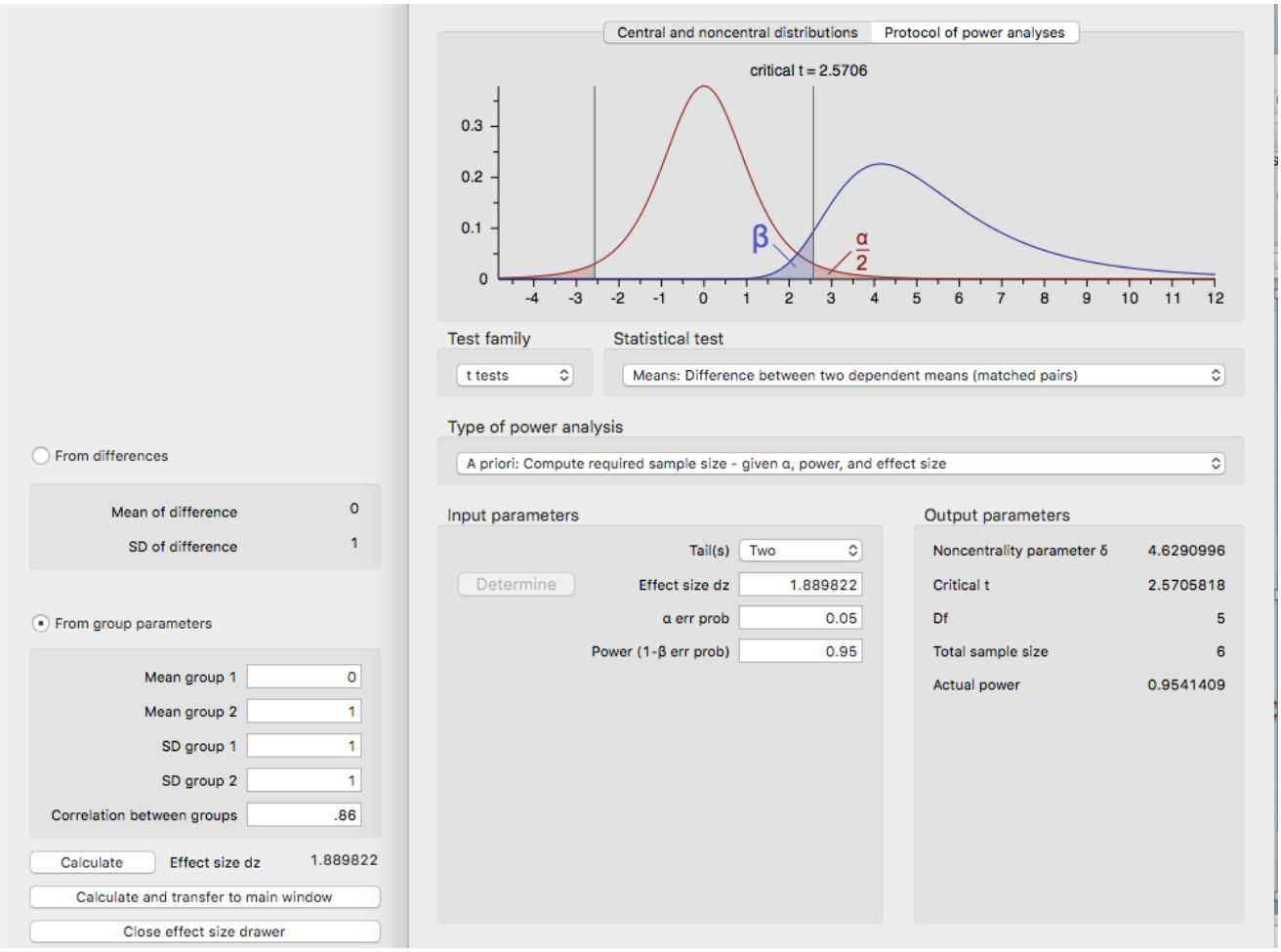
Participants

After institutional review board (IRB) approval from Baylor College of Medicine (affiliated institute of Texas Children's Hospital (TCH)) a physician or psychology intern approached the pediatric patients and their caregivers at TCH. We recruited patients who were post-implant of a pacemaker or ICD, ranging in age from 12 to 17. Justification for the sample size follows. Consent and assent was obtained from the individuals and their caregiver to proceed with the study. Study participation did not accrue extra cost to the patient's family, as the ETT was scheduled as a SOC. No remuneration was provided to participants. Referral sources for individuals found to be experiencing extremely high levels of distress were available if the family inquired. There were no high-risk incidents to report.

Sample size

An a priori power analysis was conducted to determine how many cases were sufficient to have a 95% chance of detecting an effect of a specified size with the desired amount of power. Though not a requirement for feasibility studies (Bowen et al., 2009; NIHR, 2016; Tickle-Degnen, 2013), the power analysis was conducted to establish statistical methods that would likely be used in a preliminary pilot study. The test-retest correlation for the STAI-C ranges from 0.86 – 0.95 (Spielberger & Edwards, 1973). Participants ranging from 12-17 years of age were recruited, so the alpha documented for adolescents ($\alpha = 0.86$) was employed for this power analysis. When calculated using the G*power program, 6 cases were suggested to achieve a power of 0.95 and an effect size of 1 (Figure 3).

Figure 3. Power analysis screen capture



Sample

Parents of pediatric patients and their children between ages 12-17 years attending an outpatient electrophysiology device clinic appointment at Texas Children's Hospital in Houston, Texas with a scheduled ETT were invited to participate. Participants were excluded if they lacked fluency in English, had a physical or intellectual disability that precluded questionnaire completion (e.g., significant developmental delay), or had insufficient reading ability. A Spanish short form for consenting was available for Spanish speaking parents with English speaking children. Participants included 6 pediatric outpatients (Mean age = 15.6 years; *SD* = 2.37; 50% male). Participants self-

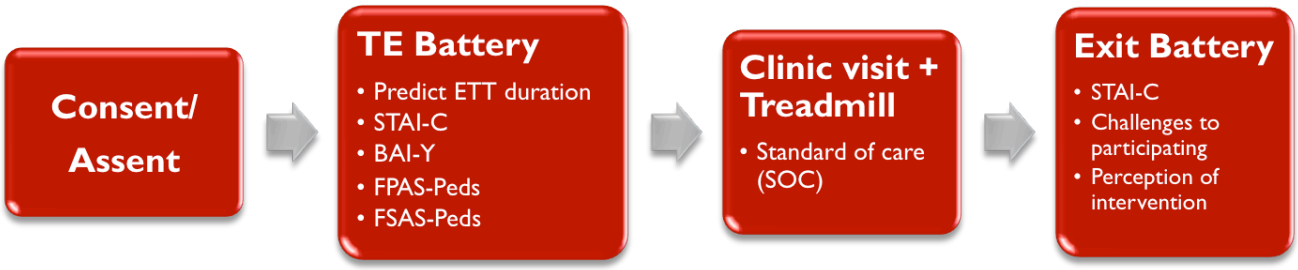
identified as Hispanic (33.3%), White non-Hispanic (50%), and Asian or Pacific Islander (16.7%). Patients were required to have an implanted device (ICD =3, PM = 3). Mode time living with implanted device was longer than 1 year (66%). Comprehensive medical record review including medication was not available to our research team, however to our knowledge, none of the participants were on anxiolytic medication. Diagnoses included channelopathies, such as Atrioventricular Block and Long QT Syndrome.

