

FEASIBILITY AND ACCEPTABILITY OF A PSYCHOSOCIAL CARE PROGRAM FOR PATIENTS WITH AORTIC DISEASE

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ABSTRACT

The aorta is the largest blood vessel in the human body and transports blood from the heart to the rest of the body. Aortic disease, or structural abnormalities of the aortic walls, can be life threatening, with the present study paying particular attention to thoracic aortic aneurysms and dissections. However, little research attention has been paid to the psychological impact of these conditions, though the data that does exist suggests that psychological distress is highly prevalent within these patient populations.

As such, the present study aimed to design and pilot test a manualized intervention for aortic aneurysm and dissection patients in a rural-serving cardiothoracic surgery clinic. The manual and intervention focused on four topics: 1) disease-specific information, 2) the mental and physical benefits of physical activity and health as a value to encourage increased activity, 3) cognitive behavioral therapy-based tactics to challenge distorted thoughts and/or beliefs regarding their health, 4) the importance of engaging in values-based activities to lead a fulfilling life and protect against mental health symptomatology for future well-being. Ultimately, the goals of the present study were to assess and improve multiple psychological and behavioral outcomes in a group of aortic aneurysm and dissection patients.

Results indicated that post-intervention, patients reported significantly less emotional impact and concern about their illness, in addition to feeling that their illness was, overall, less threatening than prior to study engagement. In addition, participants reported significantly less cardiac-related avoidance at post-intervention. Objective physical activity data showed that patients engaged in more total vigorous activity from pre- to post-intervention. Though the study is limited by small sample size, these results provide preliminary evidence to indicate that educational programs may improve health-related quality of life in patients with aortic disease.

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PATIENTS WITH AORTIC DISEASE

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Introduction

The aorta is the largest blood vessel in the human body with an important role; the aorta is responsible for transporting oxygenated blood from the left ventricle to the rest of the body (Komutrattananont et al., 2019). Aortic disease is an umbrella term for many different structural abnormalities of the aorta including weakened or torn aortic walls or aortic occlusions (Eduardo & Eagle, 2021). Aortic aneurysms occur when the walls of the aorta become weak, distended, and brittle leaving the aorta more prone to tearing, or dissection (National Heart, Lung, and Blood Institute A, 2022). Aortic aneurysms can be the result of multiple etiologies, with the most common being unmanaged hypertension (National Heart, Lung, and Blood Institute B, 2022), in addition to genetic connective tissue disorders including Marfan syndrome, Loey-Dietz syndrome, or Ehlers-Danlos syndrome (Diletta et al., 2021). Aortic aneurysms and dissection are diagnosed via various imaging methods (Kallianos & Burris, 2020) and clinical decisions regarding medical intervention depend on multiple factors including size, location, and etiology. The decision regarding treatment of aortic aneurysms depends on size, with some patients being put under medical surveillance, and others undergoing surgical intervention to repair the distension (Isselbacher et al., 2022). Aortic dissections occurring in the ascending portion of the thoracic aorta (Type A) are a medical emergency that requires immediate surgical intervention, while those occurring in the descending portion (Type B) can often be managed pharmacologically (Levy, 2023; Brunkwall et al., 2012; Nienaber et al., 2010).

Psychological distress and associated consequences in those with aortic dissections have not been well studied, and even less information exists regarding those with aneurysms. Rates of depressive symptomatology in dissection survivors and those with aneurysms are high, with reported ranges between 25 and 50% (Chaddha et al., 2015; Adam et al., 2018; Jordan et al.,

2024). Rates of posttraumatic stress disorder (PTSD) are consistently higher in Type A and B thoracic aortic dissection survivors (21.4-23%; Chen et al., 2020; Lin et al., 2021; Pasadyn et al., 2020) than in the general population (6.1-8.3%; Goldstein et al., 2016; Kilpatrick et al., 2013). Importantly, the prevalence of PTSD is higher in Type A aortic dissection than Type B aortic dissection patients (Lin et al., 2021), likely due to the more emergent nature and, therefore, differing interventional approaches and subsequent impact on functioning post-treatment.

Given the paucity of information regarding psychological distress in aortic aneurysm and dissection patients, valuable information may be gleaned from the literature regarding psychological distress in similar open-heart surgeries such as coronary artery bypass graft (CABG) patients. Broadly, rates of psychological distress in CABG patients are high (major depressive disorder: 50%; generalized anxiety disorder: 10%; Waterman et al., 2020; Del Re et al., 2022; Celano & Huffman, 2011), but interventions targeting increased patient education and distress both before (McCann et al., 2023; Shahmoradi et al., 2022; Salzmänn et al., 2020) and after (Sørli et al., 2007; Shelley & Pakenham, 2007; Davies, 2000) surgical intervention have shown promise.

Accordingly, the present study aimed to design and pilot test a manualized intervention for aortic aneurysm and dissection patients in a rural-serving cardiothoracic surgery clinic. The manual and intervention focused on four topics: 1) disease-specific information, 2) the mental and physical benefits of physical activity and health as a value to encourage increased activity, 3) cognitive behavioral therapy-based tactics to challenge distorted thoughts and/or beliefs regarding their health, 4) the importance of engaging in values-based activities to lead a fulfilling life and protect against mental health symptomatology for future well-being. Ultimately, the

goals of the present study were to assess and improve multiple psychological and behavioral outcomes in a group of aortic aneurysm and dissection patients.

Feasibility and acceptability of psychosocial care for patients with aortic disease

Chapter I: Literature Review

Anatomy of the Aorta

The aorta is the largest blood vessel in the human body and is responsible for carrying oxygenated blood from the heart to the rest of the body (Komutrattananont et al., 2019). The aorta is contained within two major areas of the body, the thorax and the abdomen; accordingly, there are two main sections of the aorta: the thoracic aorta and abdominal aorta (Bajzer, 2004). The thoracic aorta is divided into three sections: the ascending aorta, aortic arch, and descending aorta. The ascending portion of the thoracic aorta includes the aortic root and the portion leading up to the aortic arch. The aortic root contains the aortic valve and the origin of the coronary arteries which supply blood to the heart. The aortic arch, which separates the ascending aorta from the descending aorta, houses the branches that supply blood to the brain and upper extremities (Kelley et al., 2023). The descending thoracic aorta carries blood away from the heart and down toward the pelvis; once the descending thoracic aorta reaches the diaphragm, or the muscle that separates the thorax from the abdomen, it becomes the abdominal aorta (Komutrattananont et al., 2019).

The walls of the aorta are comprised of three layers. The outermost layer is known as the tunica adventitia. This layer connects with other surrounding structures to ensure the stability of the aorta. The middle layer, or the tunica media, is made up of smooth muscle tissues that allow the aorta to dilate or narrow depending on the body's blood flow needs. The innermost layer, the tunica intima is the layer that is in contact with the blood itself and allows for the transportation of oxygen and nutrients. In addition, these specialized cells ensure that blood is not absorbed until it has reached its intended destination (Isselbacher et al., 2022).

Aortic Disease

The term aortic disease encompasses different threats to the aorta including weakened, distended, torn, or split aortic walls or occlusions of the aorta (Eduardo & Eagle, 2021). When the aortic walls become weakened, certain areas can become larger or dilated, creating a bulge. These bulges are known as aortic aneurysms and can occur in both the thoracic (thoracic aortic aneurysm) and abdominal aorta (National Heart, Lung, and Blood Institute A, 2022). For the purposes of this study, explicit attention will be paid to thoracic aortic aneurysms and related consequences, including thoracic aortic dissection, henceforth referred to as aneurysms as dissections.

Thoracic Aortic Aneurysms

Etiology. As previously mentioned, aneurysms are arterial bulges that occur in the thoracic aorta and can be present in any portion of the aorta. The diameter of a normally sized thoracic aorta is dependent on many factors including age, gender, lifestyle factors, and the diameter of both the descending aorta and the pulmonary artery, therefore, no single specific measurement of the diameter constitutes the presence of an aneurysm (Mao et al., 2008). The incidence of aneurysms is low; only 6-10 out of every 100,000 people will develop an aneurysm (Eagleton, n.d.). Risk factors for aneurysm include hypertension and substance use including smoking cigarettes and using stimulants (Hibino et al., 2022; National Heart, Lung, and Blood Institute B, 2022; National Heart, Lung, and Blood Institute C, 2022).

Genetics often play an important role in the development of aneurysm; a person is 20% more likely to develop TAA if there is a family history (Eagleton, n.d.). In addition, some genetic conditions, specifically connective tissue disorders, predispose individuals to developing aneurysms as they are genetically driven diseases that impact the formation of collagen and

elastin. These diseases can impact the aorta's ability to maintain its shape, making the development of aneurysms much more likely; such conditions include Marfan syndrome, Ehlers-Danlos syndrome, and Loeys-Dietz syndrome

Finally, inflammatory processes can increase the risk of aneurysm. For example, aortitis is the inflammation of the aorta itself which lead to dilation of the artery, allowing for the formation of aneurysm (National Heart, Lung, and Blood Institute B, 2022).

Diagnosis of thoracic aortic aneurysm. Multiple imaging methods may be utilized to diagnose aneurysm (Kallianos & Burris, 2020). Early detection of aneurysm is important for intervention decision-making but can be difficult as 95% of those with aneurysm remain asymptomatic until urgent intervention is required due to dissection (tearing of the innermost layer of the aorta) or rupture (a complete tearing of all three arterial layers) of the artery (Elefteriades & Rizzo, 2007). As such, aneurysms are often detected incidentally while investigating other concerns (Kallianos & Burris, 2020). For example, Mori et al. (2019) retrospectively examined over 5,000 scans involving the chest with nearly 3% (n=158) revealing aortic dilation (Mori et al., 2019). These data suggest that aortic dilation is much more common than the incidence of dissection and prompts call for increased attention to the detection, prediction, and management of more severe presentations. Further, it suggests that the potential population of aortic dilation patients in a “watch and wait” scenario is potentially much larger than previously thought.

Once an aneurysm is detected, cardiothoracic surgeons must decide whether to intervene surgically or place patients on optimum pharmacological therapy and conduct regular surveillance of the aneurysm to monitor its size (Isselbacher et al., 2022).

The Pathway from Aneurysm to Dissection

If left untreated or undetected, aneurysms can become so large that they begin to burst or tear, beginning with the innermost layer of the artery, known as aortic dissection. Aortic aneurysm size is a strong predictor of outcomes, with aneurysms greater than 6 cm being associated with a 15.6% risk of dissection, rupture, or death per year (Davies et al., 2002). Even those aneurysms that have been monitored can acutely dissect with some factors making aortic dissection more likely, including rapid, temporary, and intense surges in blood pressure, such as extremely heavy weightlifting or the use of substances that mimic sympathetic nervous system activation (e.g., cocaine and ecstasy). In addition, pregnancy and childbirth can increase risk of dissection, and this risk is even greater in those with connective tissue disorders who are already predisposed to aortic disease (Levy, 2023).

Dissection Classification by Location. There are two classifications of dissection as posited by the Stanford classification system; type A dissections involve the ascending portion of the aorta, while type B dissections involve the descending portion, including the arch (Daily et al., 1970). Type A dissection is approximately two times more common than type B (Berretta et al., 2018). Dissections can be further delineated based on the time from symptom onset to first presentation for medical attention; those with dissections that present within 14 days of symptom onset are regarded as *acute*, while those presenting after 14 days are considered *chronic* (DeSanctis et al., 1987). The prognosis for chronic dissections is slightly better than acute; chronic dissections are also more likely to be type B (Levy, 2023).

Type A Dissection Treatment and Outcomes. Type A dissection is a rare, but catastrophic medical event that requires emergent surgical intervention (Levy, 2023). While mortality rates for those with type A dissection were once as high as 1-2% per hour and 30% in the first 48 hours (Tsai et al., 2005), recent data is more promising with mortality rates of 0.12%

per hour after onset and 5.8% over the first 48 hours (Isselbacher et al., 2022). These results differ depending on whether patients were pharmacologically or surgically managed, with 48-hour survival rates being 23.7% and 4.4%, respectively. The authors attributed this reduction in mortality to better diagnostic imaging techniques and therefore, more rapid surgical intervention following symptom onset (Harris et al., 2022). 30-day mortality rates for type A dissection are between 17 and 26% (Pape et al., 2015). More recent data from German type A patients demonstrated 30-day mortality rates of 12% (Berezowski et al., 2024).

Type B Dissection Treatment and Outcomes. Intervention recommendations differ for type B dissection; research has revealed no short-term benefit to early surgical intervention versus pharmacotherapy in those without complications (e.g., ongoing pain, impending rupture, inadequate blood supply to other organs; Brunkwall et al., 2012; Nienaber et al., 2010). Therefore, most type B dissections can be managed pharmacologically with optimal blood pressure control and lifestyle modifications. However, those showing complications are often treated surgically (Harris et al., 2014). Overall, short-term survival rates for those with acute type B dissection are high, with 90% of those who are hospitalized surviving to discharge upon receiving medical management (Hagan et al., 2000). 30-day mortality in these patients is also improving; 30-day mortality rates for uncomplicated and complicated type B dissection are 4-10% and 7.3%, respectively (DiMusto et al., 2010; Suzuki et al., 2014; Yuan et al., 2018).

