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Brief Behavioral Health Intervention Program for Patients with Stable Coronary Artery Disease

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BRIEF BEHAVIORAL HEALTH INTERVENTION PROGRAM FOR PATIENTS WITH STABLE CORONARY ARTERY DISEASE

by

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ABSTRACT

Healthy eating, physical activity, stress management, and smoking cessation are widely recognized as essential for preventing and treating coronary artery disease (CAD). Research on lifestyle programs for patients with CAD has largely focused on long-term interventions (e.g., several months to one-year in duration). Further, many studies have recruited patients immediately post-cardiac event. By contrast, evaluation of brief lifestyle interventions for stable patients treated in outpatient cardiology is lacking. The present study evaluated the feasibility, acceptability, and efficacy of a 3-session behavioral health lifestyle program for patients with stable CAD being treated in an outpatient cardiology clinic. Thirty-three patients were randomized to the Intervention Group (IG) or to Treatment as Usual (TAU). Outcome measures were assessed at Post-treatment (two-weeks after Baseline) and at 30-day Follow-up. Reliable change and parametric analyses were used to evaluate study outcomes. Results indicated that the program was both feasible and acceptable to patients, as determined by a priori criteria: over 60 percent of referred and eligible patients agreed to participate, over 75 percent of consented IG participants completed the program through 30-day Follow-up, and over 80 percent of participants reported that they would recommend the program to other patients. With regard to treatment outcomes, data from 28 participants were available. Reliable change analyses revealed that at both Post-treatment and 30-day Follow-up, significantly more IG than TAU participants exhibited an increase in self-efficacy as compared with Baseline. There were no observed between-group differences on other study measures, though repeated-measures ANOVAs were underpowered. Overall, results support the feasibility and acceptability of brief lifestyle interventions in outpatient cardiology care and highlight the role of behavioral health providers

on integrated cardiology care teams in helping to increase patient self-efficacy in managing chronic disease.

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INTRODUCTION AND LITERATURE REVIEW

Coronary Artery Disease: A Brief Overview for Clinical Health Psychologists

Approximately one in every four deaths in the United States (U.S.) is attributable to heart disease (U.S. Department of Health and Human Services, 2017a). Coronary artery disease (CAD), also commonly referred to as coronary heart disease (CHD) or ischemic heart disease, is the most common form of heart disease. CAD is the cause of death for over 370,000 individuals in the U.S. yearly (U.S. Department of Health and Human Services, 2017a).

CAD is characterized by atherosclerosis and resulting complications. Atherosclerosis involves buildup of plaque, consisting of fatty substances such as cholesterol. This buildup occurs as a result of repairing repeated damage to the endothelium (lining) of arteries (Herrmann & Lerman, 2012). Indeed, cardiac risk factors such as high cholesterol, hypertension, diabetes, smoking, and older age, increase risk for coronary events in part by contributing to this process of endothelium damage (Herrmann & Lerman, 2012). Consistent repair of damage results in changes to the artery structure, including plaque growth and coronary lesions that result from plaque rupture and thrombosis (Wilson, 2012a). In turn, these may contribute to reduced blood flow and acute coronary syndromes associated with CAD, such as myocardial infarction (MI) or "heart attack" (Herrmann & Lerman, 2012).

A hallmark symptom of CAD is angina, which primarily manifests as chest discomfort. Angina results from an imbalance in myocardial supply and demand of oxygen (Garcia & McFalls, 2012). Angina may present in a predictable manner (i.e., stable angina, such as when exercise results in a demand of oxygen that exceeds supply) or in an unpredictable manner (unstable angina, which is considered an acute coronary syndrome or ACS). Typical angina is

associated with left side, substernal chest discomfort (characteristic 1), follows from physical or emotional stress (characteristic 2), and is relieved with rest or nitroglycerin (a medication for angina; characteristic 3). Atypical angina has two of the three outlined characteristics (Garcia & McFalls, 2012). The annual mortality rates for stable angina are approximately one to two percent, and thus most patients with stable angina have a good prognosis. Those with severe left ventricular dysfunction and more widespread CAD are at increased risk for mortality (Garcia & McFalls, 2012).

CAD may ultimately lead to an ACS (Herrmann & Lerman, 2012). ACS is associated with rapid increase in symptomatology or ischemia, which involves reduced blood flow (and therefore oxygen) to the heart (Wilson, 2012a). The term ACS encompasses a spectrum of unstable coronary syndromes, including but not limited to unstable angina and myocardial infarction or "MI" (Wilson, 2012a). The primary cause of ACS is plaque rupture within the arteries and subsequent clotting of the damaged area (Wilson, 2012a). Among other substances, lipoproteins, including LDL ("bad" cholesterol) primarily comprise of the plaque. Plaque and associated blood clots can reduce blood flow to the heart, and sometimes completely block the artery (Wilson, 2012a). Of note, there is increased risk of MI and death in the six months following development of ACS (Wilson, 2012a). With regard to MI, a number of complications may result from the infarction. The reduced blood supply and oxygen to the heart results in tissue damage or death. This can be associated with left ventricular failure (associated with cardiogenic shock and death as a result of inadequate blood supply to heart), rupture of the left ventricular (LV) wall, rupture of ventricular septum, ventricular arrhythmia, thromboembolism, and other complications depending on the characteristics of the MI (Vlodaver & Wilson, 2012). Given the serious nature of ACS, prompt evaluation and treatment are necessary.

Treatment for CAD and related acute coronary events may range from medicinal to surgical. Medicinal antithrombotic treatment, such as aspirin or heparin, may be initiated to treat any blood clots. Drugs to reduce heart rate and blood pressure (e.g., beta receptor antagonists, "beta blockers") may be used as well to prevent MI. Percutaneous coronary intervention (PCI), or angioplasty, is a non-surgical intervention that typically involves using a balloon, guided by a catheter, to widen the lumen (space inside of the artery), which may be narrowed due to plaque and other buildup. This subsequently improves coronary flow (Wilson, 2012b). Stents may then be used to promote maintenance of the widened lumen. Additional medications may be utilized to prevent thrombosis in the coronary vessel, and other negative responses to these procedures (Wilson, 2012b). PCI may additionally be utilized in conjunction with thrombectomy to aspirate any blood clots (Wilson, 2012b).