Experimental Design

A one-group pre-test post-test design was used to examine descriptives of this pediatric population and feasibility of implementing the proposed intervention. The primary aim of this study examined feasibility data. Secondary endpoints were to survey the effects of a treadmill test on anxiety, and to examine the strength of relationship between patient-predicted treadmill stress test duration and activity, psychosocial distress, and cardiac specific distress. All participants of the study received the intervention.

Figure 4 provides a flow diagram of the current study. A full battery was administered prior to the ETT. Participants were then asked to complete the SOC ETT. Immediately following completion of the ETT (within 5 minutes), participants completed a post-battery. The pre and post-batteries contained a measure of state anxiety (STAI-C). The post-battery also assessed broad patient/consumer value of the ETT.

Figure 4. TreadExpo study design



Measures

TreadExpo demographics questionnaire. The TreadExpo Demographics Questionnaire was used to capture participant age, gender, ethnicity/race, and educational status. The questionnaire also included patient-prediction of duration of the ETT.

State-trait anxiety inventory for children (STAI-C) - State. The STAI-C is a 40-item, self-report measure is used to examine state and trait anxiety in children (Spielberger & Edwards, 1973). Traditionally this measure is used in a population ranging from age 8 to 12 years. However, this measure has been validated in an adolescent population and may be more useful for screening purposes than the adult version of the STAI (Hoehn-Saric, Maisami, & Wiegand, 1987; Kirisci, Clark, & Moss, 1997). The reliability coefficients were calculated for State Anxiety Present ($\alpha = .87$) and State Anxiety Absent ($\alpha = 0.89$) (Kirisci et al., 1997) indicating desirable reliability in an adolescent population. The State Anxiety portion of this assessment was used for the current study.

Beck youth inventories - II (BYI-II). The Beck Youth Inventories – Second Edition were developed by Beck, Beck, & Jolly (2001) as a brief, 5 minute, self-report measure for emotional and behavioral issues in patients aged 7-18 years. All inventories measure symptoms the child or adolescent has been experiencing in the past two weeks. Separate inventories include assessment for depression, anxiety, anger, disruptive behavior, and self-concept. This study utilized the anxiety

inventory. The *Anxiety Inventory (BAI-Y)* examines worries about performance, the future, negative reactions of others, and other physiological symptoms that may be classified as anxiety. These inventories were developed based on pathological criteria as indicated by the Diagnostic and Statistical Manual for Mental Health Disorders- Fourth Edition (DSM-IV).

The modified Florida patient acceptance survey – Pediatric (FPAS-P). The Florida Patient Acceptance Survey (FPAS) was developed to measure patient overall acceptance of cardiac devices (Burns, Serber, Keim, & Sears, 2005). The FPAS is an 18-item measure, with four factors, including Return to Function, Device-Related Distress, Positive Appraisal, and Body Image Concerns. The FPAS demonstrates good internal consistency ($\alpha = 0.83$), as well as convergent, divergent, and discriminant validity compared to existing measures of QOL, symptoms, depression, and anxiety. The scale provides a total score that indicates a patient's overall acceptance of the device and the subscales may provide treatment targets. This scale was developed for an adult population ($M = 69$ years) and for the purposes of this study; item number 9 was edited (*I have continued my normal sex life*) to "I have continued kissing loved ones and/or holding hands." This item is considered a "filler item" and is not included in subscale or total score calculation (Burns et al., 2005).

Modified Florida shock anxiety scale-Pediatric (FSAS-P). The FSAS is a 10-item scale for measuring cardiac specific anxiety in ICD patients (Kuhl, Dixit, Walker, Conti, & Sears, 2006). Patients respond using a rating scale, ranging from "not at all" (1) to "all of the time" (5). The measure demonstrated good reliability ($\alpha = 0.91$) (Kuhl et al., 2006). The scale is moderately correlated with the Multidimensional Fear of Death Scale, where lower scores are indicative of greater fear of death, ($r = -0.65$), indicating moderate discriminate validity (Kuhl et al., 2006). This measure is only included in ICD patient batteries; the FSAS is intended to measure psychological

distress due to fear of ICD discharge. Lastly, item number 10 (re: fearing sexual activity) was removed from the measure.

Exercise treadmill test (ETT). Exercise treadmill tests were developed to identify coronary insufficiency and exertion in patients with possible heart disease. One such method of exercise stress testing was developed by Bruce et al. (1963, 2004). The *Bruce protocol* consists of 7 stages of testing (3 minutes per stage), increasing in speed and platform grade. Heart rate and blood pressure are sampled the end of each stage. The test score is total time on spent exercise testing in minutes.

Exit TreadExpo questionnaire. The post-questionnaire assessed challenges to participating in the study and patient's perception of the intervention. The questionnaire was administered directly after the completion of 3 blood pressure readings; approximately 5 minutes post ETT. The participant was asked to label this experience as something that could be helpful or not helpful for peers who fear heart rate increase or physical exertion.

Data Collection

Assessments were thoroughly examined after the scheduled intervention appointment to minimize missing data. Medical variables include: cardiac device placement, ETT results, and history of mental health treatment. In addition, a demographic questionnaire was utilized to document age, gender, ethnicity/race, and educational status. Participants were also asked to predict duration of their ETT total time.

Statistical Analyses

As the sample was small and deemed a feasibility study, data screening for out-of-range values, outliers, or assumption violations of the planned analyses were not conducted. The primary aims of the project were 1) to examine the feasibility of using the treadmill stress test as a clinical intervention, 2) to determine the effects of a treadmill test on anxiety, and 3) to examine the strength

of relationship between patient-predicted treadmill stress test duration and activity, psychosocial distress, and cardiac specific distress (Figure 5).

Efficacy was examined using a paired samples *t*-test, examining pre-post differences in reported state anxiety scores. H1 = Post-treatment anxiety scores improved compared to baseline anxiety scores. H0 = There was no change in anxiety as a result of the intervention. Correlational analyses were conducted to examine the strength of relationship between patient-predicted ETT duration and actual duration, anxiety, and cardiac specific distress (Figure 6). Table 3 provides an overview of study aims.