Psychological Distress in Aneurysm/Dissection Patients

Limited research attention has been given to mental health consequences in those with dissection, but the existing data have demonstrated high rates of psychological distress. Even less research has examined the mental health consequences of aneurysm.

Depression and anxiety. Though limited evidence exists, available research suggests that rates of depression and anxiety are elevated in aortic patients compared to the general population (Adam et al., 2018; Chaddha et al., 2014; Jordan et al., 2024). Importantly, engagement in physical activity has been found to be protective against depression post-operatively (Chaddha et al., 2015). It would be reasonable to hypothesize that patients who undergo surgical repair may show higher levels of mental health distress due to post-operative restrictions resulting in inactivation. However, a pilot study conducted by the Cardiac Psychology Laboratory revealed no significant differences in mental health symptomatology between surgical and nonsurgical groups in a sample of aneurysm and dissection patients (Jordan et al., 2024).

Posttraumatic Stress Disorder. Rates of posttraumatic stress disorder (PTSD) are consistently higher in type A and B dissection survivors than in the general population (Chen et al., 2020; Goldstein et al., 2016; Kilpatrick et al., 2013; Lin et al., 2021; Pasadyn et al., 2020). Prevalence of PTSD has been shown to be higher in type A than type B dissection survivors (Lin et al., 2021). This discrepancy likely exists because type A dissection nearly always requires immediate surgical intervention (Levy et al., 2023; Brunkwall et al., 2012; Nienaber et al., 2010).

Research is mixed regarding risk factors for the development of PTSD following dissection. While some studies found no sex differences in rates of PTSD following dissection (Chen et al., 2020; Pasadyn et al., 2020), female status was found to be significantly associated with PTSD risk in another (Lin et al., 2021). However, depressive symptoms have consistently been found to be positively associated with PTSD symptoms, likely due to symptom overlap including low mood and sleep disturbances (Chen et al., 2020; Lin et al., 2021; Pasadyn et al., 2020). The presence of postoperative complications (e.g., atrial fibrillation, prolonged

ventilation, renal failure) have also been shown to increase the risk of PTSD in type A survivors (Pasadyn et al., 2020). However, in a group of German type A survivors, duration of hospital stay, a potential proxy for complications/ease of physical recovery, did not affect risk of PTSD development (Adam et al., 2018).

Continued sexual activity and engagement in occupational obligations was found to be protective against the development of PTSD, perhaps due to the incidental exposure provided by continued engagement (Pasadyn et al., 2020). However, PA engagement prior to dissection has also shown protective effects for overall physical and mental well-being, but not development of PTSD (Adam et al., 2018). Evidence is mixed regarding sex differences in protective factors against PTSD for dissection survivors with one study showing that college education or higher, stronger subjective support, and greater optimism were protective for men, but not women (Chen et al., 2020). However, a different study found that optimism was an important protective factor against PTSD for both male and female, type A and B survivors (Lin et al., 2021).

Though many studies speak to patients who have met diagnostic criteria or cut-off scores for PTSD, many dissection survivors experience subclinical levels of PTSD that are still distressing and impairing (Pasadyn et al., 2020). In a study examining type A survivors, 23% of the sample met diagnostic criteria for PTSD and over half of the entire sample had at least one symptom of PTSD, even after a median of 6.8 years post-operative (Pasadyn et al., 2020).

It is important to highlight that one of the hallmark symptoms of PTSD, hypervigilance, is consistently elevated in those who have experienced type A dissection. For example, the most highly endorsed symptom in the Pasadyn et al. (2020) study was feeling “constantly on guard” with these results being corroborated by a qualitative study conducted with a group of 10 type A and B survivors (Jönsson et al., 2020). This hypervigilance to bodily sensations following

cardiac events has been detailed in other cardiac disease states, particularly as it relates to the patient experience following implantable cardioverter defibrillator (ICD) shocks. Such hypervigilance is likely maintained by body-checking behaviors (e.g., checking blood pressure, heart rate, body “scanning”) that both provide the illusion of control over future cardiac events and prompt overestimation of their risk for future events (Sears et al., 2023).

Health-related quality of life.

Health-related quality of life in Type A Dissection Survivors. Health-related quality of life (HRQoL) is defined by the U.S. Department of Health and Human Services as “a multidomain concept that represents the patient’s general perception of the effect of illness and treatment on physical, psychological, and social aspects of life” (U.S. Department of Health and Human Services, 2006). It stands to reason that those who have experienced dissection or are living with aneurysm may experience reduced HRQoL, whether due to the symptoms themselves, or the mental/emotional ramifications that often accompany these conditions, as reported above. Most available data demonstrates that HRQoL is lower in type A survivors than that of the general population (Endlich et al., 2015; Eranki et al., 2022; Jussli-Melchers et al., 2017). Data also suggests that type A patients have worse HRQoL specifically related to pain and function than aneurysm patients who also underwent surgical repair (Immer et al., 2002). Interestingly, a study conducted by St. Pierre et al. (2022) found that on the SF-36, type A dissection patients scored lower on all domains, except mental health. This finding contrasts with the aforementioned studies that demonstrate mental health symptomatology at higher rates than in the general population. There are inconsistent findings regarding the impact of age on HRQoL in type A patients; a meta-analysis demonstrated that older patients are more vulnerable to

physical consequences, while younger patients suffer more mentally (Eranki et al., 2022) while another study found no differences in HRQoL by age (Jussli-Melchers et al., 2017).

Health-related quality of life in Type B Dissection Survivors. HRQoL has also been examined in type B survivors. One such study examined HRQoL using the SF-36 before and after type B surgical repair, finding that patients reported improvements in all studied domains except emotional role, vitality, and mental health after surgical intervention. HRQoL has also been compared in type B patients who underwent elective versus urgent surgical repair, with results demonstrating no significant differences in HRQoL between groups 2.5 years post-operatively (Dick et al., 2009). Research has demonstrated that for type B patients who were managed pharmacologically, improvements were experienced in pain and social functioning and reductions were observed in emotional role domain, with all other domains remaining consistent as measured by the SF-36 (Bi et al., 2020).

HRQoL has been examined in pharmacological versus surgical intervention patients, with no significant differences in HRQoL emerging between groups. However, patients of both groups scored lower on physical functioning than the general population, with younger patients showing more impairment. As might be expected, more time since medical event and subsequent intervention was associated with greater HRQoL (Meccanici et al., 2023).

A primary concern of examining HRQoL in medically complex patients is the identification of a comparison group. Healthy age-matched adult comparisons are available on generic quality of life (QOL) measures, but the use of disease-specific measures only allows for comparisons between “unhealthy” patient groups. Generic QOL measures may lack specificity in patient populations with specific symptoms or concerns.

Physical Activity in Aortic Disease Patients

As previously mentioned, many patients with aortic disease fear PA, despite PA engagement before and after dissection repair being associated with better outcomes (Adam et al., 2018; Pasadyn et al., 2020). Current guidelines suggest that moderate cardiovascular activity is safe for patients with aortic disease and regular, moderate cardiovascular exercise could reduce strain on the aorta because of decreased blood pressure (Corone et al., 2009). Some forms of PA, however, are discouraged including very heavy weightlifting, sprinting, and contact sports, such as football or hockey (Chaddha et al., 2014; Isselbacher et al. 2022). Maximum workload weightlifting is discouraged, due to the massive spikes in blood pressure that occur when straining to lift very heavy weights (Isselbacher et al., 2022). Engagement in contact sports is discouraged due to the potential for aortic dissection as the result of blunt-force trauma (Gang et al., 2023).

These fears of PA often generalize beyond formal exercise in cardiac patients. Many cardiac patients fear and therefore avoid sexual activity due to its exertive nature. However, sexual activity is considered safe; blood pressure and heart rate are only moderately elevated during sexual activity, even at the time of climax, and normalize within two minutes of orgasm (Chaddha et al., 2014). Continued engagement in sexual activity is associated with less mental health distress, while avoidance of sexual activity is associated with reduced mental and physical HRQoL in type A survivors (Pasadyn et al., 2020). Further, limited sexual activity has been associated with both anxiety and depression in cardiac patients (Friedman, 2000; Kriston et al., 2010). Peer-reviewed, informational patient pages have been created to dispel such myths regarding PA in aortic disease patients (Martin et al., 2023).

Psychological Distress, Associated Consequences, and Interventions in Cardiac Surgery Patients

While limited information exists regarding psychological distress in aneurysm and dissection patients, a wealth of literature is available regarding other cardiac surgeries, particularly coronary artery bypass grafting (CABG). Available evidence suggests that psychological distress is highly prevalent in CABG patients and that the presence of such distress has tremendous impacts on post-surgical outcomes including quality of life, medical regimen adherence, and even mortality (McCann et al., 2023).

Psychological distress.

First, the experience of depressive symptoms following CABG is common; prior work suggests that up to 50% of post-CABG patients experience depressive symptomatology with many reaching diagnostic threshold for Major Depressive Disorder (MDD; Waterman et al., 2020; Del Re et al., 2022; Celano & Huffman, 2011). Such symptoms can persist well after anatomically successful surgical intervention and physical recovery, with a recent meta-analysis reporting that depressive symptoms are often present even one year post-operatively (Correa-Rodríguez et al., 2020).

Anxious symptomatology is also highly prevalent in patients before CABG, with multiple lines of work indicating increased rates of anxiety after successful CABG (Gallagher & McKinley, 2007; Krannich et al., 2007; Rymaszewska et al., 2003). The prevalence of generalized anxiety disorder (GAD) is elevated in CABG patients compared to the normal population, with prior meta-analytic work suggesting that approximately 10% of post-CABG patients reach the diagnostic threshold for GAD, while the 12-month worldwide prevalence for

GAD is approximately 1.3% (Lewis-Fernández et al. 2010; Mezuk et al. 2013; Ruscio et al. 2017; Tully et al., 2015).

Predictors of psychological distress. Many factors influence the development of psychological distress both pre- and post-surgical intervention. Beginning with demographic factors, evidence is mixed regarding age and sex as predictors of distress in cardiac surgery patients. A recent meta-analysis found that while some research has found no evidence of age and sex differences in post-surgical distress, other work has demonstrated small to moderately increased distress in female and younger patients. The authors hypothesized that these differences in results may be due to the limited enrollment of both younger patients and female patients (McCann et al., 2023). Marital status also has important implications on psychological distress and health outcomes post-cardiac surgery with those are partnered exhibiting less mental health symptomatology, much greater medication adherence, increased engagement with cardiac rehab, more PA, more healthful dietary habits, and less healthcare utilization than single patients (Caccamo et al., 2020; Dhindsa et al., 2020; McCann et al., 2023).

Next, other factors following cardiac surgery appear to differentially impact psychological distress; for example, angina, or chest pain, is frequently experienced in patients who undergo cardiac surgery requiring sternotomy, such as aortic repair (Kloner & Chaitman, 2017; Finn & Bower, 1976). Patients are generally not adept at distinguishing between uncomfortable and threatening chest pain, and therefore, the experience of pain can be extremely distressing, as patients often interpret it as a sign of danger (Bass & Mayou, 2002). Importantly, the relationship between pain and distress is bidirectional, with evidence showing that although post-operative pain can predict the presence of depressive symptoms, pre-existing psychological distress predicts greater post-operative pain (Perski et al., 1998). High stress levels have also

been shown to increase the risk of developing depression and lasting anxiety following cardiac surgical intervention (Curcio et al., 2019; Richardson et al., 2012).

Regarding health-promoting behaviors, PA engagement both pre- and post-operatively has proven protective against psychological distress in CABG patients (McCann et al., 2023; Kehler et al., 2019). As previously mentioned, PA has shown preservative effects on mental health in aortic patients (Chaddha et al., 2015) with research also showing that limited PA engagement puts CABG patients at risk for psychological distress (Guerrera et al., 2020; Hammen, 2018). In fact, for post-operative patients with a history of depression, lack of PA more than doubled the risk of depression (Horne et al., 2013).

Ramifications of psychological distress.

The consequences of psychological distress both pre- and post-operatively extend beyond the mental health symptomatology itself and have important implications for patient health and overall quality of life. Meta-analytic work has determined that the presence of chest pain predicts slight increases in psychological distress post-operatively and has consequences; those CABG patients experiencing post-operative pain show reduced treatment adherence which can have deleterious effects on symptom burden, quality of life, healthcare utilization, functional status, and mental health (McCann et al., 2023; Ono et al., 2022; Karawan Sayad Sallam et al., 2022; Hokkanen et al., 2021; Abd El-Moneam Ahmed et al., 2022; Tüfekçi et al., 2022; Aydin & Gürsoy, 2019). The identification and treatment of mental health distress in surgical patients is paramount, with data showing that the presence of anxiety or depression is associated with increased hospitalization, morbidity, and up to 75% greater risk of future cardiac events (Li et al., 2020; Martens et al., 2010; Tully et al., 2011).

Efficacy of interventions in reducing psychological distress.