Coronary artery bypass grafting (CABG) is another treatment for CAD, and unlike PCI, is surgical in nature. It is generally indicated for higher risk CAD symptomatology (e.g., left main stenosis [narrowing of the artery], or triple vessel disease) or in cases with comorbid diabetes (Liao, 2012). The goal of treatment is to revascularize those coronary arteries with significant (e.g., more than 50%) of luminal narrowing (Liao, 2012). In CABG surgery, arteries and veins from the body are used to re-route blood flow around blocked arteries to increase blood flow to the heart.

In the time before or after an ACS, a patient may be thought to be "stable," or be characterized as having "stable CAD." Interestingly, there is a lack of specification regarding at what point a patient is deemed "stable," even within task force recommendations from medical societies such as the American Heart Association, American College of Cardiology Foundation, and others (Fihn et al., 2012). While research studies of "stable" CAD patients have diverse

definitions of the population, they have commonly included specified time frames since ACS or revascularization. Examples of inclusion criteria include MI at least three months prior to enrollment (Fox et al., 2003; PEACE Trial Investigators, 2004), and CABG or percutaneous transluminal coronary angioplasty at least three months (PEACE Trial Investigators, 2004) or six months (Fox et al., 2003) prior to enrollment. Additionally, examples of exclusion criteria have included planned coronary revascularization (PEACE Trial Investigators, 2004; Fox et al., 2003), and hospitalization for unstable angina within preceding two months (PEACE Trial Investigators, 2004). Thus, the common aim of such criteria is to ensure that the patient is not experiencing, or in immediate recovery from, an acute coronary episode. However, active monitoring and treatment is essential even for those with "stable" CAD, as they remain at increased risk for cardiac events.

Of note, management of other common chronic conditions is essential when treating CAD, as such conditions may be associated with independent health risks and additionally contribute to increased cardiovascular risk. Hypertension, for example, is experienced by nearly one fourth of the U.S. population and is associated with increased risk of cardiac events and CAD mortality (Rosendorff et al., 2015). Among other mechanisms, hypertension is associated with endothelial dysfunction, which may subsequently affect plaque development and facilitate atherosclerosis (Rosendorff et al., 2015). High cholesterol is also associated with increased coronary risk, as high LDL levels are associated with plaque buildup that may reduce blood flow and ultimately lead to ACS (U.S. Department of Health and Human Services, 2005). Further, patients with diabetes are at a two to four-fold increased risk of cardiovascular disease, highlighting the importance of treating this highly comorbid condition (Skyler et al., 2009). While mechanisms explaining increased cardiac risk among patients with diabetes continue to be

investigated, it is thought that increased coagulability (clotting ability) may partially explain increased risk for MI (Leon & Maddox, 2015). Obesity is likewise associated with increased cardiac risk factors such as hypertension, dyslipidemia (high cholesterol or fats), diabetes, and other disorders, and is additionally associated with increased risk of cardiovascular disease mortality (Jensen et al., 2014). Lastly, smoking increases CAD symptomatology by increasing blood clotting tendency, decreasing ability to exercise, and is related to atherosclerosis (U.S. Department of Health and Human Services, 2014). Thus, treatment of these and other related health conditions may be essential for promoting cardiac and overall health.

While treatment for CAD and other common comorbid conditions may involve medicinal and/or surgical treatment, healthy lifestyle behaviors are additionally crucial for preventing and managing CAD and related diseases. Modifying lifestyle behaviors has yielded critical health benefits for patients living with CAD. Lifestyle recommendations and associated research are outlined below and serve as the foundation for the current study.

Lifestyle, Health Behaviors, and CAD: Current Recommendations

In addition to appropriate pharmacological and medical procedure follow-up, regular engagement in healthy lifestyle behaviors is necessary for cardiac health. Indeed, lifestyle changes are particularly important among cardiac populations, as healthy eating, physical activity, stress management, and smoking cessation, among other areas are essential for both the management (e.g., Fihn et al., 2012) and prevention (e.g., Arnett et al., 2019) of cardiovascular disease. For stable CAD, the American College of Cardiology Foundation, American Heart Association, and other medical bodies include recommendations to address health behavior risk factors (Fihn et al., 2012). Several of these areas, pertinent to the development of the evaluated intervention, are outlined in this section.

Healthy Eating

Healthy eating (or diet) recommendations for stable CAD may include a diet high in fresh fruit, whole grains, and vegetables, and low in saturated fat, *trans* fat, cholesterol, and sodium (Fihn et al., 2012). Indeed, comprehensive and validated diet plans exist to maximize heart-healthy eating among cardiac patients. Two of the most well-known plans include the Dietary Approaches to Stop Hypertension (DASH) plan and the Mediterranean diet. The DASH plan emphasizes reducing saturated fat, total fat, cholesterol and sodium, and involves little consumption of red meat and food/drink with added sugar. By contrast, it emphasizes increased intake of fruit, vegetables, low fat dairy products, whole grains, poultry, fish and nuts (U.S. Department of Health and Human Services, 2003, 2006). An example of the DASH eating plan for an individual consuming 2,000 calories per day may include daily consumption of 6-8 servings of grain and grain products, 4-5 servings of vegetables, 4-5 servings of fruit, 2-3 servings of low fat or fat free dairy foods, 6 or fewer servings of lean meats, poultry, and fish, 2-3 servings of fats and oils, in addition to 4-5 servings of nuts, seeds, and or dry beans per week and a maximum 5 servings of sweets per week (U.S. Department of Health and Human Services, 2015a). However, this plan may be adjusted based on an individual's needs. Adherence to the DASH plan is associated with reduced blood pressure (Sacks et al., 2001; Vollmer et al., 2001), and lower cholesterol levels (Harsha et al., 2004) among other health outcomes. Additionally, it has been shown to be associated with reduced body weight, waist circumference, and A1c levels among patients with diabetes (Azadbakht et al., 2011).