Figure 5. Primary and secondary variables

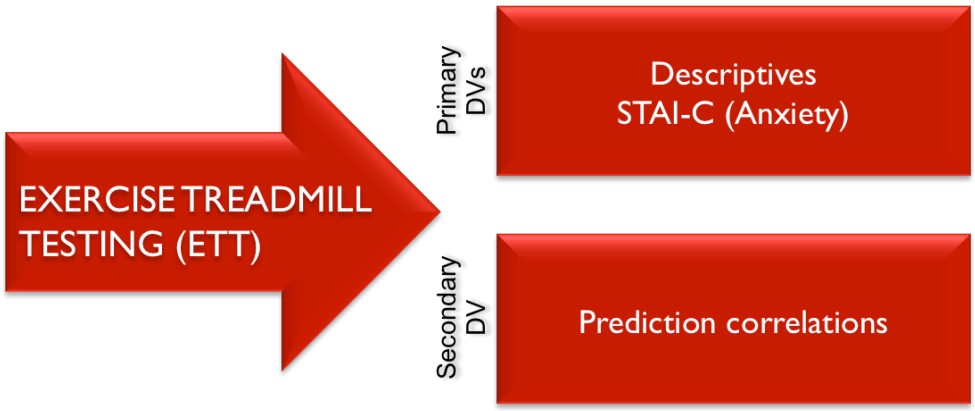
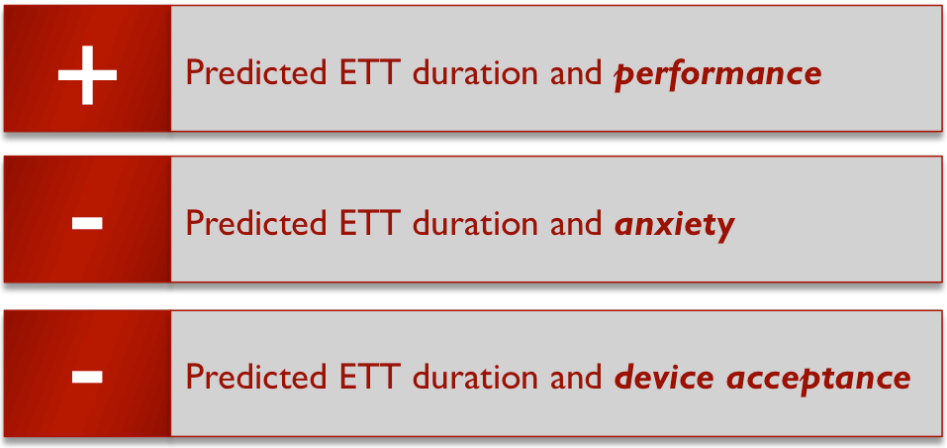


Table 3. Plan of statistical analysis

Aims	Plan	Method
Aim 1	To examine the feasibility of the study and descriptives of the pediatric implantable device sample.	Logistical analysis Descriptive statistics
Aim 2	To examine the efficacy of a single-session ETT as increased heart rate exposure for pediatric cardiac device patients.	Paired samples *t*-test
Aim 3	To examine the strength of relationship between patient-predicted ETT duration and… a. Actual ETT duration b. Anxiety c. Device acceptance	Pearson correlation

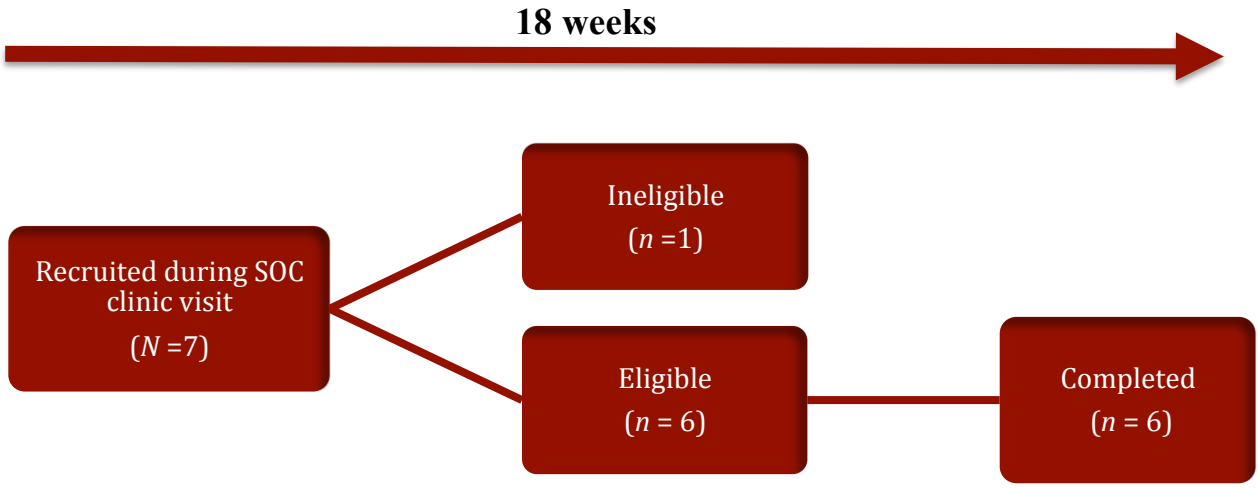
Figure 6. Correlation hypotheses



Feasibility

The study utilized an electrophysiology (EP) clinic for recruitment purposes. The EP would approach device clinic patients that were scheduled for an SOC ETT at that clinical visit. Seven patients were approached in total, with a 100% recruitment rate. One of these patients did not have an implanted device; that patient's data were not included in the analysis (Figure 7). A functional

Figure 7. Consort guidelines flow diagram



analysis of the device clinic schedule showed a low rate of ETT scheduled for eligible patients (aged 12-17), averaging one device patient scheduled for a SOC ETT per week from first patient to last patient recruited. The study underwent 4 IRB amendments in total to generate enrollment. The recruitment ratio from current IRB modification (4/1/2016) to last patient recruited (7/28/16) was 1 patient per 3 weeks.

Experience

The qualitative experience of informed consent and recruitment suggested that patients and families were predominately in support of participating in the final design of the proposed research, occasionally noting anecdotes of their child's fear of physical exertion. The EP and treadmill technicians were supportive of this research endeavor. Recruitment was largely successful due to the relationship and gatekeeper role that the physician has with the family. Patients are often present for a long clinic visit lasting 1-2 hours and completing a brief questionnaire may have been a more engaging way to pass any idle time. In the post-assessment battery, participants were asked to list the "best" and "worst" aspects of the ETT, seen in Table 4. Lastly, though the ETT was not highly appraised by patients, it was clinically feasible to examine psychological variables associated with the diagnostic test. Patients were asked if ETT could help peers who have fears of their heart rate increasing during physical exertion. Three participants indicated that ETTs could help with heart specific fears, while three participants responded with write in answers. One write-in response indicated "both yes and no, because it could be scary to hear your heartbeat, but exciting to feel your heartbeat," another stated, "I think there should be other ways." Both of these write-in responses highlight the fear and avoidance of such exertive activities.