Interventions targeting psychological distress with education and PA show promising results: first, interventions targeting increased PA in post-cardiac surgery patients have proven efficacious with increased PA levels linked to improved mood, perceptions of QoL, and well-being compared to patients who did not increase PA engagement (Gray et al., 2022; McAuley & Rudolph, 2016; Mao et al., 2020).

Interventions expressly dedicated to increasing education before surgical intervention have demonstrated efficacy in reducing patient distress, enhancing QoL, and improving health outcomes (McCann et al., 2023; Shahmoradi et al., 2022; Salzmann et al., 2020). Importantly, patient perceptions of the quality of information provided matter; in a study examining the impact of education in post-operative cardiac patients, those who perceived educational information as “high quality” showed greater reductions in anxious and depressive symptomatology than those who perceived the information as “low quality” (Davies, 2000).

Patients who received psychological care interventions (e.g., aimed toward encouraging patients to feel and express their emotions, rely on social support, and seek information following surgery) demonstrated moderately lower levels of both anxiety and depression than those who received the standard of care, even up to two years post-operatively (Sørli et al., 2007). Participation in cardiac rehabilitation programs has been associated with small reductions in the likelihood of future cardiac events and post-operative distress and interventions with goals of improving psychological skills often take place in this setting (Beatty et al., 2023; McMahon et al., 2017; Rutledge et al., 2013). Meta-analytic work examining the effects of psychological treatment in cardiac rehabilitation programs demonstrated that while such treatments were efficacious in reducing depressive symptoms, no significant differences emerged in anxious

symptoms between intervention and control groups (Linden et al., 2007). In contrast, one study reported increased anxiety from baseline following two-week engagement in cardiac rehabilitation with authors attributing this rise in anxiety levels to more knowledge regarding potential risks (Caccamo et al., 2020). Shelley and Pakenham (2007) utilized psychologists to provide individualized cognitive behavioral techniques to pre-operative, first-time CABG patients. Participants with high levels of self-efficacy benefitted from the intervention post-operatively as evidenced by lower ratings of pain and distress while those with lower self-efficacy reported greater distress, possibly due to being made aware of their vulnerability. Although the bulk of the available research is focused on pre-operative education, there is some evidence to show that post-operative education versus care as usual can also improve patient outcomes including rehospitalization (Bates et al., 2014).

One RCT aimed to determine if the timing of educational intervention (pre- versus post-surgery) impacted outcomes including knowledge of post-CABG self-care and symptoms, with no significant differences emerging (Fredericks, 2009).

Common-Sense Model of Illness Self-Regulation

The common-sense model of illness self-regulation describes how individuals conceptualize their illness(es) to cope intellectually, behaviorally, and emotionally (Leventhal et al., 1980; Leventhal et al., 1984; Leventhal et al., 1982). The model has five facets: cause, timeline, controllability, consequences, and identity. First, there are many attributions patients can make about the sources of responsibility for their illness, whether it be emotional/psychological (Moss-Morris et al., 1996), environmental, or biological (Heijmans & de Ridder, 1998; Leventhal et al., 2016). Timeline refers to the beliefs an individual has regarding the duration of the illness, whether they believe that they will heal quickly, or if the

illness carries a “life sentence” (Leventhal et al., 2016). The controllability component of the common-sense model refers to the degree to which patients feel that they can have an impact on their illness and its progression through behavioral means (e.g., adhering to medical regimens; Leventhal et al., 2016). Many patients wonder about the consequences that their illness will have on their life whether it be social, emotional, physical, or financial, among other possible outcomes (Leventhal et al., 2016). Identity refers to both being able to label or name the illness itself (versus symptoms for which a diagnosis has not yet been made) and perceptions regarding illness symptomatology (Leventhal et al., 2016).

This conceptual framework of illness self-regulation goes beyond conceptualization and has important implications for patients. Specifically, illness representations have been found to impact the cognitive processing of information about their illness, symptoms, coping behaviors, and medical regimen adherence (Croyle & Ditto, 1990). These representations also affect patients’ decisions regarding healthcare utilization (Leventhal et al., 1980; Leventhal et al., 1992) and have effectively predicted success in chronic illness coping (Hampson et al., 1990). Such implications have been examined in CABG patients, with those viewing their condition as chronic feeling less control over their condition and the ability of medical regimen adherence to have positive effects, in addition to greater perceived consequences of their condition (Hermele et al., 2007).

Behavioral Activation and Physical Activity

Behavioral activation (BA) is a behaviorally based treatment protocol used for the treatment of depression, with aims to fight deactivation through the identification of values, and subsequently, the encouragement of values-based activity engagement (Lejuez et al., 2011). The protocol posits that deactivated patients lack environmental reinforcement from engagement in

positive, valued activities, and therefore remain stuck in a cycle of depressive thoughts/feelings, limited activity engagement, and a lack of reinforcement from their environment (Jacobson et al., 1996; Dimaggio & Shahar, 2017; Hopko et al., 2006). As mentioned above, many patients who undergo cardiac surgery endorse the experience of depressive symptomatology and report deactivation (Waterman et al., 2020; Del Re et al., 2022; Celano & Huffman, 2011). Importantly, a qualitative study aimed at determining common values of CVD patients elucidated nine values including “to have or maintain a healthy lifestyle”, with a subtheme of wanting help with increasing PA levels (Bente et al., 2021). PA interventions with a BA foundation have shown significant reductions in depressive symptomatology and significantly increased self-reported PA engagement in women with diabetes, with this increased PA engagement being associated with increased social engagement (Schneider et al., 2016).

Efficacy of Cognitive Behavioral Therapy Treatments in Patients with Cardiovascular Disease

Cognitive behavioral therapy (CBT) is a psychotherapeutic intervention aimed at targeting both thoughts/beliefs (e.g., identifying distorted thinking patterns and realigning thoughts with reality) and behaviors (e.g., reducing avoidance behaviors; American Psychological Association Division 12, n.d.). CBT has demonstrated efficacy in improving outcomes in patients with CVD including reductions in anxiety, depression (Holdgaard et al., 2023; Li et al., 2021), and stress (Holdgaard et al., 2023). In addition, CBT interventions in CVD patients have been shown to improve heart-related quality of life, a measure assessing both physical and emotional quality of life in patients with CVD (Oldridge et al., 2014), and adherence to cardiovascular rehabilitation programs (Holdgaard et al., 2023). Finally, CBT interventions for CVD patients have proven effective in reducing both readmissions for CVD-

related problems and rates of both fatal and nonfatal CVD events, even at seven years post-intervention (Holdgaard et al., 2023; Gulliksson et al., 2011).

Study Purpose

Accordingly, the goal of the present study was to pilot study a manualized intervention for aneurysm and dissection patients based on the principles of CBT and BA to increase patient education, allowing for challenging of faulty beliefs about their disease state and ultimately, reduce disease-specific distress. A second goal was to increase PA levels through education about value-driven behavior and the role of PA in promoting a healthy lifestyle. The intervention focused on four topics: 1) disease-specific information, 2) the mental and physical benefits of PA and health as a value to encourage increased PA, 3) CBT-based tactics to challenge distorted thoughts and/or beliefs regarding their health, 4) the importance of engaging in values-based activities to lead a fulfilling life and protect against mental health symptomatology for future well-being. This multi-faceted approach to improving patient quality of life was novel in both its design and intended population, those with aortic disease.

Chapter II: Methods

Study Aims

The purpose of the present study was to pilot-test the feasibility, acceptability, and efficacy of a four-session manualized intervention based on principles of CBT and BA for utilization in a group of patients with aneurysms and dissections. The intervention provided information spanning multiple domains including 1) disease-specific information, 2) the mental and physical benefits of PA and health as a value to encourage increased PA, 3) CBT-based tactics to challenge distorted thoughts and/or beliefs regarding their health, 4) the importance of engaging in values-based activities to lead a fulfilling life and protect against mental health symptomatology for future well-being. The study targeted both general and disease-specific distress with a secondary behavioral target of increasing PA.

Aim 1

The current study aimed to determine the feasibility and acceptability of a CBT and BA-based manualized intervention for survivors of dissection and those living with aneurysms in a rural-serving cardiothoracic surgery clinic. Evaluation of feasibility was determined by the recruitment effort's success (i.e., the proportion of approached patients who agreed versus refused to participate) including reported barriers for those who declined to participate, rates of intervention completion, and attrition. Intervention acceptability was evaluated using a questionnaire completed after the final session.

Hypothesis 1. It was anticipated that over 50% of approached patients would be interested in participating in the intervention due to its unique nature and the high documented rates of psychological distress in this patient population. It was hypothesized that certain barriers would prohibit actual participation, such as patient distance from ECHI and time constraints.

However, the option of three different treatment delivery modalities was predicted to allow for greater participation than if only in-person participation was offered. It was predicted that attrition rates may be of concern given that patients were expected to engage in the intervention for approximately 1.5 hours each week for four weeks, regardless of treatment delivery modality.

Aim 2

The current study aimed to further establish levels of general psychological and disease-specific distress in dissection survivors and patients living with aneurysm. In addition, the study aimed to examine how distance from treating hospital at the time of dissection may impact the experience of psychological distress. Distress was determined using various measures of both general psychological and disease-specific distress.

Hypothesis 2. It was predicted that both general psychological and disease-specific distress would be highly prevalent in both survivors of aortic dissection and those living with aneurysms, consistent with prior pilot work conducted by the East Carolina University Cardiac Psychology Laboratory (Jordan et al., 2024). Further, it was hypothesized that those residing farther from the treating hospital at the time of dissection would display higher rates of general psychological distress than those closer.

Aim 3

The current study aimed to determine whether the proposed intervention was effective at reducing general psychological distress, disease-specific distress, and increasing PA levels. Outcomes regarding both disease-specific and psychological distress were evaluated using validated and normed scales, described below. PA was measured using actigraphy watches provided to patients at baseline and returned after intervention completion.

Hypothesis 3. It was predicted that patients who completed all four sessions of the intervention would show reduced disease-specific and general psychological distress and increased PA levels at intervention conclusion compared to baseline.

Aim 4

The current study aimed to determine if controllability, a facet of the common-sense model of illness self-regulation, differs between pre-and post-intervention. This outcome was measured using the Brief Illness Perception Questionnaire, described below.

Hypothesis 4. It was predicted that the proposed combination of disease-specific education, CBT strategies to challenge faulty thinking about their condition, and the use of BA-based tactics to increase value-driven PA would improve patient perceptions of controllability regarding their diagnoses.

Procedure

Participants

In congruence with previously established guidelines for pilot feasibility studies using quantitative measures (Teresi et al., 2022), we aimed to recruit thirty participants. Ultimately, 28 participants were recruited with 15 participants completing the intervention. Eligibility status for the current study included being at least 18 years old, English-speaking, and with a documented history of either aneurysm or dissection. Those patients who were under 18 years old, not proficient in the English language, had a contraindication to PA, or had no documented history of aneurysm or dissection were not approached for participation in the study.

Study Recruitment

The present study was approved by the East Carolina University and Medical Center Institutional Review Board, at which point study recruitment began. A review of patients on the

cardiothoracic surgery department's schedule was conducted, with patient eligibility being determined through a preliminary review of their electronic health record (EHR). Patient eligibility was confirmed by their physician or nurse practitioner. Then, eligible patients were approached and informed of the study by a team member during their regularly scheduled appointment. The study team member described the study and outlined what was expected of participating patients. If patients expressed interest in study participation, the study team member and patient completed the informed consent process and time was provided for patients to ask questions. Following the provision of informed consent, patients completed baseline measures and were given the actigraphy watch with instructions to wear the watch for at least four hours each day and take it off when showering/bathing. In addition, participants were provided with copies of disease-specific manuals at the time of consent.

Baseline measures included the Patient Health Questionnaire (PHQ-2), the Generalized Anxiety Disorder Questionnaire (GAD-2), the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), the CDC Healthy Days Core Module (CDC HRQOL-4) the Cardiac Anxiety Questionnaire (CAQ), the Fear About Exercise Questionnaire (FAE), the Brief Illness Perception Questionnaire (BIPQ), and the Duke Activity Status Index (DASI). Participants completed these measures again following completion of the intervention, with the addition of an intervention evaluation questionnaire. Participants were compensated for their time with \$15 at the time of consent and \$15 after intervention completion for a total of \$30.

Intervention Plan and Outline

The present study intervention took place over four sessions via multiple delivery modalities. The intervention utilized CBT principles, particularly the introduction of cognitive

restructuring and BA to provide disease-specific and general psychoeducation, help participants challenge and reframe maladaptive thoughts about their condition, and increase PA levels.

To allow for maximum exposure and ease of intervention administration, the intervention was delivered via three modalities depending on patient preference. First, traditional in-person groups were offered. Second, virtual groups were offered for those who either could not or did not wish to attend in person. These groups, both in-person and virtual, contained two to three participants in each group, allowing for more direct communication between group facilitators and participants, conversation between participants. Cardiac psychology laboratory members served as group facilitators, with those having at least two years of clinical training (rising third years) being eligible to lead groups and those with one year of clinical training (rising second years) being eligible to serve as secondary facilitators. Facilitators only lead group sessions after attending a group training led by the current author to gain familiarity with the manual, intervention, and disease-specific education. In-person and virtual group sessions lasted approximately 60 minutes. If participants were unable to attend a session, make-up sessions (whether virtual or in-person) were offered on an individual basis with the present author and this option was utilized on two occasions.