Similar to the DASH plan, the Mediterranean diet emphasizes increased consumption of fruit, vegetables, grains, beans, and nuts. Dairy products, fish, poultry, and red wine are consumed in low to moderate amounts, and red meat is consumed minimally. Of note, specific

definitions for the Mediterranean diet have varied, especially in terms of the recommended quantity of consumption for various food groups; however, in general, Mediterranean-style diets are high in monounsaturated fat (mainly olive oil) and low in saturated fat (Davis, Bryan, Hodgson, & Murphy, 2015). Overall, research has shown that adherence to such diets is associated with lower incidence of cardiovascular disease mortality (Fung et al., 2009), lower cardiac death and nonfatal MI, and reduced frequency of other cardiac events such as unstable angina, stroke, heart failure, and pulmonary or peripheral embolism (de Lorgeril et al., 1999). It is also associated with reduced all-cause, CVD, and cancer mortality in the U.S. population (Mitrou et al., 2007).

While differences exist with regard to the DASH and Mediterranean diet plans, both emphasize increased consumption of fruit, vegetables, whole-grains, beans, and nuts, in addition to regular consumption of poultry and fish. Both eating patterns also limit saturated fat. Indeed, it is unsurprising that diets emphasizing reduced saturated fat and *trans* fat have been associated with positive health outcomes, as this may help to manage lipid levels that contribute to atherosclerosis and plaque buildup. Specifically, for cardiac health it is recommended to limit saturated fat to no more than six percent of total calories, *trans* fat to less than one percent of total calories, and cholesterol to less than 200 mg/day (Fihn et al., 2012). In addition, limiting sodium (consistent with the DASH plan) may reduce blood pressure (Fihn et al., 2012). Specifically, reducing to no more than 2,300 or 2,400 mg of sodium per day is recommended for cardiac health, and lowering to 1,500 mg/day can further help lower blood pressure (Eckel et al., 2014, U.S. Department of Health and Human Services, 2006). Reducing by 1,000 mg/day, even if the resulting outcome is above recommended limits, may still yield benefits (Eckel et al., 2014). Of course, other comorbid medical conditions such as diabetes may further inform diet

recommendations (e.g., reduced carbohydrates). Healthy eating recommendations for the proposed intervention follow AHA guidelines and DASH guidelines and are additionally largely consistent with aspects of the Mediterranean diet that are shared with DASH (e.g., a diet high in fruit, whole grains, and vegetables, and low in saturated fat).

Physical Activity

Physical activity recommendations for stable CAD include engagement in 30-60 minutes of moderate intensity aerobic activity, such as brisk walking, at least five days per week (Fihn et al., 2012). There is also evidence that resistance training two days per week may yield benefits, such as improvements in quality of life and physical strength (Fihn et al., 2012). For at-risk patients at first diagnosis, cardiac rehabilitation and home-based programs that are physician-directed are recommended. Risk assessment with an exercise test and/or physical activity history is also recommended for patients more generally (Fihn et al., 2012)

Among patients with CAD, exercise-based cardiac rehabilitation is associated with reduced mortality (Taylor et al., 2004). One meta-analysis found 20% reduced risk of all-cause mortality and 26% reduced risk of cardiac mortality among those who participated in cardiac rehabilitation versus usual care, highlighting the importance of exercise in this population (Taylor et al., 2004). Physical activity may improve cardiac health through a variety of mechanisms. For example, it is associated with lower rates of LDL, blood pressure, and diabetes, in addition to better weight management (Eckel et al., 2014, Lichtenstein, et al., 2006). In these ways, physical activity may lower clinical risk factors for CAD and cardiac events. Additionally, relevant biological pathways for improved cardiac functioning may also include improved endothelial function and collateralization, which may help improve blood supply to the heart (Heaps & Parker, 2011; Newcomer, Thijssen, & Green, 2011). For this reason, it is unsurprising

that walking programs emphasizing regular engagement in moderate aerobic exercise have yielded beneficial results (Coke & Fletcher, 2010; Lau, Thompson, Burr, & Dougherty, 2016; Faulkner, Gerhard, Stoner & Lambrick, 2012; Nemoto, Hirokazu, Masuki, Okazaki, & Nose, 2007.). For example, one study found that after engaging in a 6-month walking program (walking three times per week), participating individuals with myocardial ischemia experienced increased exercise capacity and reduced diastolic blood pressure reactivity compared with control individuals (Neumann, Brown, Waldstein, & Katzel, 2006).

Stress Management

Risk factor modification for patients with stable CAD includes management of psychological factors. Patients with stable CAD report high levels of stress, and stress is associated with increased cardiac events (Rosengren et al., 2004). Therefore, unsurprisingly, stress management is a component of many cardiac rehabilitation programs. Both behavioral and physiological mechanisms may account for the link between stress levels and CAD risk. For individuals experiencing depression, behavioral mechanisms may include reduced healthy behaviors such as medical adherence, healthy diet, and regular exercise, (Fihn et al., 2012). Physiological mechanisms linking stress and increased CAD risk may include effects from repeated activation of the sympathetic nervous system (Krantz, Whittaker, & Sheps, 2012). While rigorous work is needed in this area, directions for additional research include cardiac autonomic dysfunction, impaired endothelial functioning, low-grade inflammation, platelet hyperactivity, increased coagulation, among others (Carney & Freedland, 2009; Davison, Alcántara, & Miller, 2018; Poole, Dickens, & Steptoe, 2011). Acute stress and other negative emotions such as anger may also lead to increased risk for cardiac events (Krantz et al., 2012). Therefore, it is critical to manage both acute and chronic stress.

Among patients with CAD, screening for and treating depression in particular may be an important part of treatment. Estimates suggest that approximately 20% of patients with CHD meet criteria for a depressive disorder immediately post MI (Bush et al., 2005; Thombs et al., 2005). While there are fewer studies on the persistence of depression in this population, research suggests that it may persist for many patients (Thombs et al., 2005). Depression is associated with increased risk for MI and cardiac events more generally; one meta-analysis indicated that depressed individuals were 1.3 times as likely as non-depressed individuals to experience any CHD event, and 1.3 times as likely to experience MI (Gan et al., 2014). Unsurprisingly, for stable CAD patients, the American College of Cardiology Foundation, American Heart Association, and other medical bodies indicate that it is reasonable to screen patients for depression and refer to treatment when needed (Fihn et al., 2012).