Table 4. Commentary on attributes of ETT

Participant #	Best part of ETT	Worst part of ETT
1	“Running, skipping”	“Walking”
2	“Exercise”	“Running”
3	“Not wearing mask”	“Not letting me go longer”
4	"Hated all of it"	“Tired”
5	“Fun”	“Tired”
6	“Walking at the beginning”	“Running”

Anxiety

State anxiety was measured using the STAI-C. State anxiety was measured pre-and post-ETT to examine differences in state arousal. A paired samples t-test was indicated to examine pre-post differences with extremely small sample sizes (de Winter, 2013), though de Winter (2013) warns against use of this with poor within pair correlation. A paired sample t-test indicated no statistically significant findings within pair correlation ($r = 0.07$, $p = 0.89$). Though not statistically significant, differences between pre- ETT state anxiety ($M = 34.00$, $SD = 8.67$, $n = 6$) and post-ETT state anxiety ratings ($M = 31.67$, $SD = 7.61$, $n = 6$), $t(5) = 0.51$, $p = 0.315$, $d = 0.29$ (Figure 8) using a one-tailed *t*-test indicated an overall decrease in state anxiety report. Two participants showed mild to moderate decrease in state anxiety, while the remaining 4 participants did not show significant increase in state anxiety post-ETT. The results indicated failure to reject the null hypothesis.

The STAI-C is normed on a group of young adolescents (4^{th}-6^{th} graders) with separate norms for male and female students. Speilberger and colleagues (Spielberger & Edwards, 1973) proposed use of the STAI-C with children and adolescents across a range of reading levels. This tool was thought to best capture state anxiety in the adolescent cardiac population, with potential hypoxic event history. Table 5 provides the means for the STAI-C State measure for the normative sample alongside. A one-sample *t*-test, comparing means from the TreadExpo sample to published normative sample means (Spielberger & Edwards, 1973), did not indicate a statistically significant

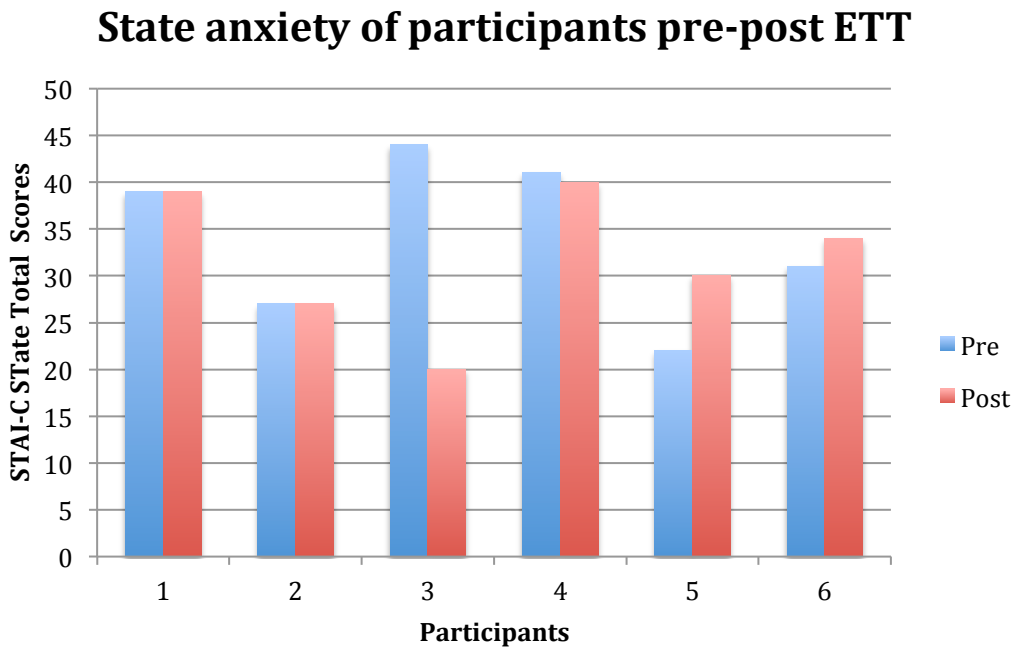
difference. Females from the current sample fell in higher percentiles than did their male counterparts. General anxiety was measured using the BAI-Y during the pre-ETT battery. BAI-Y scores ranged from 3 (Average) to 27 (Moderately elevated) with the mean score of 9.83 (Average) (Table 6).

Table 5. STAI-C State norms and TreadExpo sample

	Norms		**TreadExpo**			
			Pre		**Post**	
	Male	Female	Male	Female	Male	Female
Raw score *M* (*SD*)	31.8 (5.84)	30.6 (5.62)	32.33 (11.06)	35.67 (7.57)	28.00 (7.21)	35.33 (7.23)
T-scores	53	53	53	61	42	60
Percentile	62nd	62nd	62nd	86th	22nd	83rd

Note: Normative means from STAI-C manual (1973)

Figure 8. State anxiety total scores



Device Specific Anxiety

Patient device acceptance is one way of measuring device specific psychological adjustment. The FPAS-P measure consists of a total score, as well as several subscores (i.e. Return to life, Device distress, and Body image concerns). The FPAS-P demonstrated good internal consistency score (α = 0.89) with this sample. A key for interpretation of scores is provided in Table 7. FPAS-P Total score indicated low overall device acceptance (FPAS-P Total *M* = 58.17, *SD* = 7.89) (Figure 9). Subscores were also calculated and are seen in Table 6 and Figure 10 below.

Table 6. Descriptives for TreadExpo measures

Scale	*M*	Range	*SD*
Treadmill time (hh:mm:ss)			
Prediction	00:10:00	00:02:00 – 00:21:00	00:06:32
Actual	00:09:58	00:05:39 – 00:13:00	00:02:29
General anxiety			
BYI-A	9.83	3-27	8.86
STAI-C State (pre)	34.00	22-44	8.67
STAI-C State (post)	31.67	20-40	7.61
Device specific anxiety			
FPAS-P Total	58.17	47 - 66	7.89
Return to life	13.17	8-17	3.19
Device distress	20.17	17-24	2.99
Body image concerns	9.67	8-10	0.82
FSAS (ICD only)	21.00	14-34	11.27

Table 7. FPAS-P score interpretation guide

FPAS-P Measure	Score	Interpretation
FPAS-P Total	Low	Poor acceptance
	High	Good acceptance
Return to life	Low	Avoiding activities
	High	Returning to activities
Device distress	Low	More device distress
	High	Less device distress