The third treatment modality required interested participants to watch pre-recorded videos of the present author detailing the information from each module in the same way that it is provided during the group formats. However, due to the individual nature of the pre-recorded videos treatment modality, participants in this format could not benefit from either asking questions in-vivo or hearing comments and questions from other participants. Initially, it was planned that participants would be sent links to pre-recorded videos via Microsoft Teams, however, Microsoft Teams lacked the capability to ascertain whether patients had watched each

video in its entirety. Therefore, participants were sent videos embedded within a Qualtrics survey; Qualtrics allowed for settings that prevented submission of the survey until enough time had passed to ensure the video had been played in its entirety. In addition, the creation of a Qualtrics survey allowed for the creation of an open-ended survey area so that participants could take note of any questions they had whilst watching. The four videos were each approximately twenty minutes long. The present author called each participant in this group once survey results indicated that they had watched each of the four videos to check in and allow for participants to ask questions regarding session content.

As noted above, four sessions were conducted, whether via in-person or virtual groups or via pre-recorded video. The first session of the series provided disease-specific education. As the sample was comprised of both aneurysm and dissection patients, disease-specific education was different, particularly as it related to the actual pathophysiology of their disease state. As such, patients were divided by diagnosis for the first session to allow for easier dissemination of disease-specific education. For the pre-recorded video modality, the present author recorded two separate videos: one for those with a diagnosis of aneurysm and one for those with dissection. For those participating in group modalities (both in-person and virtual), patients attended the first disease-specific education class separately and then came together for the remaining three sessions. The second session detailed the mental and physical benefits of PA and the exploration of health as a value to encourage increased PA. Importantly, activity restrictions were similar for both patient groups, and therefore, information about the safety of PA engagement was the same. The third session prioritized the teaching of CBT-based tactics to challenge distorted thoughts and/or beliefs regarding their health. The fourth and final session emphasized the importance of

valued activity engagement to promote meaning and fulfillment in their lives and protect against mental health symptomatology for future well-being.

After the fourth session, participants were re-administered measures completed at baseline. Those participating in in-person groups completed paper and pencil measures. Those participating in virtual groups completed the measures via Qualtrics survey sent at the end of the fourth week. Those in the pre-recorded video group completed measures via Qualtrics survey after they watched the final video and completed the fourth check-in call.

Measures and Information from EHR

Demographic Information

A review of participant's electronic health records (EHR) was conducted to obtain demographic information including sex, age, race, ethnicity, marital status, employment status, education level, and insurance type. The three former variables were collected to serve as a proxy for patient socioeconomic status (SES).

Medical Information

Information regarding other medical comorbidities (e.g., diabetes mellitus, hypertension, and chronic kidney disease, among others) was collected from patients' EHR to gain information about medical complexity. This information was used to calculate the Charlson Comorbidity Index (CCI; Charlson et al., 1987), a measure that predicts 10-year survival rates in those with advanced disease states, to gain information about patient disease burden and to quantify participant medical complexity.

Measures

Patient Health Questionnaire- 2-item. The PHQ-2 is a brief, valid, 2-item screening measure for depressive symptoms including anhedonia and depressed mood (Kroenke et al.,

2003). This measure was developed from the traditional 9-item version to provide a briefer scale to be used in either larger assessment batteries or clinical settings. Patients are asked to indicate how often they have experienced each of the two previously mentioned symptoms in the most recent two-week period, rated on a scale of 0-3 and ranging from “not at all” to “nearly every day.” Scores on the two items are summed to calculate a total PHQ-2 score, with scores above three warranting further screening and indicating the potential presence of major depressive disorder. The PHQ-2 has demonstrated good internal consistency with a Cronbach’s alpha of 0.77 (Maroufizadeh et al., 2019).

Generalized Anxiety Disorder Questionnaire- 2-item. The GAD-2 is a brief, valid, 2-item screening measure used for the assessment of generalized anxiety disorder symptoms including feelings of nervousness and inability to manage worry (Kroenke et al., 2007). This measure was developed from the traditional 7-item version to provide a briefer scale to be used in clinical populations. Patients are instructed to gauge how often they have experienced the aforementioned symptoms in the last two weeks, rated on a scale of 0-3 and ranging from “not at all” to “nearly every day”. Scores on the two items are summed to calculate a total GAD-2 score, with scores above three warranting further screening and indicating the potential presence of generalized anxiety disorder. The GAD-2 has demonstrated good reliability ($\alpha = .77$) and validity in addition to high correlations with GAD-7 total scores ($r = 0.94, p < 0.01$), indicating good utility in clinical populations (Ahn et al., 2019; Hughes et al., 2018).

Primary Care PTSD Screen for DSM-5. The PC-PTSD-5 is a five-item screening measure designed to assess for the presence of PTSD with questions based on DSM-5 criteria (Prins et al., 2015). In the initial validation study conducted with a sample veterans, the PC-PTSD-5 showed exceptional diagnostic accuracy with excellent sensitivity (95%) and specificity

(85%; Prins et al., 2016). The PC-PTSD-5 has also been used and validated within civilian populations (Williamson et al., 2022; Lathan et al., 2023) with results demonstrating that cut-off scores of four maximized sensitivity and demonstrated adequate specificity in a civilian population.

Cardiac Anxiety Questionnaire. The Cardiac CAQ is an 18-item self-report measure developed to examine cardiac-specific anxiety. The CAQ has three subscales: cardiac fear, cardiac-related avoidance, and heart-focused attention. Participants must indicate how often they felt or behaved in accordance with each item on a 5-point Likert scale ranging from zero (never) to four (always). The scores of all items are averaged to provide an overall CAQ scale score. Items that comprise each of the three scales are also averaged to calculate subscale scores. Both CAQ total and subscale scores can be compared to averages provided by the author from its initial validation study to indicate whether patients show higher or lower-than-average cardiac anxiety as compared with post-cardiac angiography patients. The scale has demonstrated good internal consistency ($\alpha_s = 0.83$) and convergent validity with other previously validated measures of psychological distress (Eifert et al., 2000).

Healthy Days Core Module. CDC HRQOL-4 is a four-question module that is a subset of the CDC's Healthy Days Measure. The CDC HRQOL-4 assesses one's perceptions about their health status generally, the number of days patients felt physically unwell over the past month, the number of days patients felt mentally unwell over the past month, and how many days patient's mental or physical health limited their ability to engage in activities as usual over the past month (Centers for Disease Control and Prevention [CDC], 2000). The CDC-HRQOL-4 has shown good construct, internal, and test-retest validity in a group of non-institutionalized American adults (CDC, 1998; Hennessy et al., 1994; Andresen et al., 2003).

Fear About Exercise Questionnaire. The FAE Questionnaire is a 5-item questionnaire designed to evaluate fear associated with PA and exertion (Farris et al., 2019). Items aim to assess the examinee's beliefs about their ability to safely engage in exercise. Specifically, the questionnaire assesses the degree to which patients believe that: 1) a physical event might occur during exercise, 2) they won't be able to breathe sufficiently well during exercise, 3) a cardiac event will happen during exercise, 4) they must stop or slow down exercise because of health, and 5) they should avoid exercising alone due to safety concerns. Participants must rate their responses on a 5-point Likert scale ranging from "strongly agree" to "strongly disagree." The tool was developed within a patient population attending cardiovascular pulmonary rehabilitation. Fear of exertion was found to be significantly negatively correlated with patient outcomes (Farris et al., 2019). Measures of internal consistency were not reported.

Brief Illness Perception Questionnaire. The BIPQ is a 9-item self-report measure of cognitive and emotional manifestations of illness (Broadbent et al., 2006). Specifically, questions focus on aspects of personal attributions and perceptions of control over disease course. Psychometric reliability and validity have been established in many different patient populations. Research has shown that patients' illness perceptions, as measured by the BIPQ, are associated with important outcomes, including medical regimen adherence, quality of life, self-management behaviors, and functional recovery (Petrie et al., 2007).

Duke Activity Status Index. The DASI is a 12-item scale that assesses self-reported functional ability by evaluating examinees' ability to complete major activities of daily living including household and self-care tasks and recreational activities, including playing sports, and sexual functioning. The tool is valuable in determining patient daily functioning levels. The measure is scored using the metabolic equivalence of task (MET) and has shown good reliability

(Spearman's correlation: 0.58-0.81) in patients with various manifestations of heart disease (Hlatky et al., 1989).

Intervention Evaluation Questionnaire. After the final session, participants were asked to complete a measure assessing their satisfaction with the intervention and any perceived benefits they may have experienced from having participated. Specifically, they were asked if they saw improvements in their levels of aortic disease education, confidence in their ability to manage their health, satisfaction with the program, their perception of the clarity and ease with which program information could be understood, and interest in additional programs for aortic patients in the future. In addition, an open-ended question asked patients to provide any other feedback that they have regarding the intervention.

Data Analysis

IBM SPSS Statistics (Version 31, IBM Corp.) was used for all data analysis. Descriptive statistics were run to compile demographic and medical information. In addition, dependent samples t-tests were used to draw comparisons and understand differences between participant scores on measures and physical activity pre- and post-intervention. Additional assumptions for dependent samples t-tests (i.e., normal distribution of data, extreme outliers) were assessed for each variable. When either of these assumptions were violated, a non-parametric test, specifically Wilcoxon signed-rank tests were utilized given the paired nature of the data was used.

Aim 1. To determine the feasibility of the proposed intervention, recruitment efforts, program completion, and attrition rates were collected. To determine if the intervention was feasible in the ECHI Cardiothoracic Surgery clinic, records were kept that indicated the number of patients approached, if they agreed to participate in the intervention, and if not, the reason that

was given for declining which were coded to allow for modifications of future interventions offered by the cardiac psychology laboratory. The frequency and percentage of patients who completed the intervention and attrition rate was calculated.

To assess participant perception of the intervention, descriptive statistics were calculated based on the intervention evaluation questionnaire.

Aim 2. To further establish rates of general psychological and disease-specific distress in dissection survivors and aneurysm patients, descriptive statistics were run. Specifically, these analyses examined scores on the PHQ-2, GAD-2, PC-PTSD-5, BIPQ, FAE, and CAQ. An initial aim of the study was to determine if distance from treating hospital at time of dissection had an impact on posttraumatic stress symptoms as measured by the PC-PTSD-5. However, only four participants with dissections enrolled in the study and as such it is unlikely that these analyses would have yielded statistically meaningful results.

Aim 3. To determine the impact of the intervention on disease-specific, general psychological distress, and PA levels, dependent samples t-tests were conducted. For general psychological and disease-specific distress, dependent samples t-tests were run on scores on the PHQ-2, GAD-2, PC-PTSD-5, CAQ, BIPQ, and FAE at baseline and post-intervention. PA engagement at pre- and post-intervention were determined using accelerometer data that provides information on step count, daily active minutes, and sedentary time. Pre- and post-intervention data were compared using dependent samples t-tests to determine if changes in PA engagement were present.

Aim 4. To determine whether patient perceptions of controllability as delineated by the BIPQ differed between pre- and post-intervention, dependent samples t-tests were conducted.

Chapter III: Results

Socioeconomic Demographic Variables

A total of 15 participants were recruited from the cardiothoracic surgery department and completed the intervention. All participants had diagnoses of either aneurysm or dissection. Participants ranged in age from 45 to 82 years old with an average age of 65 years old ($SD = 10.67$). The majority of participants identified as male (66.7%), White (66.7%), Non-Hispanic/Latino (93.3%), married (66.7%) and retired (53.3%). Education level was unable to be assessed as it rarely appeared in participants' medical charts. The majority of participants (53.3%) had Medicare insurance coverage. See Table 1 below for full demographic variables.

Mental and Physical Health Variables

The most common primary aortic diagnosis for participants was ascending aneurysm (73.3%). The majority of participants had not had an ED visit (60.0%) or been hospitalized over the past year (53.3%). Of those who had been hospitalized (seven patients; 46.7%), most had been hospitalized for reasons related to cardiovascular disease; only one had a non-cardiovascular disease related hospitalization. A Charlson Comorbidity Index (CCI) score was calculated for each patient to gauge medical severity given factors including age and other medical comorbidities. The CCI provides a predicted 10-year survival rate. The average score on the CCI ($M = 3.29$, $SD = 2.03$, $range = 0-9$), communicated an average predicted 10-year survival rate between 54% and 77% (Charlson et al., 1987).

Mental health diagnoses were not collected from patient's EHR as prior research has demonstrated poor accuracy for behavioral health concerns in EHRs including diagnoses and treatment, both outpatient services and psychiatric hospitalizations (Madden et al., 2016).