While research regarding the link between anxiety and CAD is less well studied than that of depression and CAD, several recent meta-analyses have demonstrated anxiety to be associated with increased cardiac risk. For example, one meta-analysis found elevated anxiety symptoms to be associated with 41% increased risk of cardiovascular mortality, 41% increased risk of coronary heart disease, and 35% increased risk of heart failure (Emdin et al., 2016). Another found anxiety symptoms to be associated with 48% increased risk of cardiac death in cohorts of initially healthy individuals (Roest, Martens, de Jonge, & Denollet, 2010). Further, individuals experiencing chronic stress experience increased cardiac risk **(**Davison et al. 2018; Rozanski, 2014). Therefore, individuals demonstrating symptoms related to negative affect more generally, whether this manifests primarily depressive symptoms, anxious symptoms, or other negative emotions, may be good candidates for stress management interventions. Such interventions often include a combination of relaxation techniques, cognitive techniques, and behavioral techniques

(Fihn et al., 2012). Stress management interventions have been associated with positive physical and psychological outcomes among those with stable CAD more generally. Additional information on results of such interventions is described in the "Lifestyle Interventions and CAD" section below. While the present study discusses stress and its relation to CAD, it is also important to note that other cardiac conditions such as heart failure and arrhythmias are associated with psychological distress that may necessitate intervention (Dornelas & Sears, 2018).

Smoking Cessation

Tobacco use is the leading cause of preventable death, disease, and disability in the U.S., and thus is critical for improved health (U.S. Department of Health and Human Services, 2019). For patients with stable CAD, it is recommended that providers encourage smoking cessation and avoidance of exposure to second-hand tobacco smoke. Subsequent follow-up and treatment is recommended for smoking cessation, which may include behavioral and pharmacological interventions (Fihn et al., 2012).

With regard to cardiac health, smoking is associated with increased atherosclerosis, increased blood clotting, and increased risk for stroke (U.S. Department of Health and Human Services, 2014). Heavy smokers (e.g., over 25 cigarettes/day) may be 5.5 times as likely to experience fatal CAD than nonsmokers, and 5.8 times as likely to experience non-fatal MI (Willet et al., 1987). Biological mechanisms linking smoking to cardiovascular health include impacts on vasomotor dysfunction, inflammation, modification of lipid profiles, and thrombosis risk factors, among others (Ambrose & Barura, 2004). While cigarette smoking is clearly associated with increased cardiac risk, smoking cessation can yield important health benefits in a relatively short time frame. Reduced risk of heart attack and improved lung functioning may

occur in as little as two weeks to three months of quitting (U.S. Department of Health and Human Services, 1990; U.S. Department of Health and Human Services, 2004). Further, smoking cessation yields important improvements in cardiac health. For example, one study found that current male smokers younger than the age of 55 were 2.9 times more likely than non-smokers to experience MI, but the risk after two to three years of abstention was comparable to never-smokers (Rosenberg, Kaufman, Helmrich, & Shapiro, 1985). A meta-analysis also found 36% risk reduction of mortality for patients with CHD who quit smoking versus those who did not, among studies with various evaluation timelines (Critchley & Capewell, 2003). Such studies highlight the importance of smoking cessation among those with stable CAD.

Thus, engagement in healthy lifestyle behaviors is essential in maintaining overall and cardiac-specific health. Evaluation of research interventions targeting such behaviors for cardiac patients is outlined next.

Lifestyle Interventions and CAD

Interventions developed to improve lifestyle and health behaviors among patients with CAD have had diverse foci, with various emphases on diet, physical activity, and stress management, among other areas. Intervention lengths, specifics of the research population (e.g., women, individuals with elevated depressive symptoms), and outcome measures have varied as well, and thus, it is unsurprising that research in this broad area has yielded variable results. Overall, study results have been very promising for psychological variables, and more mixed for physical cardiac risk marker and cardiac event variables. However, a few key studies have yielded very positive results for improving physical health via lifestyle intervention, encouraging additional research in this area.

There have been several very successful, long-term, comprehensive lifestyle interventions for improving health among patients with CAD. For example, one randomized controlled study evaluated an intervention which included education and behavioral modification components related to diet, exercise, psychological factors, and smoking behavior for patients with coronary disease and recent history of PCI (Lisspers et al., 1999). The intervention began with a four-week residential stay, including group and individual sessions, and continued in outpatient format for the duration of a year. At the end of treatment, the intervention group demonstrated increases in exercise frequency and diet knowledge and a decrease in weight compared with the control group. No differences were observed for psychological factors or clinical events (Lisspers et al., 1999).

Another comprehensive, year-long program with a focus on diet (low fat, whole foods, plant-based; no more than 10% of calories from fat), moderate exercise (three or more hours per week), stress management (at least one hour per day of activities such as stretching, progressive relaxation, breathing techniques, and/or visualization), and social support (group sessions twice per week) demonstrated improvements in cardiac-related health behaviors such as diet, exercise, and stress management, in addition to quality of life over the course of the one-year follow-up (Billings, 2000; Koertge, et al., 2003). Additionally, there was a significant decrease in physical risk for cardiac events (e.g., lower plasma lipids, blood pressure, weight, and higher exercise capacity; Koertge et al., 2003). In an earlier five-year trial investigating similar treatment components, the intervention group experienced significant decrease in angina at one and five-years post-study initiation (91% reduction at year one, and 72% reduction at year five) versus the control group (186% increase at year 1, 36% decrease at year 5- in part due to revascularization). Patients in the intervention group also experienced decreased stenosis after both one and five

years, versus increased stenosis observed in the control group at both time points. Additionally, the intervention group experienced fewer cardiac events (MI, angioplasty, CABG, cardiac hospitalizations, cardiac-related death) during the 5-year follow-up (control group 2.47 times as likely as experimental group to experience any cardiac event; Ornish et al., 1998).