Body image concerns	Low	More body image concern
	High	Less body image concern

Figure 9. Device acceptance total scores

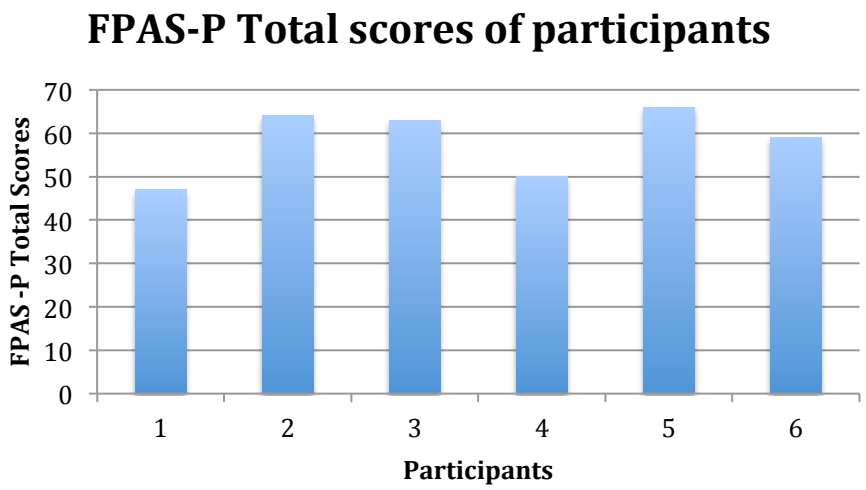
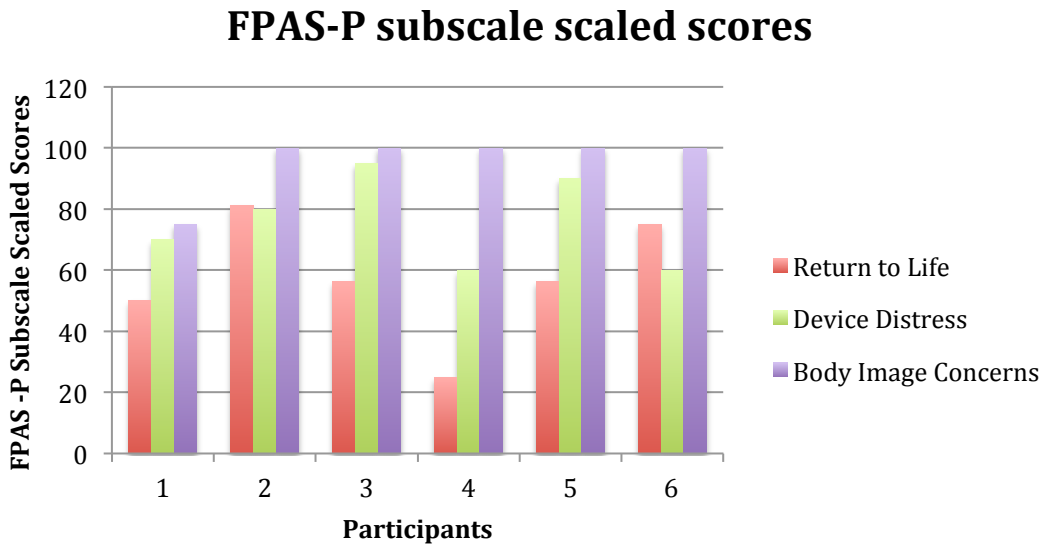


Figure 10. Device acceptance subscale scaled scores



Correlations

Correlations were conducted using a Pearson product-moment correlation coefficient. The relationship between predicted ETT duration and actual ETT duration did not yield significant results. However, the strength of relationship between predicted ETT and anxiety (BAI-Y) did yield statistically significant results ($r = 0.85$, $n = 6$, $p = 0.033$) indicating a large effect. No statistically significant relationships were seen between predicted ETT duration and state anxiety (STAI-C). Results indicated no significant relationship between predicted ETT duration and device acceptance. There was a strong, negative correlation between post-ETT state anxiety (post STAI-C) and patient device acceptance (FPAS-P) ($r = -0.82$, $n = 6$, $p = 0.048$).

Lastly, exploratory analyses were conducted on the subscales of the FPAS-P to identify other relationships of interest. The FPAS-P demonstrated good internal consistency ($\alpha = 0.97$). The Return to Life subscale yielded a strong, negative correlation with generalized anxiety (BAI-Y) reports ($r = -0.84$, $n = 6$, p 0.036). The Body Image Concerns subscale indicated a strong, positive correlation with Total ETT duration ($r = 0.85$, $n = 6$, $p = 0.032$), such that those reporting less body image concerns engaged in the ETT longer. There was also a strong, negative correlation between the device distress subscale and the post-state anxiety (STAI-C) scale ($r = -0.84$, $n = 6$, $p = 0.036$), such that lower device distress scores (higher reported device distress) are correlated with high post-ETT state anxiety. Though not statistically significant, the following results table (Table 8) indicated possible trends with a larger sample size.

Table 8. Correlational analyses

	N	*M*	*SD*	1	2	3	4	5	6
1 Prediction	6	10.00	6.54	--					
2 Actual	6	9.98	2.49	0.45	--				
3 BAI-Y Total	6	9.83	8.86	0.85*	0.13	--			
4 FPAS-P Total	6	58.17	7.89	-0.28	0.42	-0.49	--		
5 FSAS-P	3	21.00	11.27	0.94	0.73	0.97	-0.41	--	

6 Pre STAI-C[a]	6	34.00	8.67	0.45	-0.01	0.23	-0.59	0.62	--
7 Post STAI-C[a]	6	31.00	7.61	0.28	-0.30	0.63	-0.82*	0.61	0.07

Note: * $p < 0.05$ (2-tailed); [a] STAI-C State only measure used pre and post

Discussion

Despite the small sample size, the current study provided support to continue investigation of the impact of ETT on psychosocial factors among the pediatric cardiac device population. Overall, the current EP clinic embedded study indicated moderate feasibility for the current study design, after multiple logistical adjustments to the recruiting process, the protocol, and the personnel necessary to complete the procedures. The qualitative experience of informed consent and recruitment suggested that patients and families saw inherent value in approaching the fears of exertion via ETT. Due to the exhaustive efforts of completing the current feasibility study and feedback from potential participants of previous amendments, funding would be necessary to compensate participant families for their time, parking (~$5/hr), and absence from school and achieve a larger sample for any future pilots.

Qualitative results from this study suggested strong relationships between predicted ETT duration and general anxiety ($r = 0.85$, $p = 0.033$), post-ETT state anxiety and device acceptance ($r = -0.82$, $p = 0.048$), general anxiety and report of normal daily functioning ($r = -0.84$, $p = 0.036$), body image and Total ETT duration ($r = 0.85$, $n = 6$, $p = 0.032$), and post-ETT state anxiety and report of device distress ($r = -0.84$, p 0.036). Non-statistically significant findings include overall decrease in state anxiety after a single-session ETT (and more importantly little to no increase) indicating potential efficacy for a repeated exposure study. Other non-significant findings included female patients' report of state anxiety decreasing more in percentile rankings than did males and lower device acceptance in females indicated a need for further data collection with this population.