Table 1*Participant Socioeconomic Demographic Variables*

Demographic variable		n	%
Sex	Male	10	66.7
	Female	5	33.3
Race	White	10	66.7
	Black	5	33.3
Ethnicity	Non-Hispanic/Latino	14	93.3
	Hispanic/Latino	1	6.7
Marital status	Single	3	20.0
	Married	10	66.7
	Widowed	1	6.7
	Legally separated	1	6.7
Employment status	Employed	5	33.3
	Retired	8	53.3
	Disabled	2	13.3
Insurance	Medicare	8	53.3
	Medicaid	1	6.7
	Private	5	33.3
	Veterans Affairs	1	6.7

However, psychotropic medication prescription status was collected, with nearly 40% of the sample being actively prescribed psychotropic medications.

Self-Reported General Psychological and Disease-Specific Distress

General Psychological Distress

General psychological distress, both pre-and post-intervention, was measured utilizing the PHQ-2, GAD-2, and PC-PTSD-5. Assumptions of normality were violated regarding depressive symptoms as measured by the PHQ-2 between pre- and post-intervention. Therefore, a Wilcoxon signed-rank test was used to examine potential differences. Results of this analysis indicated no

significant difference in depressive symptoms between pre-and post-intervention, $Z = -0.77$, $p = 0.44$, $r = -0.20$. One participant (6.6%) met the threshold for further examination of depressive symptoms both at the time of consent and post-intervention.

Results of dependent samples t-tests comparing anxiety as measured by the GAD-2 between pre ($M = 1.27$, $SD = 1.75$) and post-intervention ($M = 0.93$, $SD = 1.03$) were non-significant $t(14) = 0.86$, $p = 0.20$, $d = 0.22$. Regarding reported scores at or above threshold for further examination of symptoms, at time of consent, 13.3% (2/15) reported such symptomatology while at post-intervention, 6.6% of patients (1/15) were at this threshold.

There was no significant difference in posttraumatic stress as measured by the PC-PTSD-5 between pre- ($M = 1.07$, $SD = 1.54$) and post-intervention ($M = 1.07$, $SD = 1.54$), $t(13) = 0.00$, $p = 0.50$, $d = .00$. One participant was excluded from this analysis given that they reported exposure to a Criterion A traumatic event at baseline, but denied exposure to such an event at study end. Regarding reported scores at or above threshold for further examination of symptoms, at time of consent, 6.6% (1/15) reported such symptomatology while at post-intervention, no participants met this threshold. Importantly, all participants were provided with local outpatient and crisis hotline resources at consent and post-intervention.

Disease Specific Distress

Disease-specific distress was measured using the CAQ, FAE questionnaire, and BIPQ. First, regarding the CAQ, results showed no significant difference in total CAQ scores between pre- ($M = 1.41$, $SD = 0.53$) and post ($M = 1.42$, $SD = 0.50$) intervention, $t(14) = -0.027$, $p = 0.49$, $d = -0.01$. Additionally, there was no significant difference in heart-focused attention between pre- ($M = 1.19$, $SD = 0.85$) and post-intervention ($M = 1.23$, $SD = 0.56$), $t(14) = -0.218$, $p = 0.42$, $d = -0.06$. No significant difference was found in cardiac-related fear from pre- ($M = 1.32$, $SD =$

0.71) to post-intervention ($M = 1.50$, $SD = 0.50$), $t(14) = -1.20$, $p = 0.12$, $d = -0.31$. However, results of dependent samples t-tests demonstrated that participants reported significantly less cardiac-related avoidance between pre- ($M = 1.80$, $SD = 1.1$) and post-intervention ($M = 1.48$, $SD = 1.00$), $t(14) = 2.24$, $p = 0.02$, $d = 0.58$.

No significant differences were found between fear of exercise between pre- ($M = 14.53$, $SD = 5.68$) and post-intervention ($M = 12.47$, $SD = 4.64$), though the result approached significance with participants reporting less fear of exercise post-intervention $t(14) = 1.61$, $p = 0.07$, $d = 0.42$.

Results of the BIPQ demonstrated a significant reduction in overall perceived threat posed by their illness between pre- ($M = 39.47$, $SD = 9.05$) and post-intervention ($M = 34.10$, $SD = 12.33$), $t(14) = 1.94$, $p = 0.04$, $d = 0.50$. Assumptions of normality were violated regarding emotional impact of their condition between pre- and post-intervention, therefore, a Wilcoxon signed-rank test was used to examine potential differences. Results of this analysis indicated that emotional impact of their condition was significantly reduced between pre-and post-intervention, $Z = -1.67$, $p = 0.05$, $r = 0.43$. Results also demonstrated that patients viewed their conditions as significantly less concerning between pre- ($M = 6.87$, $SD = 2.82$) and post-intervention ($M = 4.53$, $SD = 2.9$), $t(14) = 2.70$, $p = 0.01$, $d = 0.70$. There were no significant differences in patient's perceived understanding of their illness, impact of their illness on their life, illness duration, control over illness, perceived treatment efficacy, and their experience of symptoms, all $ps > 0.05$. See Tables 2 and 3 for further information.

Measures Assessing Function

To assess for differences in function as measured by the Duke Activity Status Index (DASI), a Wilcoxon signed-rank test was utilized as the assumption of normality was not met

Table 2*Self-Report Data Between Pre- and Post-Intervention: Dependent Samples T-tests*

Measure	Pre- Intervention (<i>M, SD</i>)	Post- Intervention (<i>M, SD</i>)	<i>t</i> (14)	<i>p</i>	<i>d</i>
GAD-2	1.27, 1.75	0.93, 1.03	0.86	0.20	0.22
PC-PTSD-5*	1.07, 1.54	1.07, 1.54	0.00*	0.50	0.00
CAQ	1.41, 0.53	1.42, 0.50	-0.03	0.49	-0.01
HFA	1.19, 0.85	1.23, 0.85	-0.22	0.42	-0.06
Avoidance	1.80, 1.1	1.48, 1.00	2.24	0.02	0.58
Fear	1.32, 0.71	1.50, 0.50	-1.20	0.12	-0.31
FOE	14.53, 5.68	12.47, 4.64	1.61	0.07	0.42
BIPQ	39.47, 9.05	34.10, 12.33	1.94	0.04	0.50
Concern	6.87, 2.82	4.53, 2.9	2.70	0.01	0.70
Understanding (coherence)	5.13, 3.85	3.07, 3.26	1.52	0.08	0.39
Treatment control	4.13, 3.78	4.27, 2.94	-0.11	0.46	-0.03
Timeline	6.87, 3.18	5.80, 3.47	1.28	0.11	0.33
Personal control	5.07, 2.43	5.93, 2.82	-0.77	0.23	-0.20
Symptoms	2.60, 2.23	2.93, 2.55	-0.84	0.21	-0.22
Impact on life	4.12, 2.72	4.07, 2.34	0.08	0.47	0.02
CDC- HRQOL-4					
Physical health not good	6.60, 6.99	8.27, 8.96	-0.54	0.30	-0.14

Mental health not good 5.12, 7.73 4.53, 6.56 0.42 0.34 0.11
 *one patient's data omitted given criterion A inconsistency: $t(13)$

Table 3

Self-Report Data Between Pre- and Post-Intervention: Wilcoxon Signed- Rank Tests

Measure	<i>Z</i>	<i>p</i>	<i>r</i>
PHQ-2	-0.77	0.44	-0.20
BIPQ: Emotional impact	-1.67	0.05	0.43
DASI	-1.47	0.14	-0.38
CDC-HRQoL-4: Subjective health ratings	.00	1.00	.00
CDC-HRQoL-4: Health interfering days	-0.79	0.43	-0.20

following visual inspection demonstrating outliers and negative skew. Results demonstrated no significant difference in reported functional ability between pre- and post-intervention, $Z = -1.47$, $p = 0.14$, $r = -0.38$.

The CDC-HRQOL-4 was administered to patients to assess overall perception of health, days over the past month where physical health and mental health were “not good” and how many days either physical or mental health interfered with function. Results demonstrated no significant differences in days where physical health was not good between pre- ($M = 6.60$, $SD = 6.99$) and post-intervention ($M = 8.27$, $SD = 8.96$), $t(14) = -0.54$, $p = 0.30$, $d = -0.14$. There was also no significant difference between pre- ($M = 5.12$, $SD = 7.73$) and post-intervention ($M = 4.43$, $SD = 6.56$) regarding number of days where mental health was not good, $t(14) = 0.42$, $p = 0.34$, $d = 0.11$. Assumptions of normality were violated regarding self-reported rating of their health (i.e., poor, fair, good, very good) between pre- and post-intervention. Therefore, a

Wilcoxon signed-rank test was used to examine potential differences. Results demonstrated no significant difference in subjective ratings of health between pre- and post-intervention, $Z = .00$, $p = 1.00$, $r = .00$. Assumptions of normality were again violated regarding self-reported number of days where physical or mental health interfered with usual activities, and a Wilcoxon signed-rank test was again used. Results indicated no significant difference in number of health-interfering days between pre-and post-intervention, $Z = -0.79$, $p = 0.43$, $r = -0.20$.

Physical Activity

Physical activity was measured objectively utilizing accelerometers provided at time of consent. Baseline and post-intervention physical activity was collected including total sedentary time, total and continuous moderate activity time, and total and continuous vigorous activity time. Importantly, the accelerometers measured physical activity in hours, and the values in the following section are reported as such.

Results demonstrated no significant differences in pre- ($M = 15.64$, $SD = 1.81$) and post-intervention ($M = 15.29$, $SD = 3.74$) total sedentary time $t(11) = 0.42$, $p = 0.41$, $d = 0.12$. There were also no significant differences in total moderate physical activity between pre- ($M = 3.83$, $SD = 2.12$) and post-intervention ($M = 4.12$, $SD = 2.25$), $t(11) = -0.67$, $p = 0.26$, $d = -0.19$.

Results of analyses demonstrated a significant increase in total vigorous physical activity time between pre- ($M = 1.05$, $SD = 0.82$) and post-intervention ($M = 1.43$, $SD = 0.99$), $t(11) = -2.62$, $p = 0.01$, $d = 0.76$. No significant difference was observed between pre- ($M = 0.06$, $SD = 0.11$) and post-intervention ($M = 0.21$, $SD = 0.37$) in continuous vigorous physical activity, $t(11) = -1.21$, $p = 0.13$, $d = -0.35$. Assumptions of normality were violated for pre-and post-intervention moderate continuous activity, therefore, Wilcoxon's signed-rank test was utilized. Results

indicated no significant difference in continuous moderate activity between pre- and post-intervention, $Z = -1.48$, $p = 0.14$, $r = -0.43$. See Tables 4 and 5 below.

Table 4

Physical Activity Data Between Pre- and Post-Intervention: Dependent Samples T-tests

Activity type (measured in hours)	Pre-Intervention (<i>M</i> , <i>SD</i>)	Post/mid- Intervention (<i>M</i> , <i>SD</i>)	<i>t</i> (11)	<i>p</i>	<i>d</i>
Total sedentary time	15.64, 1.81	15.29, 3.74	0.42	0.41	0.12
Total moderate time	3.83, 2.12	4.12, 2.25	-0.67	0.26	-0.19
Total vigorous time	1.05, 0.82	1.43, 0.99	-2.62	0.01	0.76
Continuous vigorous time	0.06, 0.11	0.21, 0.37	1.21	0.13	-0.35

Table 5

Physical Activity Data Between Pre- and Post-Intervention: Wilcoxon Signed-Rank Test

Activity type	<i>Z</i>	<i>p</i>	<i>r</i>
Continuous moderate time	-1.48	0.14	-0.43

Analysis of Study Aims

Aim 1: Intervention Feasibility and Acceptability

Feasibility. Recruitment efforts including number of patients who were screened and deemed eligible, approached, and amenable to study participant were recorded to assess feasibility of the present study. As noted above, the cardiothoracic surgery department's clinic schedule was reviewed to determine which patients were eligible for participation. Of 124 patients who were deemed eligible, 42 patients were not approached either due to lack of

recruiter availability (n=30) or at the recommendation of medical providers (n=12). 82 total patients were approached and offered study participation. Of these 82, 28 patients (34%) consented to study participation. Of these 28, six participants chose to participate in the traditional in-person groups, three opted to take part in the virtual groups, and two participants requested to participate in both the virtual/in-person groups due to availability constraints. 17 participants participated in the asynchronous pre-recorded video modality. Regarding attrition, of the 28 total patients who agreed to intervention participation, 15 completed the intervention in its entirety demonstrating an attrition rate of 46.4%. See Figure 1 for study recruitment flow.