With regard to interventions with a primarily psychological focus, a recent review and meta-analysis found that while psychological interventions were associated with reduced psychological symptoms (small/moderate effect) and reduced cardiac mortality (small effect), they were not associated with total mortality, subsequent revascularization, or non-fatal MI (Whalley, Thompson, & Taylor, 2014). These results are similar to earlier reviews demonstrating modest effects for reducing psychological distress, and small or non-existent effects for cardiac mortality, total mortality, revascularization, and non-fatal MI (e.g., Rees, Bennett, West, Smith, & Ebrahim, 2004). However, several studies, such as The Stockholm Women's Intervention Trial for Coronary Heart Disease (SWITCHD), serve as excellent illustrations of how stress reduction programs may have beneficial effects for cardiac patients. In this study, women with history of MI, CABG, or PCI, occurring approximately four months prior to intervention commencement, were recruited for a 20-session group stress management intervention lasting approximately one year. The intervention focused on risk factor education, cognitive restructuring, relaxation techniques, coping, and self-care (Orth-Gomér et al., 2009). Over the course of the intervention and follow-up (end of follow-up was, on average, 7-years post-randomization), 7% of women in the intervention group died vs. 20% in usual care (Orth-Gomér et al., 2009). While exact mechanisms of action are unknown, this study illustrates the strong impact that a psychological intervention may have on mortality for individuals with coronary disease. In a similar study, individuals who engaged in a CBT program with a focus on stress

management (20, two-hour sessions over the course of one year) experienced 45% fewer recurrent acute MIs compared to treatment as usual during the follow-up period (mean=94 months; Gulliksson et al., 2011).

In another study, Blumenthal and colleagues evaluated the effects of adding stress management with a focus on CBT principles (12 weekly, 1.5-hour group sessions) to cardiac rehabilitation training. The authors described cardiac rehabilitation training as largely consisting of aerobic exercise, three times per week, utilizing 70-85% of heart rate reserve, in addition to general education about CHD and nutritional guidelines, with two classes devoted to stress management. Individuals in the intervention group demonstrated reduced stress levels after treatment, in addition to lower rates of clinical events such as all-cause mortality, fatal or non-fatal MI, stroke/TIA, unstable angina requiring hospitalization, or coronary or peripheral artery revascularization (18% for intervention group vs. 33% for control group) over the 5-year follow-up period (Blumenthal et al., 2016). In an earlier study evaluating the benefit of added stress management training (1.5-hour group sessions for 16 weeks) vs. added exercise training (supervised 35 minutes of aerobic exercise training, three times per week for 16 weeks) to usual care for those with CAD, improvements in depression for both intervention groups vs. usual care were observed. Additionally, clinical variables such as left ventricular ejection fraction (LVEF) during mental stress testing and flow-mediated dilation were improved for intervention group participants vs. control individuals. (Blumenthal et al., 2005).

As suggested by the results of aforementioned meta-analyses (i.e., Rees et al., 2004; Whalley et al., 2014), not all psychological intervention studies have yielded anticipated benefits for cardiac patients. For example, one intervention for female patients with CAD demonstrated no benefit for clinical risk markers (e.g., waist circumference, high sensitive C-reactive protein,

fibrinogen) among individuals participating in a 20-session, group-format, year-long CBT stress management program versus those in usual care (Claesson et al., 2006). Similarly, another comprehensive intervention, the Enhancing Recovery in Coronary Heart Disease (ENRICHD) study, evaluated psychological intervention (maximum of six months CBT-focused treatment, sertraline added as adjunct as needed) for those with depression and/or low perceived social support. In this study, there were no observed difference between individuals who were in the intervention vs. the control group in terms of mortality (Carney et al., 2004). However, improvements in depressive symptoms and low social support were observed for patients receiving the intervention (Berkman et al., 2003), and follow-up analyses revealed reduced cardiac mortality and nonfatal MI for white men only (Schneiderman et al., 2004). Additionally, a year-long CBT group intervention for female cardiac patients, focusing on psychological variables specifically, found no differences between intervention group individuals and control group individuals in terms of depressive symptoms (Koertge et al., 2007). Such results prompt further investigation of factors related to intervention success. For example, it could be that stress management interventions are most helpful when the program additionally includes other lifestyle modifications such as diet and exercise, as such interventions are often associated with reduced physical risk markers such as atherosclerotic burden (Jhamnani et al., 2015).

Comprehensive risk reduction programs are not limited to clinical research trials. Engagement in cardiac rehabilitation programs are recommended by AHA and the American College of Cardiology Foundation for individuals with ACS and for individuals immediately post PCI or CABG (Smith et al., 2011). These programs offer a multifaceted approach for improving cardiac health. Programs may include a focus on healthy behaviors such as lifestyle and exercise, nutritional and psychosocial counseling, and medication management, among other

services (Balady et al, 2011). These programs are associated with improvements on cardiac risk factors and reduced mortality (Balady et al., 2011). However, less than 40% of heart attack survivors and less than 40% of patients who receive CABG participate in cardiac rehabilitation (Balady et al., 2011). Lack of accessibility, lack of insurance coverage, and lack of referral (particularly for women and ethnic minorities) contribute to low attendance rates (Balady et al., 2011). Given the high prevalence of and adverse health consequences associated with CAD, it is essential to offer clinical services that are feasible and acceptable for both patients and clinics to facilitate usage.

A potential avenue through which to increase accessibility and acceptability of services to patients and providers is via brief treatment protocols, within the patient centered medical home. In this context, brief treatment may reduce temporal or financial barriers for patients, and thus translate into increased attendance and health gains. Fortunately, there have been several promising studies demonstrating effectiveness of brief (approximately one to seven sessions in length) behavioral health treatment for cardiac patients (e.g., Black et al., 1998; Mayou et al. 2002; McLaughlin et al., 2005). Results of these studies are encouraging, with evidence of decreased depression (Black et al., 1998), improvements in quality of life (Mayou et al. 2002), and reduced anxiety and functional limitation (McLaughlin et al., 2005). However, these studies have often been conducted only with those with elevated psychological distress (e.g., McLaughlin et al., 2005) or in a hospital setting (e.g., Mayou et al. 2002). Additional research is needed regarding efficacy of brief interventions in outpatient cardiac care for those both with and without elevated psychological distress.