Recruitment

Throughout this project there were severe limitations to the pace of recruitment. The original study underwent 4 IRB amendments prior to the current study design (Table 9). These adjustments were "major" as the study transitioned from a traditional RCT model to a one armed pre-post design.

The number of exposure sessions and measures used to capture psychosocial data was drastically decreased to achieve greater feasibility. Previous amendments were not feasible due to patient burden, including duration of study involvement (i.e. school absences) and financial (i.e. parking) cost.

Table 9. Study design amendments

Design #	WLC	Treadmill sessions	Follow-up	Measures	Rationale for change
1	Yes	3	Yes	7	Excessive participant time burden
2	Yes	2	Yes	7	Excessive participant time burden
3	No	2	Yes	4	Research personnel limitations
4	No	1	No	4	Current design

The project was accepted for internal "funding" from the Cardiovascular Clinical Research Core program at Texas Children's Hospital in Houston, Texas. Initially, the project was awarded 15% time from the EP, a research nurse, and a research coordinator. During the last amendment, the study began to use SOC ETT, which disabled our ability to utilize a research nurse to run the treadmills and therefore rely on the clinical treadmill techs. After nearly a solid month of zero recruited patients, the main EP discussed scheduling ETTs for patients who have not undergone a stress test recently with colleagues. These discussions may have been the impetus for the relative flux of recruitment during summer months. These months may have been popular for adolescent clinic visits, as they would not accumulate absences from school, another possible explanation for the recruitment pattern.

Due to the nature of a feasibility study, among other functional limitations including billing and clinic schedule, patients with a SOC scheduled treadmill became the focus of recruitment. The EP lab typically runs 5-7 ETT per day, indicating need to expand eligibility criteria to a larger age

range, as well as patients without implanted devices. A candid discussion with an EP physician indicated there were low rates of follow-up ETTs for device patients after the initial diagnostic treadmill. This was particularly the case for the population of interest; ICD and PM patients aged 12-17. It would be beneficial to engage other EPs in the study to increase the number of scheduled ETTs for device patients.

Recruitment percentage was partly successful due to the relationship and gatekeeper role that the physician has with the family. Patients are often present for a long clinic visit lasting 1-2 hours and completing a brief questionnaire may have been a more engaging way to pass any idle time. In discussion of the data collected, the EP reported that two participants were noted to have abnormal electrical rhythm during the ETT. The ETT provided diagnostic information to titrate medications and pace functioning on the devices while the patient was in clinic. The use of the ETT during these clinic visits may have precluded clinically adverse events in the real world. After further review of the clinical literature and guidelines, no such guidelines exist regarding the recommended recurrence of a diagnostic ETT in the pediatric population. In fact, much of the existing literature focuses on the recommendation to refrain from exercise stress tests as a screening tool for coronary disease in a pediatric population (Fowler-Brown et al., 2004) and disregards recommendations for routine treadmill stress tests. The pediatric device population is in dire need of recommendations for exercise stress test frequency.

Analyses

Despite the proposition of a feasibility test, hypothesis testing was conducted given that 74% of self-proclaimed feasibility studies provide hypothesis-testing results (Arain et al., 2010). These results were obviously limited efficacy tests of a convenience sample. The mean difference of state anxiety pre-post ETT was not significant. This is contrary to the main hypothesis of ETTs reducing

state anxiety in device patients. However, the exposure literature would suggest that prolonged or multiple exposure time points are required to establish a therapeutic benefit(Öst et al., 2001; Powers et al., 2010). Indeed, this assertion was the rationale for our original designs incorporating multiple ETTs. Nonetheless, we continue to seek further exploration of a dose effect of heart rate exposure, a parallel to traditional exposure therapy protocol.

Further comparison with the normative sample indicated no statistical differences, leading to a possible conclusion that the effect size was limited due to a floor effect on anxiety with the current sample of device patients. The effect may have also been limited due to previous ETT exposure history of the current sample, as all participants had experienced one or more ETT since their diagnosis. Our sample were not diagnosed anxiety patients so the ability to reduce anxiety was limited, and the full possible value of ETT in anxious ICD patients remains to be studied.

Identification of a clinically anxious population may lead to more significant findings of a treatment effect. Similarly, future studies should continue to examine sex differences as have been published in the adult literature (Sears & Conti, 2003) and extant pediatric literature (Sears et al., 2011), as our data may indicate a trend for female pediatric patients to report higher levels of state anxiety surrounding device management or heart rate increase.

The positive relationship between predicted duration of ETT test and general anxiety may indicate possible self-limiting behavior, where the adolescent is able to accurately guestimate the ETT length to stop. From the TPB (Ajzen, 1991), we can surmise that the pediatric device patient's attitude and perceived behavioral control affected their intentions of functioning on the treadmill test. This relationship may also be confounded by athleticism, where those that predict they can complete a longer duration due to physical endurance also report higher anxiety, a possible product of a specific phobia that has been maintained and exacerbated. This brings to question if athletes with

devices qualitatively differ from their peers; do athletes have greater heart rate anxiety because there is more at risk? Clearly, only future research can more fully address this question.

The negative relationship between device acceptance and post-ETT state anxiety report may lead to the belief that exposure to elevated heart rate is more beneficial for those reporting greater device acceptance. Perhaps the individuals who accept the implanted device for the job of maintaining safe electrical rhythms experience anxiety extinction upon completion of the ETT without a critical event, thus reporting lower state anxiety. This assertion may also map onto the TPB model where device acceptance moderates the relationship between perceived behavioral control and behavior. Regardless, increasing device acceptance may be the key to lifelong positive psychological adjustment to implanted cardiac devices. Dunbar and colleagues (Dunbar et al., 2012b) propose device acceptance to be an AHA intervention target for all device patients. A question arises with the adolescent population, are adult measures of device acceptance truly measuring acceptance, or could these reports be confounded by the adolescent's knowledge and understanding of the device. Educational components from the CBT based SSMP manual (Sears et al., 2007) could potentially be tailored to pediatric ICD and PM patients, with the goal of increasing device education and acceptance.

The negative relationship between report of return to daily functioning and general anxiety may indicate returning to daily functioning to be sufficient exposure to varying heart rates for one to report levels of anxiety in a normative range. In a larger sample of pediatric ICD patients, it would be expected for about 84% to report avoidance of activities and places (Sears & Conti, 2004). This again suggests that the analyses for this study achieved a floor effect given the overall well adjustment of the sample, or perhaps the PM patients had a large effect on the sample means. More

data are needed to better understand PM patients' cognitions and behaviors, particularly avoidance behaviors.