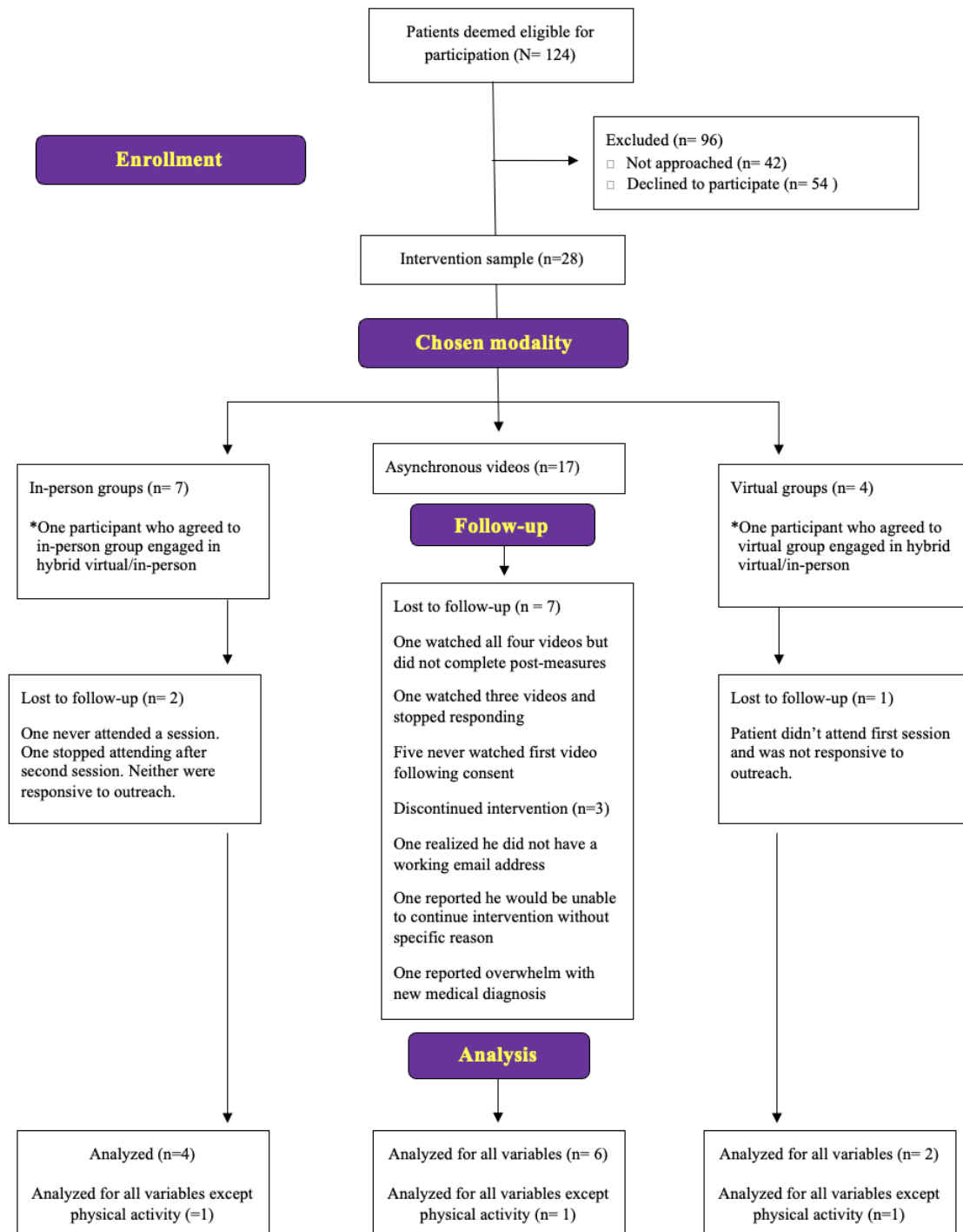
Of those 15 participants who completed the intervention, four participated in the in-person group option, two participated in the virtual groups, seven were in the asynchronous modality, and two opted for hybrid in-person/virtual participation. Two in-person and one virtual group interventions were conducted.

Reported Barriers to Participation. As previously stated, 82 patients were approached for participation in the study with 28 agreeing to intervention participation. Thus, 54 patients declined to participate. 29 (56%) participants did not offer a reason for declining to participate in the study. Six participants (11%) declined citing specific psychosocial barriers including insufficient time, transportation limitations, or difficulty using technology. Seven participants (13%) reported that they were simply uninterested in participation, with some citing a lack of psychological distress concerning their condition. For twelve patients (22%), their reason for declining participation was not captured due to recruiter failure to record.

Study Acceptability. Participants were administered a survey assessing study acceptability following study completion. The survey asked participants to rate the degree to which they felt the program improved their disease-specific knowledge and confidence to

Figure 1

Recruitment and Study Flow



manage their health, their satisfaction with the program, the clarity and accessibility of information provided in the study, and if they would be interested in future aortic programming. Participants rated their agreement with corresponding statements on a 5-point Likert scale (strongly disagree to strongly agree; one to five). In addition, an open-ended item allowed for participants to provide other feedback, comments, or concerns.

The majority of participants (13 participants; 86.7%) felt that the intervention helped them to understand their condition better, with a mean item score of 4.2 ($SD = 0.68$). Nearly all (93.4%) participants reported feeling more confident to manage their health following study completion ($M = 4.20$, $SD = 0.56$) and reported satisfaction with the program ($M = 4.27$, $SD = 0.59$). All participants (100%) reported that the information provided during the intervention was clear and easy to understand ($M = 4.53$, $SD = 0.52$). Over half (60%) of participants reported that they would be interested in additional programs for aortic patients in the future ($M = 3.93$, $SD = 0.88$). Importantly, no participants disagreed or strongly disagreed with any of the statements posed by the intervention evaluation questionnaire.

Nine out of 15 participants provided additional feedback in the open-ended “feedback, comments, or concerns” section of the survey. Initially, the present author sought to, along with another graduate student, code these responses according to various themes and assess for inter-rater reliability. However, a lack of initial coding scheme and small sample size (nine responses) likely make this analysis unlikely to be meaningful. Instead, patient responses were summarized and grouped.

One participant praised the intervention overall and highlighted that they saw no areas for improvement. Four participants highlighted that information provided by the study was helpful, with one of these participants also stating that they appreciated the option for both in-person and

virtual participation. Two participants reported that they enjoyed the study. One participant reported satisfaction particularly related to the relaxation skills offered throughout the intervention. Another highlighted that the program has “caused me to maybe do some self-study.” Finally, two participant responses were unrelated to the present intervention, one highlighting their satisfaction with their medical team’s explanation of their condition and the other describing feeling uncomfortable regarding their experience of shortness of breath due to a different medical condition.

Aim 2: Further Establishing Rates of General Psychological and Disease-Specific Distress within Aortic Disease Patients

General Psychological Distress. At the time of consent, before any intervention procedures took place, participants, regardless of aortic diagnosis ($n=28$), reported low levels of PTSD symptomatology ($M = 0.96$, $SD = 1.40$) as measured by the PC- PTSD-5, which has a possible range of 0-5, with four being the recommended cut-off for further examination of symptoms. For those with type A dissection ($n=2$), posttraumatic stress symptomatology was denied ($M = 0$, $SD = 0$). For those with Type B TAD ($n=2$), the average PC-PTSD-5 score was 2.5 ($SD = 3.54$). For those with ascending aneurysm ($n=24$), the average PC-PTSD score was 0.92 ($SD = 1.4$). For all groups, average scores were below recommended PC-PTSD cut-offs for further examination of symptoms, with 7% of participants ($n=2$) reporting scores at or above the threshold.

Participants ($n=28$) also reported low levels of depressive symptomatology at the time of consent as measured by the PHQ-2 ($M = 1.07$, $SD = 1.39$) with a possible range of 0-6. For those with type A dissection ($n=2$), the average PHQ-2 score was 0.50 ($SD = 0.71$), For those with type B dissection ($n=2$), the average PHQ-2 score was 3 ($SD = 2.83$). For those with ascending

aneurysm ($n=24$), the average score on the PHQ-2 was 1.07 ($SD = 1.39$). For those with type A dissection and ascending aneurysm, average scores were below recommended PHQ-2 cut-off scores (three), while the average score for type B dissection patients was at the threshold recommended for further examination of symptoms. Overall, 7% of participants ($n=2$) reported scores at or above the recommended threshold.

On a brief measure of anxious symptoms, the GAD-2, participants ($n=28$) again reported low levels of anxiety ($M = 1.54$, $SD = 1.75$) at time of consent. With regard to anxious symptoms by group, participants with type A dissection ($n=2$) had an average GAD-2 score of 1 ($SD = 1.41$). Patients with type B dissection ($n=2$) had an average GAD-2 score of 1.5 ($SD = 0.71$). The average score for patients with ascending aneurysm was 1.58 ($SD = 1.86$). For all groups, average scores were below recommended GAD-2 cut-off scores for suspicion of generalized anxiety disorder (three). Overall, 21% of participants ($n=6$) reported scores at or above the threshold.

Initially, data analysis plans included utilizing Pearson's correlations to determine if dissection survivors who lived further away from the treating hospital at time of dissection displayed greater distress than those who lived closer. However, only four participants of the initial 28 who consented to participate in the study had an aortic dissection diagnosis, rendering this analysis unlikely to yield meaningful results.

Disease-Specific Distress. Disease-specific distress was measured using the Cardiac Anxiety Questionnaire (CAQ), the Brief Illness Perception Questionnaire (BIPQ) and the Fear About Exercise (FAE) questionnaire.

At the time of consent, participants' ($n=28$) average total score on the CAQ was 1.43 ($SD = 0.66$; range 0-4). Those with type A dissection ($n=2$) had an average score of 1.47 ($SD = 0.20$),

those with type B dissection ($n=2$) had an average score of 1.97 ($SD = 0.82$), and those with ascending aneurysm ($n=24$) had an average score of 1.38 ($SD = 0.68$). When considering cardiac related fear as measured by the CAQ, participants' average score was 1.45 ($SD = 0.80$; range 0-4). Those with type A dissection ($n=2$) had an average fear score of 1.32 ($SD = 0.26$), while those with type B dissection ($n=2$) had an average fear score of 2.25 ($SD = 1.06$). Patients with ascending aneurysm ($n= 24$) had an average fear score of 1.39 ($SD = 0.81$). At the time of consent, participants' average score on the avoidance subscale was 1.71 ($SD = 1.04$). Participants with type A dissection displayed an average avoidance score of 1.9 ($SD = 0.14$) and type B dissection participants had an average score of 1.8 ($SD = 0.85$). Aneurysm patients had an average avoidance score of 1.68 ($SD = 1.11$). Finally, when considering heart-focused attention, the total sample at time of consent ($n=28$) displayed an average score of 1.11 ($SD = 0.72$). Type A dissection patients ($n=2$) had an average score of 1.30 ($SD = 1.30$) and type B patients ($n=2$) had an average score of 1.7 ($SD = 2.12$). Patients with ascending aneurysm had an average heart-focused attention score of 1.05 ($SD = 0.61$).

Considering the BIPQ at time of consent, participants' ($n=28$) average score for overall perceived threat posed by illness was 42.25 ($SD = 12.55$). Subscales have a possible score between 0 and 10 with higher scores indicating more negative illness perceptions. At the time of consent, participants ($n = 28$) reported the following average scores on each subscale: consequences (4.43), timeline (6.64), personal control over illness (5.14), treatment control (5.64), experience of symptoms (3.18), concern about illness (6.64), coherence (5.86), and emotional impact of condition (4.89).

Scores on the FAE varied between five and 24, demonstrating significant range with the average score at time of consent being 14.14 ($SD = 5.18$).

Aim 3: Determine Intervention Impact on Disease-Specific and General Psychological Distress and Physical Activity Levels

Disease-Specific Distress. Disease-specific distress was captured using the CAQ, BIPQ, and FAE. First, regarding results of the CAQ, between pre- and post-intervention, participants ($n=15$) displayed significantly reduced cardiac-related avoidance ($p = 0.02$) with a moderate effect size ($d = 0.58$). There were no significant differences in overall cardiac anxiety, heart-focused attention, or cardiac-related fear.

Results from the BIPQ demonstrated that participants viewed their conditions as, overall, significantly less threatening from pre- to post-intervention ($p = 0.04$,) with a moderate effect size ($d = 0.50$). Analysis of BIPQ subscales showed that patients reported significantly reduced emotional impact of their condition between pre- and post-intervention ($p = 0.05$) with a moderate effect size ($d = 0.47$). In addition, patients reported significantly less concern about their conditions between pre-and post-intervention ($p = 0.01$) with a moderate to large effect size ($d = 0.70$). No significant differences were observed between pre-and post-intervention on items assessing treatment control, perceptions of illness timeline, experience of symptoms, or illness impact on life (all $ps > 0.05$). However, patients reported relatively greater understanding of their illnesses, with results approaching significance ($p = 0.08$, $d = 0.39$).

Regarding fear about exercise, no significant differences were found between pre- and post-intervention, though the result approached significance with participants reporting less fear of exercise post-intervention, with moderate effect size ($p = 0.07$, $d = 0.42$).

General Psychological Distress. General psychological distress was measured utilizing the PHQ-2, GAD-2, and PC-PTSD-5. No significant differences were observed between pre-and post-intervention in depressive, anxious, or trauma symptomatology.

Physical Activity Levels. Physical activity was measured utilizing accelerometers provided to participants at the time of consent. Baseline and post intervention physical activity was collected in units of hours including total sedentary time, total and continuous moderate activity time, and total and continuous vigorous activity time. There were no significant differences in total sedentary time, continuous vigorous physical activity time, and total and continuous moderate activity time between pre- and post-intervention. However, results demonstrated a significant increase in total vigorous activity time between pre- and post-intervention ($p = 0.01$, $d = 0.76$).