Present Study

The present study evaluates the feasibility, acceptability, and efficacy of a brief behavioral health intervention program aimed at addressing lifestyle behaviors for patients with stable CAD in outpatient cardiology care. Results from longer interventions suggest that lifestyle interventions may be very effective in addressing psychological and physical factors related to cardiac health, and results from previous brief studies in hospital settings and with populations experiencing psychological distress are promising. Importantly, patients often receive lifestyle intervention and related information after an ACS, and indeed, recruitment for previous lifestyle studies has largely been from hospital settings. The present intervention was designed for implementation in outpatient cardiac care, to be accessible to a wide range of patients with stable CAD status— including those without history or with distant history of ACS and/or hospitalization. Thus, this research addresses a critical gap in the literature for a population at risk for cardiac morbidity and mortality. The brief nature is intended to increase feasibility and acceptability to both clinics and patients, and implementation in the patient's cardiac clinic increases accessibility for both patients and providers. This also helps address a recognized need for developing integrated behavioral health into specialty cardiac clinics (Dornelas & Sears, 2018). Results of this study are intended to inform future development of interventions for brief secondary prevention in outpatient cardiology care.

Feasibility and Acceptability

A focus of feasibility and acceptability is critical in intervention development to help inform program changes that will allow for successful implementation and impact on patient care. In general, feasibility studies, or pilot studies, can be used to evaluate and inform recruitment, study procedures, program implementation and refinement, and more (Leon, Davis,

& Kraemer, 2011). Importantly, it is essential to establish a priori criteria with which to deem a program feasible or acceptable (Jones, Olds, Currow, & Williams, 2017). A priori criteria for feasibility and acceptability for the present study included:

Feasibility

1) At least 60% of referred and eligible patients agree to participate (Horton et al., 2013)
2) At least 75% of the consented intervention group patients complete the study intervention and outcome measurements through 30-day follow-up (Horton et al., 2013)

Acceptability

1) At least 80% respond "Yes" to the Yes/No question at post-treatment: "Would you recommend this intervention to other patients with coronary artery disease?" (Jones et al., 2017).

Efficacy

While efficacy is not typically a main focus of studies evaluating feasibility and acceptability (Eldridge et al., 2016; Leon et al., 2011), preliminary tests of efficacy were conducted for the purpose of informing future development of this and similar programs.

Primary tests of effectiveness included investigation of study effects with regard to:

1) Patient confidence in managing cardiac disease, as indicated by perceived self-efficacy and illness perceptions.
    - Hypothesis 1: Participants in the Intervention Group (IG) will report greater self-efficacy in managing disease over time as compared with participants in the Treatment as Usual (TAU) group.

- Hypothesis 2: Participants in the IG will report less threatening illness perceptions over time as compared with participants in the TAU group.

2) Psychological outcomes as indicated by depressive and anxious symptoms.

- Hypothesis 3: Participants in the IG will report greater decreases in depressive symptomatology over time as compared with participants in the TAU group.
- Hypothesis 4: Participants in the IG will report greater decreases in anxious symptomatology over time as compared with participants in the TAU group.

Secondary tests of effectiveness included evaluation of how the proposed intervention may increase preparedness to engage in healthy eating and physical activity. These tests were considered exploratory given that modules differentially emphasized certain lifestyle behaviors, and that participants only completed two out of five potential modules.

- Hypothesis 5: Participants in the IG will report greater self-efficacy for both healthy eating and physical activity, in addition to greater engagement in these behaviors over time, as compared with participants in the TAU group.

RESEARCH DESIGN AND METHODOLOGY

Participants and Recruitment

Participants

Participants included patients with stable CAD, being treated by a board-certified cardiologist at a college of medicine outpatient faculty practice. The clinic is a patient-centered medical home (PCMH) with over 15 specialties. For the present study, stable CAD was defined as:

1) CAD as indicated by history of at least one MI, at least one coronary artery bypass graft surgery, at least one coronary stent, and/or at least one coronary vessel with stenosis $\geq$ 70%.
2) Stable status as indicated by no MI, unstable angina, or ACS within the past three months, no coronary revascularizations within the past three months, and no planned revascularizations.

Exclusion criteria include:

1) Age < 30 years or > 79 years
2) Women who are pregnant or breast feeding
3) Non-English-speaking
4) Participation in another clinical trial concurrently or within 30 days before screening
5) Cognitive impairment as indicated by diagnosis in medical chart
6) Psychotic symptoms as indicated by diagnosis in medical chart

7) Current treatment for non-skin malignancy, malignant melanoma, or advanced kidney disease (indicated by stage 4 or 5 or on dialysis)
8) Psychological safety concerns, including plans to harm oneself within the past two months and/or suicide attempt within the past year
9) Ejection fraction < 30%
10) Physician determination of inappropriateness for study, due to anticipated life expectancy of <1 year, presence of a survival limiting or uncontrolled illness, and/or hemodynamically important valvular disease.

Adults unable to consent, individuals who were not yet adults (infants, children, teenagers), pregnant women, and prisoners were also not eligible for the study.

Recruitment

Individuals were identified for study inclusion criteria via medical chart review and patient interaction during regularly scheduled medical appointments with the cardiologist. Interested individuals then spoke with the graduate research assistant to complete study screening, and to complete the consent process if desired. At times, individuals indicated interest in the study, but did not have time to review the consent form on the day of their office visit. In such cases, an alternate time was scheduled to complete the consent process at the patient's convenience, to ensure ample time for all patient questions to be answered.

Study Procedures

Study protocol was reviewed and approved by the Institutional Review Board (see Appendix A) and HIPAA Compliance Officer. Data storage followed clinic IT Security guidelines.

The study consisted of two research groups: the Intervention Group (IG) and Treatment as Usual (TAU). Both groups completed the informed consent process and signed a HIPAA release form to facilitate release of PHI from the PCMH to the research team. Then, participants were randomly assigned to each group via a random number generator, and participants had an equal chance of being assigned to either group. The principle investigator generated the random allocation sequence, enrolled participants, and assigned participants to the interventions. Thus, this trial was an unblinded, randomized design.