The positive correlation between body image report and Total ETT duration, such that those reporting fewer body image concerns were able to engage in the ETT longer suggests that body image may be a critical component of efficacy, possibly affecting an adolescent's attitude or approach to physical activity. Adult literature has identified body image concerns as a major component to psychological adjustment to cardiac devices (Dubin et al., 1996; Lüderitz et al., 1994). This is a vacant area of the pediatric cardiac device literature that requires future attention. Pediatric oncology literature has examined the effects of body image and has not identified significant differences between oncology patients and healthy controls (Fan & Eiser, 2009). Body image changes may differ across oncology patients possibly contributing to difficult comparison, whereas implantable device patients typically experience similar physical changes; rather it is the perception of the changes that determines psychological outcomes and potentially self-limiting behaviors.

The negative relationship between post-ETT state anxiety and device stress, such that low reports of device distress (indicating high distress) were correlated with high post-ETT state anxiety indicated device distress to be a critical factor in understanding this population. Single-session exposure may have less of an effect on state anxiety of individuals reporting higher levels of device distress. Future studies may indicate exposure for heart rate and device specific anxiety to have a dose effect on individuals with high levels of distress. Similar to the single-session workshop for specific anxiety, perhaps repeated exposure is needed to build mastery and greater impact perceived behavioral control and behavior outcomes. In addition, there is first a need for a larger sample and second a need for examination of a dose effect with repeated trials of a Bruce protocol over a short period of time, or perhaps pairing an educational component with a regularly scheduled ETT would

increase self-efficacy to manage physical activity; incorporating true exposure theory elements. Adult patients participate in structured cardiac rehabilitation, where ETT duration increases with a cardiac rehabilitation program. Very few pediatric centers in the country have established cardiac rehab, though the answer may be to examine prescription for exercise in this population, increasing daily functioning and heart rate exposure, for a long term goal of increased time on the treadmill and overall cardiovascular functioning.

While it is important to not speculate causation from a correlational analysis, these data provide fodder for future research projects. Certainly some findings seemed intuitive; such as the more one reports having returned to normal functioning, the lower the reported general anxiety; likewise, the relationship between high device distress and high state anxiety following a treadmill test. While other findings lead to further questions, such as the correlation between high anxiety and prediction of longer ETT duration, begging the question of a self-fulfilling prophecy leading to accurate prediction times. More information is needed to understand if self-limiting behaviors or negative cognitions are at play. Regardless, the ETT protocol has promise as a tool to better understand the pediatric device population and as an interventional component for pediatric cardiac patients.

Structure of Clinic Visits

Electrophysiology lab visits last approximately 45-60 minutes, including multiple blood pressure (BP) readings, the ETT, and a cool down period. First, the patient's resting supine BP was assessed. The patient was then asked to quickly move from a supine to standing position for another BP reading. Next, the patient was asked to engage in a hyperventilation task, followed by BP reading. The patient then completed a treadmill test with cool down period and three additional BP readings. The patient was administered the post-ETT state anxiety inventory following the cool down

period; likely enough time to reduce heart rate closer to baseline than a more anxiety provoking heart rate during the ETT. SUDs ratings may have been more efficacious at discerning exertion-related distress. Each of these tasks was conducted with the parent/family in the lab, possibly confounding results.

As previously mentioned, adolescents, though having variable amounts of autonomy, are a component of a larger system. Adolescents are privy to modeling and suggestion of others. As the major component of the current study, the ETT, was a SOC procedure, the primary investigator did not alter the clinic flow by standardizing the procedure for study purposes. There are multiple time points in a traditional EP lab visit that were not standardized for research purposes that may have contaminated results. It was noted that the treadmill technicians would occasionally provide attentive feedback to patient's complaints of leg pain or lethargy, asking if one is "okay". This could have possibly contaminated the patient's perception of their performance or ability to continue to perform. It was also noted that the patient has the option to view a small television while completing the ETT. In clinical psychological terms, this behavior could be seen as an avoidance mechanism, perpetuating any anxieties or device related fears, while serving as a temporary distraction during a high level of exertion.

As adolescents absorb information from their surroundings, they may receive messages of illness and the need to limit physical behavior at home. This is in stark contrast to an ETT, where the purpose is to exhaust one's physical limitations as a diagnostic tool, defining upper and lower limits of heart rate. Though patients may be given medical clearance to participate in sports, parents are often sending different messages to their teens, perhaps out of personal anxiety about their child's health. Particularly if this parental message is received as a younger child, the adolescent may continue to self-limit, never fully reaching high levels of exertion, though medically appropriate. In

both of these examples, the parent may unknowingly impose on the child's perceived behavioral control and ultimately self-efficacy with regard to completing exertive tasks. Parental education and targeting parental maladaptive cognitions of their child's health may be another adjunct intervention to adolescents' adjustment to their device.

Research Involving Pediatric Patients

Research with pediatric patients differs from research with adults in that these participants do not have their own autonomy to decide to stay at a clinic visit for an extra 20-30 minutes; they are part of a system that has to also provide consent for the participation. Though this did not appear to deter families from consenting, but future studies with multiple treadmill exposures might increase difficulty with recruitment. The high recruitment rate (100%) observed here leads the primary investigator to believe that this is an important issue for families and young patients with electrical disorders. Future studies should consider use of parental measures of self and patient anxiety. Modeling is an important developmental concept and parents may possess the key to home intervention.

Since the ICD and pacemaker were initially developed for use in adults, much less is understood about the experiences of pediatric device recipients. Research has demonstrated that young age and increased rate of shock are risk factors for poor psychosocial adjustment. Additionally, there is now evidence that children and adolescents with devices have lower physical QOL than their peers who are not chronically ill (Webster et al., 2014). These children also have difficulty re-engaging in physical activity, which affects patient QOL. Interventions have been developed to aid in the psychological adjustment of adults; however, the major limitations of interventions for ICD patients is that they have been designed for, and exclusively tested on adults and have neglected the pediatric population.

Limitations

This current study encountered many logistical challenges and the results should be interpreted with caution. First, the recruitment rate was severely slow as the total time elapsed for study recruitment spanned almost two years. This was due to a combination of having a narrow age range for eligible participants and examining effects of a diagnostic test without national guidelines on frequency of re-testing. EPs appear to seldom schedule ETTs for device patients who have already completed one ETT at diagnosis or are asymptomatic. The slow recruitment rate led to an extremely small sample size, which cannot represent the diversity in pediatric cardiac samples. Comprehensive medical record review including medication review was not available to our research team so we cannot determine whether medications provided any impact on our experience and findings. The results indicated that having such a small sample may have contributed to a floor effect for examining anxiety, as anxiety reports fell within normal limits, therefore increasing difficulty of establishing a meaningful treatment effect for anxiety. Lastly, the structure of a SOC treadmill tests may have contaminated findings. As previously mentioned, the technicians offered use of the TV during the ETT, which may have served as a safety behavior, allowing the participant to "escape" from experiencing heart rate increase. The technicians also provided participants with reassuring comments as an attempt to engage the participant in a longer ETT duration. Future studies with this population would be wise to address the aforementioned limitations of the current study.