Aim 4: Determine Intervention Impact on Feelings of Personal Control over Illness

No significant differences were observed in perceptions of personal control over illness between pre- and post-intervention ($p = 0.23$, $d = -0.20$).

Chapter IV: Discussion

The present study sought to determine the feasibility and acceptability of a four-session intervention based in principles of behavioral activation and traditional cognitive behavioral therapy. Additional study aims included further establishing rates of general psychological and disease-specific distress in aortic disease patients and determining whether general psychological distress, disease-specific distress, and perceptions of personal control over illness differed significantly between pre- and post-intervention.

It was hypothesized that at least 50% of patients who were approached for participation in the study would be interested in participating. In addition, it was hypothesized that attrition may be of concern given the time commitment required for participating individuals (approximately 1.5 hours for each of the four sessions). Regarding other aims, it was hypothesized that following intervention completion, participants would experience a reduction in general and disease-specific psychological distress, increased physical activity levels, and an improvement in feelings of personal control over their condition.

Results of the study revealed 1) increased participation in the present study compared to similar interventions without virtual options, 2) high satisfaction with the intervention itself and information provided by the program, 3) reductions in appraisal of threat posed by illness, 4) reduced concern about medical condition, 5) reduced emotional impact of medical condition, 6) reduced cardiac-related avoidance and 7) increased engagement in vigorous physical activity. The findings of the study and their significance will be discussed in further detail below.

Review of Major Study Findings

Feasibility

Review of the cardiothoracic surgery department's schedule throughout the recruitment period showed that 124 patients were eligible for study participation, 82 patients were approached, 28 agreed to participate and 15 completed the entire intervention (46.4% attrition). Of the patients who finished the intervention, five participated in the in-person group option (of seven who consented; 28.6% attrition), three participated in the virtual groups (of four who consented; 25% attrition), seven were in the asynchronous modality (of seventeen who consented; 58.8% attrition). One patient who had initially signed up for the in-person group and one who had initially signed up for virtual group participation ultimately opted for hybrid in-person/virtual participation given time/availability constraints.

Acceptance rate for intervention participation was 34%; though it was hypothesized that 50% of patients approach would be interested in participating, these results show promise. This study expanded on past work conducted by the Cardiac Psychology Laboratory which identified the provision of virtual options as a future direction to promote feasibility. This intervention was conducted with a sample of ICD patients recruited from the East Carolina Heart Institute and utilized a nearly identical method for recruitment with results demonstrating a participation rate of 17.07% (Harrell et al., 2024). Importantly, this study offered only traditional, in-person participation and was three sessions versus the four required by the current intervention. Despite greater demands posed by the present study, the participation rate doubled that of the prior study, with a likely explanation for this increase being that the present study offered additional modes of participation that combat cost of participation, distance from treating hospital, and time

constraints, barriers frequently cited for those receiving healthcare in eastern North Carolina (Burch, 2022; Jordan et al., 2024).

Acceptability

One primary aim of the present feasibility study was to determine acceptance of the intervention for aortic disease patients. Study acceptability was assessed using a survey administered following completion of the intervention. The survey asked participants to rate the degree to which they felt the program improved their disease-specific knowledge and confidence to manage their health, their satisfaction with the program, the clarity and accessibility of information provided in the study, and if they would be interested in future aortic programming. Participants rated their agreement using statements on a 5-point Likert scale (strongly disagree to strongly agree; one to five). In addition, an open-ended item allowed for participants to provide other feedback, comments, or concerns.

The majority of participants felt that the intervention improved their understanding of their condition (86.7%) and confidence in managing their health (93.3%). Participants reported high satisfaction with program itself, and the clarity of information provided, with over half reporting interest in additional aortic disease programming in the future. On the open-ended feedback portion of the survey, participants praised the information provided by the study, expressed appreciation for the provision of virtual options, and highlighted that they enjoyed the study.

General Psychological Distress

General psychological distress was measured at baseline and post-intervention within domains including depression (measured using PHQ-2), anxiety (measured utilizing GAD-2), and posttraumatic stress (measured using PC-PTSD-5). No significant differences emerged in

scores between pre- and post-intervention in any of the three domains. Importantly, average scores within each domain were below recommended cut-off scores for further examination of symptoms both at baseline and post- intervention. One participant (6.6%) met the threshold for further examination of depressive symptoms as measured by the PHQ-2 both at the time of consent and post-intervention. Regarding reported scores at or above threshold for further examination of PTSD symptoms, at time of consent, 14.3% (2/14) reported such symptomatology while at post-intervention, 7.1% of patients (1/14) were at or above this threshold. As noted above, one patient was excluded from analysis of PTSD symptomatology given that they reported exposure to a Criterion A traumatic event at baseline but not at post-intervention.

One possible explanation for why general psychological distress did not differ between pre- and post-intervention is that the sample, at baseline, displayed low levels of distress. It is also possible that improvements in general psychological distress were not observed due to the specificity of the present intervention; as the focus of the material was entirely related to *disease-specific* distress, perhaps participants did not view the psychological tactics as generalizable to more general mental health distress. Next, prior interventions aiming to increase PA in post-cardiac surgery patients found significant improvements in mood post-intervention, but it is important to highlight that such studies have had an express focus on increasing PA (Gray et al., 2022; Mao et al., 2020). Perhaps the present study was missing an active ingredient for improvement of depressive symptoms in that physical activity was encouraged but received less attention than the aforementioned studies given that the present intervention had other, additional aims.

Disease-Specific Distress

The present study examined several aspects of disease-specific distress including cardiac anxiety (CAQ), illness perceptions (BIPQ), and fear of physical activity engagement (FAE).

Cardiac anxiety as measured by the CAQ demonstrated that at both baseline and post-intervention, participants in the present study reported lower levels of overall cardiac anxiety, cardiac-related fear, heart-focused attention, and cardiac-related avoidance than the average patient with cardiovascular disease as delineated by Eifert et. al (2000). No significant differences in overall cardiac anxiety, heart-focused attention, or cardiac-related fear emerged between baseline and post-intervention, however, participants reported significantly lowered levels of cardiac-related avoidance following intervention engagement. It is possible that avoidance was significantly reduced while other variables did not change due to mechanisms associated with exposure-based models of fear reduction. These models posit that repeated confrontation (versus avoidance) of anxiety-provoking stimuli, such as information about the heart and relevant disease-state, is an integral step toward habituation (Foa & Kazak, 1986) or inhibitory learning (Craske et al., 2008) which can ultimately lead to lower anxiety and fear. It is important to highlight that hypervigilance, or heart-focused attention as measured by the CAQ, may function as a safety behavior thereby reducing efficacy of exposures and maintaining fear (Craske et al., 2008; Salkovskis, 1991; Well et al., 1995).

Norms for the CAQ for aortic patients do not exist, however, the creators of the CAQ (Eifert et al., 2000) provided average scores in their initial validation sample of post-angiography patients including overall cardiac anxiety ($M = 1.67$, $SD = 0.81$) and the three subscales: cardiac-related fear ($M = 1.68$, $SD = 0.92$), cardiac-related avoidance ($M = 1.83$, $SD = 1.13$), and heart-focused attention ($M = 1.54$, $SD = 0.96$). In the present study, at the time of consent,

average scores on overall cardiac anxiety and all three subscales were below the averages reported by Eifert et al. (2000), though the means of the present study and the validation study may not provide a valid comparison as the samples were different with regard to cardiac health status.

The BIPQ was used to assess illness threat perceptions overall and in domains including concern, understanding of illness, how much they believe medical treatment can help their condition, illness timeline, personal control over illness, experience of symptoms, emotional impact of their illness, and impact of illness on life. Results indicated that participants viewed their illness as, overall, less threatening, less concerning, and having lesser emotional impact from baseline to post-intervention. All other comparisons yielded insignificant results. Importantly, no cut-off scores for the BIPQ have been delineated by the original authors (Broadbent et al., 2006). However, a study conducted within a sample of patients with spinal cord injuries utilized the Hospital Anxiety and Depression scale cut-offs for reference in combination with receiver operating characteristic curves and the Youden index to identify optimal BIPQ cut-offs with results revealing that scores between 42 and 49 were indicative of moderate threat perception and scores of 50 and above communicated high threat perceptions (Kuiper et al., 2022). As noted above, at post-interventions, participants average total score on the BIPQ was 34.10, below cut-off scores suggested by the Kuiper et al. study. However, the authors of this study did not identify cut-off scores for the eight BIPQ subscales.

Though it might intuitively follow that increased disease-specific education would result in improved perceptions of personal and treatment control over illness, prior work by Petrie and Weinman (2012) suggests that emotional representations regarding illness such as overall threat perception, concern, and emotional impact may be the most proximal effects of psychoeducation

interventional without measurable differences in perceptions of controllability. This work provides a possible explanation for why the present study's hypothesis that perceptions of controllability would be reduced from pre- to post-intervention was not supported.

The finding that perceptions of overall threat and emotional impact due to illness was significantly reduced from pre- to post-intervention has important clinical implications. A prior study examining whether illness representations as measured by the BIPQ could predict anxiety and depression in patients with coronary artery disease found that with the exception of concern, there was a positive relationship between all domains (treatment control, personal control, emotional impact, coherence, timeline, identity, symptoms; with higher scores indicating more negative perceptions) and anxiety (Al-Sutari & Khraisat, 2025). Thus, the findings that emotional impact and overall perceived threat posed by illness were significantly reduced from pre- to post-intervention indicate that interventions targeting these specific illness representations may reduce overall anxiety associated with their condition. Though, of note, no differences emerged in overall cardiac anxiety between pre- and post-intervention.

It is important to consider whether it is beneficial for participants to experience reduced concern, emotional impact, or threat perception of their illness; might reduction in these factors impact engagement in health-promoting behaviors? Results of a study conducted with a sample of Chinese stroke survivors found a negative relationship between illness perceptions and health-promoting behavior engagement. That is, as negative illness perceptions became stronger, engagement in health promoting behaviors was reduced with the authors hypothesizing that this was due to associated feelings of overwhelm (Liu et al., 2020). Importantly, this relationship was mediated, in part (43.7%) by coping style (positive versus negative). Similarly, the impact of illness perceptions as measured by the BIPQ on self-care maintenance behaviors in a group of

Italian participants with chronic diseases demonstrated that negative illness perceptions were associated with reduced engagement in self-care maintenance behaviors (Mezza et al., 2025).

Conversely, Manika et al. (2021) found that participants who had been exposed to online information about human papilloma virus (HPV) that was less factually correct perceived greater risk than those who had received factually correct information about HPV from a healthcare provider. Though the authors claim that "...perceptions of knowledge acquired through the Internet (rather than information from a health professional's office), leads to enhanced risk perceptions with positive impacts on health behavior change outcomes," and that lower perceived risk may be associated with "potentially detrimental effects on health behavior change outcomes," it is important to note that the study did not measure true behavior change, only *intentions* for behavioral change. It is also important to highlight that the sample utilized in this study was young (18-26) and healthy with regard to the condition (HPV) in question. This could have important implications on perception of risk and results of this study are likely not generalizable to older adults who have complex medical conditions.

There was no significant difference in fear about exercise between pre- and post-intervention; as described above, models of exposure posit that continual approach of feared stimuli is a preliminary, active ingredient in reducing fear (Craske et al., 2008; Foa & Kazak, 1986). It is possible that fear of exercise did not change from pre- to post-intervention because the study did not involve any formal PA component, it only encouraged increased activity. As will be discussed further in the Future Directions section, an intervention that includes physical activity engagement as part of the study protocol may more effectively target fear about exercise.

Study Strengths

The present study had many notable strengths. First, there have been no prior studies examining the provision of education and psychological principles on physical activity, disease-specific distress, or general psychological distress in a sample of patients with aortic disease.

Second, the present study offered participation modalities (i.e., traditional in-person groups, virtual groups, and asynchronous pre-recorded videos) in efforts to mitigate barriers to participation reported in prior studies conducted by the Cardiac Psychology Laboratory at East Carolina University (Harrell, 2025; Jordan et al., 2024) and by patients residing in eastern North Carolina (Burch, 2022). Such barriers included financial, transportation, and time limitations. The provision of virtual group and asynchronous participation mitigated multiple access barriers as participants could watch the pre-recorded videos at their convenience rather than attending a class at a certain day and time. Virtual options may also have reduced transportation barriers (and subsequently, financial burden) for those who were unable to participate in in-person groups due to distance from ECHI. This study confirmed the importance of this innovation and accommodation to help patients engage in the study.

This facet of the study is particularly important as ECU Health has a massive patient catchment area. Specifically, ECU Health serves a patient population of approximately 1.5 million people over 29 counties in eastern North Carolina (ECU Health, n.d.). This large catchment area means that patients may drive up to two hours to receive medical care. Understandably, when faced with long travel times, participation in an in-person intervention is not always feasible, even if there is a desire to participate.