After completing the consent and randomization process, participants scheduled their Baseline appointments at their earliest convenience. Baseline appointments consisted of completing an intake (Cardiac Research Questionnaire, see Appendix B) and questionnaires. After Baseline, IG participants participated in a 3-session lifestyle program lasting approximately two weeks, and then completed a 30-day follow-up. By contrast, TAU participants completed a Baseline appointment, 2-week follow-up appointment, and a 30-day follow-up appointment. Upon completing this participation period (lasting approximately six weeks), TAU participants were then offered the option to participate in the lifestyle program. Additional information is provided in the "Study Protocol" section below.

Study Protocol

Intervention Group (IG)

IG participants participated in the lifestyle program, titled "CLIMB" (Cardiac Lifestyle Intervention for Maintaining Healthy Behaviors). CLIMB consisted of three sessions. During the first session, participants completed a baseline assessment consisting of a cardiac research questionnaire (Appendix B) and psychosocial questionnaires. Then, participants immediately (same day) completed Session 1. During Session 1, participants received feedback regarding

their Baseline questionnaire responses, completed a values exercise to elicit engagement, and identified motivations for change. They also selected preferred modules for Sessions 2 and 3 (one module for each session), from a choice of five modules. This format allowed for selection of material most relevant to the participant and is similar in format to a recent effective intervention for patients with heart failure or chronic obstructive pulmonary disease (Cully et al., 2017). Session 1 ended with the participant making a behavioral goal for the next session. During Sessions 2 and 3, material relevant to the elective modules (one module per session) was reviewed and relevant behavioral goals were made for each session. At the end of Session 3, participants completed post-intervention questionnaires. Questionnaires were additionally administered at 30-day follow-up.

Elective modules topics include "Healthy Eating," "Physical Activity," "Reducing Stress and Worry," "Mood Management" and "Smoking Cessation Education." Each participant who participated in the "Physical Activity" module received clearance from the cardiologist to do so. Common elements among modules included review of the behavioral goal from the previous session, psychoeducation, identifying and problem-solving barriers to performing relevant health behaviors, and making behavioral goals. Elective module descriptions can be found in Appendix C. Module topics were included based on research regarding the importance of targeting healthy eating, physical activity, psychological factors, and smoking cessation to improve health for patients with stable CAD. While weight management is another important topic for cardiac health, low-intensity (fewer than or equal to five sessions) weight management interventions have not translated into clinically meaningful weight loss for patients (U.S. Department of Health and Human Services, 2013). Given the brief nature of the intervention, a weight management module was not selected for the evaluated program. However, patients interested in

weight management activities were encouraged in modules that seemed most relevant to their weight management needs (e.g. “Healthy Eating”).

The timeline for IG participation included:

1) Baseline assessment: Approximately one hour (Baseline questionnaires completed)
2) Session 1: Approximately one hour, immediately following Baseline (same-day)
3) Session 2: Approximately one hour, one week following Session 1
4) Session 3: Approximately 1.5 hours, one week following Session 2 (Post-treatment questionnaires completed)
5) 30-day follow-up: Approximately one hour, 30 days following Session 3 (30-day follow-up questionnaires completed)

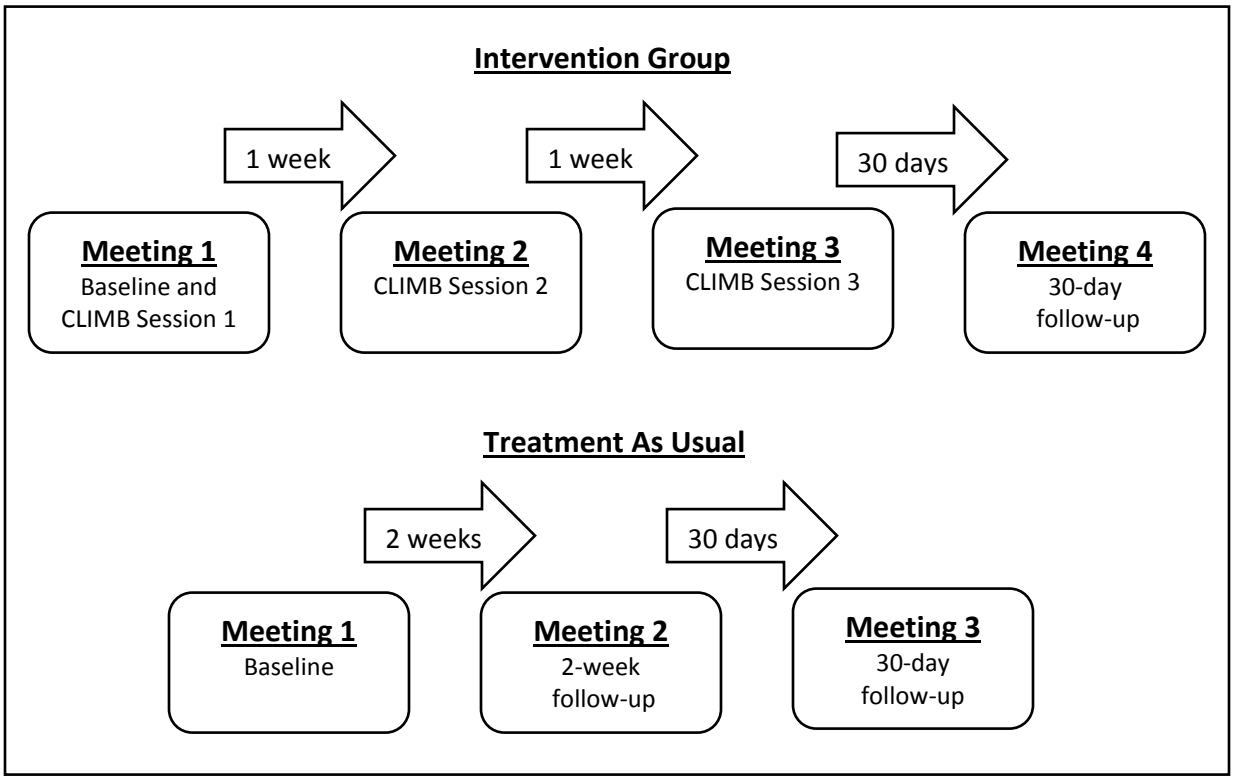


Figure 1. *Group participation timelines*

Treatment as Usual (TAU)

The TAU group continued to receive their usual medical care while they completed research questionnaires over the course of approximately six weeks. The TAU group filled out study questionnaires at time points comparable to the IG: at Baseline, at 2-week follow-up (two weeks after Baseline), and at 30-day follow-up (30 days after the 2-week follow-up). After this point, they were given the option to participate in the CLIMB program. Participation timelines for IG and TAU participations are displayed in Figure 1.