Staff and physician availability was a major logistical limitation for this study. Future studies would require a more hands-on approach from a research coordinator and 25-50% time from a research assistant to initiate recruitment immediately following IRB approval and assure the project is on track with future ETTs scheduled for the population of interest. Engagement of all clinical EPs

may peak interest in scheduling SOC treadmill visits, particularly if ETTs result in medication titration or device adjustments.

In conclusion, this project and future projects could be feasible with several structural changes, including increase in time and effort of research personnel, increased engagement of clinic EPs, expanding eligibility criteria, and funding to compensate families for parking. While this research is in the early stages, the data collected suggested further examination of this population may be warranted. The present study has provided information regarding the feasibility and abundant challenges to research within the pediatric electrophysiology population. Future steps should be taken to mediate the above challenges and proceed with a larger scale pilot study. Continuing research in this field is a progression toward improved healthcare in young people, affording the opportunity to develop into the adherent and well-informed adult patient.

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APPENDIX A: IRB Approval Letter

April 1, 2016

CARIDAD MAYLIN DE LA UZ
BAYLOR COLLEGE OF MEDICINE
PEDIATRICS: CARDIOLOGY

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H-37302 - EXAMINATION OF TREADMILL STRESS TEST EXPOSURE THERAPY FOR PEDIATRIC CARDIAC DEVICE PATIENTS

APPROVAL VALID FROM 11/18/2015 TO 10/20/2016

Dear Dr. DE LA UZ

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

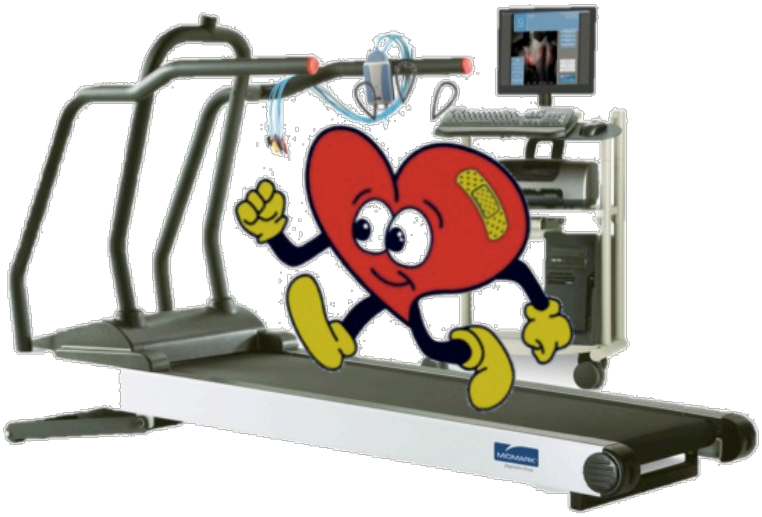
Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

JULIE PAMELA KATKIN, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

APPENDIX B: Pre-Treadmill Questionnaire



TreadExpo Questionnaire

Please Note: Information from this study is confidential and will be used only for research purposes.

Marking Instructions:

1. Mark selection spaces with an X or a check mark.
2. Mark only one answer for each question
3. Use ALL CAPITAL LETTERS when writing words

What We Are Asking You To Do:

1. Please answer the questions on the following pages as completely as you can.
2. Read the questions carefully.
3. If you don't understand some of the questions, ask your caregiver or a study staff member. We can help you finish filling out the form.
4. Take your time.

THANK YOU FOR PARTICIPATING!

TreadExpo Questionnaire

1. How old are you? _____ years old.

2. What gender are you?
   ___ Male
   ___ Female
   ___ Other

3. What grade are you in? _____

4. What kind of cardiac device do you have?
   ___ Pacemaker (PM)
   ___ Implantable cardioverter defibrillator (ICD)

5. How long ago did you get your device?
   ___ Less than 3 months ago
   ___ About 6 months ago
   ___ About 1 year ago
   ___ More than 1 year ago
   Other: _____

6. Which of the following groups best describes your race or ethnicity:
   ___ Hispanic, Latino, or Latin American
   ___ Asian or Pacific Islander
   ___ Black or African American
   ___ White or Caucasian
   ___ Another group: _____

7. *I am afraid to do this physical activity* _____
   (For example: play basketball, play tag, participate in PE class)

Prediction:

8. How many minutes do you think you can go on the treadmill test?

   _____ Minutes

Beck Anxiety Inventory – Youth

The Modified Florida Patient Acceptance Survey - Pediatric (FPAS-Peds)

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

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

STAI-C

----------FOR ICD PATIENTS ONLY----------

The Florida Shock Anxiety Scale (FSAS)

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

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

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

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

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

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

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

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

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

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

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

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

7. I worry about the ICD firing and creating a scene.

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

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

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

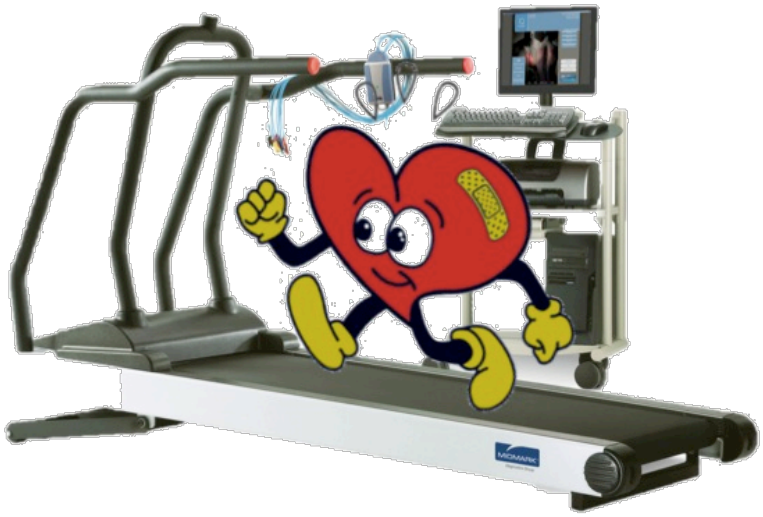
9. I have unwanted thoughts of my ICD firing.

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

Thank you for participating!!!

APPENDIX C: Post-Treadmill Questionnaire

Post-Treadmill Questionnaire



Please answer the questions on this page and complete the brief form on the next page. Thank you for your time!

1) **What was the best part of having the treadmill stress test?**

2) **What was the worst part of completing the treadmill stress test?**

3) **Do you think having practice with treadmill stress tests would help kids who are worried about their heart? (Circle one)**

   a) **Yes, this could help me get use to my heart beating fast.**

   b) **No, hearing my heart beat fast is too scary.**

   c) **Other: _____**

STAI-C