In addition, the asynchronous option allowed for more opportunities for exposure to study information. The pre-recorded video on aneurysm-specific education was rewatched, in

total, five times. The dissection-specific education video was not rewatched; however, only one participant who had experienced dissection chose the asynchronous study option. The second video focused on psychoeducation regarding physical activity including associated benefits and strategies for increasing PA was rewatched four total times. Interestingly, the third pre-recorded video, teaching cognitive strategies to use in conjunction with previously learned disease-specific education, was rewatched the most, with a total of 10 rewatches. Finally, the fourth and final video provided psychoeducation on the importance of engaging in valued activities to improve and maintain mental health and was rewatched twice. Foundational work in cognitive psychology demonstrates that information is retained better and longer following repeated exposures (Ebbinghaus, 1964); therefore, perhaps those who opted to rewatch videos received a greater “dose” of the present intervention. Although sample sizes of study groups were likely too small to yield meaningful results regarding differences in outcomes by group, this may be an area worthy of exploration in future work.

An additional strength of the asynchronous, pre-recorded video study condition is that the information and its delivery was standardized. Standardization of this condition allows for greater internal validity and, thus, increased reliability of study results for those in the asynchronous condition. In addition, this standardization would allow for easier replication of the intervention.

Study Limitations

The present study also had notable limitations. First, the study had a small sample size ($n = 15$). When conducting dependent samples t-tests with a small sample, outliers can be quite influential, and assumptions of normality may be violated. In addition, the potential effects of conducting multiple comparisons within the same dataset, particularly with such a small sample,

cannot be ignored; making multiple comparisons increases the risk of Type 1 error, so it is possible that false positives exist. Although steps were taken to analyze the data in a way that mitigates these concerns (i.e., utilizing non-parametric tests when assumptions were violated), the present study was likely underpowered and could have fallen victim to Type 1 error. Therefore, the results may be inflated or not able to be generalized, as discussed in more depth below. Moreover, sample sizes for each group (in-person groups, virtual groups, asynchronous videos) were so small that comparisons to determine efficacy by participation type were unlikely to yield statistically meaningful results. Therefore, the present study cannot speak to superiority of one treatment modality over another.

In addition, the results of the present study may not be generalizable as the study was conducted with a sample recruited from a rural serving clinic in eastern North Carolina. Given the highly specific geographical area of the sample, results, may not be generalizable to aortic patients in different regions, particularly with regard to feasibility. Perhaps recruitment and attrition rates would be improved for those living in more urban areas who likely face fewer barriers to participation (e.g., shorter travel time to facilities, wide availability of public transportation).

In addition, the offering of multiple delivery modalities (i.e., in-person and virtual groups, asynchronous pre-recorded videos) likely reduced barriers associated with time constraints, transportation limitations and associated financial barriers. However, there were limitations associated with this approach; first, the non-traditional methods to participation (i.e., asynchronous and virtual groups) still required that participants have technological literacy, access to functioning technology, and high-speed internet access. According to the North Carolina Department of Information Technology (n.d.), 1.2 million adults in North Carolina do

not possess the technology skills necessary to utilize the internet, over half a million do not have a desktop computer and/or smartphone, and 43,000 or 35% of homes in rural areas of North Carolina lack sufficient infrastructure to even allow for internet connectivity.

Furthermore, different delivery modalities may have had confounding effects on study results and the sample size within each of these three groups were too small to analyze data and draw meaningful conclusions about potential group differences. However, given that a primary purpose of the proposed study is to assess the feasibility of the intervention, offering multiple delivery options allowed for further determination of patient preference to inform future similar interventions. However, it is important to note that patient preference may not be in line with what future data may show about the superiority of one modality versus another in terms of patient outcomes.

An additional logistical limitation regarding the provision of virtual groups is that participants did not have to present in-person for the final session, and therefore, did not have a built-in opportunity to return accelerometers post-intervention. The same barriers (i.e., transportation) that were likely overcome by providing virtual options for participation hindered total and complete data collection for two participants who completed the entire intervention but did not return accelerometers and therefore, whose physical activity data could not be analyzed.

Furthermore, there were additional limitations associated with the accelerometers provided at time of consent. First, it is possible that for participants, the simple act of wearing the device may function as an active ingredient in increasing physical activity due to the knowledge that they are being monitored, a theory in line with the Hawthorne effect (Adair, 1984; Sullivan & Lachman, 2017).

Next, according to the MotionWatch 8 manual, the battery is supposed to last between three and six months given the settings utilized by the present study (CamNtech, 2024). Average time for intervention completion was 45 days, with all but two participants completing the intervention before three months had elapsed (*range* = 14 days to 141 days). However, for four out of the twelve patients for whom accelerometer data was available, their watches ceased recording prior to their completion of the intervention. Completion times for these patients were 43, 74, 89, and 141 days. Therefore, for these patients, true *post-* intervention physical activity data could not be gleaned. Future studies should consider utilizing accelerometers with longer battery life depending on length of intervention.

Next, attrition was a considerable concern and was highest for the asynchronous pre-recorded video modality, perhaps due to the largely self-driven nature of the intervention. The asynchronous nature meant that participants were not bound to specific times for group participation or check-in. Though, as discussed in study strengths, this allowed for more flexible participation, it also meant that participants could watch the videos at their own pace, which was, at times, quite slow. Perhaps a lack of time pressure created an environment where participants more easily forgot about study obligations. It is also possible that those who agreed to participate in the asynchronous modality checked their email inboxes infrequently, and therefore, did not receive prompts for participation. Lastly, perhaps patients who agreed to participate in the least demanding option were less motivated to engage in the study from the start, choosing only to participate because of perceived ease versus true interest in learning new information and making changes. The other, synchronous options for participation required that patients present, whether virtually or in-person, at specific dates and times, likely creating a greater sense of obligation for continued participation.

Finally, inconsistent capture of patient reasons for declining study participation was a significant study limitation that likely impacted ability to assess feasibility as perhaps additional unnamed barriers to participation existed that could help to better inform future interventions. Though study recruiters were provided with a pen-and-paper checklist with detailed instructions on study recruitment, perhaps de-identified electronic tracking for each patient approached, with forced responses for each question, would mitigate this concern in the future.

Future Directions

The present study had an important finding in that patients reported significantly reduced cardiac-related avoidance post-intervention. However, there were no significant differences reported in total cardiac anxiety, heart-focused attention, or heart-related fear. As discussed above, prior research on reducing fear of anxiety-provoking stimuli indicates that avoidance maintains anxious symptomatology. Therefore, it is possible that an intervention which provides further exposure to disease-specific education and more comprehensive education on cognitive behavioral techniques could more effectively target cardiac-related fear. In addition, a dedicated, integrated physical activity component could amplify these effects by way of exposure to sensations (i.e. increased heart rate, shortness of breath, chest sensations) which can become avoided post-cardiac event (Farris et al., 2019; Levine et al., 2025). Such an intervention would likely work well in a setting such as cardiac rehabilitation, where the provision of psychosocial information is quite common (Holdgaard et al., 2023; Oldridge et al., 2014). However, special attention should be paid to cardiac hypervigilance such as repeatedly checking cardiac statistics such as heart rate and blood pressure, particularly when such checking is done in response to feared thoughts or bodily sensations as these behaviors can maintain cardiac anxiety (Sears et al., 2023). In addition to potential reductions in disease-specific distress, prior work has

demonstrated that patients who participated in a CBT-based intervention which utilized disease specific education as a tool for cognitive restructuring, in addition to care as usual, experienced fewer recurrent cardiovascular events than participants who received only care as usual (Gulliksson et al., 2011).

Future studies conducting similar interventions in patients with aortic disease should also consider conducting the study in a more populous area or across multiple sites to obtain a larger sample for more powerful testing of the current intervention. In addition, larger sample size may provide greater variability in pre-intervention psychological distress related to participant health status, and therefore, would help examine the efficacy of the present intervention in more distressed participants.

It may also behoove future researchers to conduct similar studies with an express focus on telehealth modalities. As cost-of-living increases and access to technology and internet services becomes greater, participants may be less willing to engage in traditional, in-person interventions. This would likely be of greater importance in a sample like that of the present study where financial barriers and far distance from treating hospital present barriers to engagement. By examining how to improve telehealth modalities, the provision of high-quality psychosocial resources may become more equitable.

As discussed in study limitations above, the asynchronous modality presented unique sets of challenges. Perhaps email delivery only was not the most efficient form of communication; it may benefit future studies to implement automated text messages/phone calls to participants to remind them of study tasks.

Future studies should also consider carefully the accelerometers used when conducting similar studies. As indicated above, battery life may be of significant concern, particularly as it

relates to engagement in modalities like the asynchronous condition of the present study where patients may have longer completion times. Future work may consider utilizing wearable technology that patients already possess, such as smart watches or rings, particularly as these become more widely available. However, one to one comparison may be difficult as these devices vary widely in how they collect data. In addition, this method would limit generalizability of results as recruiting only patients who own wearable technology, and therefore can afford these devices, would create selection effects.

Finally, a dismantling study based on the present intervention would be helpful in informing the design of future similar programs. A dismantling study would help to elucidate specific components which made the present study successful in reducing some factors of disease-specific distress to allow for the addition of the active ingredients to future interventions.

Conclusions

The present study examined the feasibility, acceptability, and impact of a four-session intervention which provided disease-specific education and traditional CBT and behavioral activation principles in a sample of patients recruited from a rural-serving cardiothoracic surgery clinic. Additional aims included to further determine rates of disease specific and general psychological distress in patients with aortic disease, to determine whether the intervention had an impact on general psychological and/or disease specific distress and physical activity levels, and to determine the impact of the intervention on feelings of personal control over their illness. Results demonstrated that post-intervention, patients reported less cardiac-related avoidance, viewed their conditions as less threatening overall and reported less concern and emotional impact of their condition. Objective physical activity data showed that patients engaged in more total vigorous activity from pre- to post-intervention.

Several important limitations of the current study were elucidated particularly regarding sample size and generalizability, many of which are a function of the rural area in which the study was conducted. Though such limitations exist, this intervention serves as foundational work upon which future studies can build and tailor to allow for more comprehensive, person-centered care for patients with aortic disease.

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Appendix A: IRB Approval Memo

Notification of Initial Approval: Expedited

From:
Social/Behavioral IRB
To: Caroline Martin
CC: Samuel Sears

Date: 4/11/2025

Re:
[UMCIRB 25-000013](#)

Feasibility of a psychosocial care program for aortic patients

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) occurred on 4/10/2025. The research study is eligible for review under expedited category # 4,5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

As the Principal Investigator you are explicitly responsible for the conduct of all aspects of this study and must adhere to all reporting requirements for the study. Your responsibilities include but are not limited to:

1. Ensuring changes to the approved research (including the UMCIRB approved consent document) are initiated only after UMCIRB review and approval except when necessary to eliminate an apparent immediate hazard to the participant. All changes (e.g. a change in procedure, number of participants, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the UMCIRB before they are implemented;
2. Where informed consent has not been waived by the UMCIRB, ensuring that only valid versions of the UMCIRB approved, date-stamped informed consent document(s) are used for obtaining informed consent (consent documents with the IRB approval date stamp are found under the Documents tab in the ePIRATE study workspace);
3. Promptly reporting to the UMCIRB all unanticipated problems involving risks to participants and others;
4. Submission of a final report application to the UMCIRB prior to the expected end date provided in the IRB application in order to document human research activity has ended and to provide a timepoint in which to base document retention; and

5. Submission of an amendment to extend the expected end date if the study is not expected to be completed by that date. The amendment should be submitted 30 days prior to the UMCIRB approved expected end date or as soon as the Investigator is aware that the study will not be completed by that date.

The approval includes the following items:

Name

Description

1.8 Merged information consent and application or waiver of HIPAA authorization 040625.doc

Consent Forms

25-000013 Protocol 3.docx

Study Protocol or Grant Application

Application-for-Waiver-or-alteration-of-HIPAA-Authorization 020625

HIPAA Documentation

BIPQ

Surveys and Questionnaires

CAQ

Surveys and Questionnaires

CDC HRQOL 4

Surveys and Questionnaires

CDM Dissertation Proposal FINAL.docx

Study Protocol or Grant Application

DASI

Surveys and Questionnaires

Fear about Exercise Questionnaire

Surveys and Questionnaires

GAD-2

Surveys and Questionnaires

Handout for Asynchronous Video Patients

Additional Items

Handout for Virtual Group Patients- Study Flow and How to Join Webex Meetings

Additional Items

Intervention Evaluation Questionnaire

Surveys and Questionnaires

martin-et-al-2023-aortic-disease-101-breaking-down-myths-of-type-a-aortic-dissection-for-patients-and-families (4).pdf

Additional Items

PC-PTSD-5

Surveys and Questionnaires

PHQ 2

Surveys and Questionnaires

Request-for-Preparatory-Review-of-PHI 010825.docx

HIPAA Documentation

sorrell-et-al-2024-vascular-disease-patient-information-page-coping-with-a-serious-vascular-disease-diagnosis (2).pdf

Additional Items

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.