Telephone Contact

For IG participants, Baseline and Session 1 always occurred at the PCMH. For subsequent sessions, if participants were unable to participate at the PCMH to complete a

scheduled session within one calendar week after the specified session date (e.g., for Session 2 within 14 days of Session 1) or within three business days prior to the specified time point, then participants had the option to participate by telephone. For the TAU group, the Baseline session always occurred at the PCMH. Participants were permitted to complete 2-week and 30-day follow-up data either in-person or by telephone.

Study Data

Study data was stored on Health IT encrypted file shares. Only research team members had access to these files. Psychosocial questionnaires were administered using Qualtrics and associated with ID number only. Upon completion of the study, participants had the option to request a summary of their research participation to be released to the PCMH and included in their medical records. This included information regarding their participation attendance, research module selection, engagement, and any referrals that were requested during the study.

Measures

Participants, in collaboration with the research team member, completed the cardiac research intake form. This contained demographic and clinical information relevant for the lifestyle program.

Feasibility and Acceptability

Attendance and Eligibility Screening Records

Attendance and eligibility screening records were used to evaluate a priori feasibility criteria.

Program Development Questionnaire.

This measure was created by the research team to evaluate participant reactions to different components of the program, and to elicit feedback more generally to inform future refinement of the intervention. This measure was administered at Post-treatment to IG participants. The Program Development Questionnaire is included in Appendix D.

Satisfaction with Care Questionnaire

This measure was created by the research team to evaluate satisfaction with the provided intervention. Item 4 on the measure ("Would you recommend this intervention to other patients with coronary artery disease?") was used to evaluate the a priori criteria for acceptability. This measure was administered at Post-treatment to IG participants. The Satisfaction with Care Questionnaire is included in Appendix E.

Efficacy Outcomes: Primary

Self-Efficacy for Managing Chronic Disease Scale (SEMCD-6)

The SEMCD-6 is a six-item measure of self-efficacy for managing chronic illness. Each item is scored on a Likert scale of 1-10, with higher scores indicating greater levels of self-efficacy. The overall score has a high internal consistency (Cronbach's alpha = .88-.91), and evidence suggests that the scale is one-dimensional in structure (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001; Ritter & Lorig, 2014). The total score is the mean of the six items. This measure has been used in other brief interventions for patients with cardiopulmonary conditions (e.g.,

Hundt et al., 2018). Importantly, self-efficacy is shown to be a predictor of health behavior change (see Sheeran et al., 2016 for meta-analysis).

Brief Illness Perception Questionnaire (BIPQ)

The BIPQ is a nine-item measure evaluating overall patient perceptions of illness (Broadbent, Petrie, Main, & Weinman, 2006). The measure is a shortened form of the longer Illness Perceptions Questionnaire-Revised (IPQ-R; Moss-Morris et al., 2002). Each BIPQ item refers to a different domain of illness perceptions (Leventhal et al., 1997; Leventhal, Brissette, & Leventhal, 2003). Examples include: perceived control of illness, emotional reaction to illness, and understanding of illness. The first eight items are scored on a Likert scale of 0-10, and items 3, 4, and 7 are reverse-scored. The ninth item is an open-ended question regarding perceived causes of illnesses and was not used in the present study. Scores on the first eight items may be summed for a total score, with higher scores representing more threatening views of illness. Test-retest reliability of individual items (one through eight) over a six-week period ranges from .61-.75, with the exceptions of one item (personal control, $r = .42$) (Broadbent et al., 2006). Test-retest reliability of a Dutch translation indicates good test-retest reliability of the total score (ICC = .72; Hallegraef, van der Schans, Krijnen, & de Greef, 2013). Evaluations of various translations of the BIPQ also suggest good internal consistency for the total score: $r = .74$ for Polish translation (Nowicka-Saur et al., 2015) and $r = .73$ for the Dutch translation (Hallegraef et al., 2013). Research has demonstrated that less threatening illness perceptions among cardiac patients are associated with better quality of life (e.g., Janssen, de Gucht, van Exel, & Maes, 2013). Additionally, one study found that individuals receiving an intervention to address illness perceptions after MI returned to work sooner and reported less angina than other individuals—

illustrating the importance of evaluating illness perceptions among patients with cardiac disease (Petrie, Cameron, Ellis, Buick, & Weinman, 2002).

Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a brief self-report measure of depressive symptoms (Kroenke, Spitzer, & Williams, 2001). The questionnaire consists of 9 items, with each item representing a different depressive symptom. Item scores represent frequency with which symptoms are present, ranging from 0 (not at all) to 3 (nearly every day). Psychometric analysis of the PHQ-9 demonstrates strong criterion and construct validity and internal consistency with a Cronbach's alpha of .83-.92 (Cameron, Crawford, Lawton, & Reid, 2008; Kroenke et al., 2001). Summed scores of 0-4 are considered minimal depressive symptoms, scores of 5-9 are considered mild depressive symptoms, scores of 10-14 are considered moderate depressive symptoms, scores of 15-19 are considered moderately severe depressive symptoms, and scores of 20-27 are considered severe depressive symptoms (Kroenke et al., 2001).

Generalized Anxiety Disoder-7 (GAD-7).

The GAD-7 is a brief self-report measure of anxious symptoms (Spitzer, Kroenke, Williams, & Löwe, 2006). The questionnaire consists of 7 items and is a screening measure for anxious symptoms typically experienced by those with generalized anxiety disorder. Item scores represent frequency of the experienced symptoms, ranging from 0 (not at all) to 3 (nearly every day). Psychometric analysis of the GAD-7 demonstrates good internal consistency among both primary care and general populations, test re-rest reliability (ICC = .83), and criterion and construct validity (Löwe et al., 2008; Spitzer et al., 2006). Summed scores of 0-4 suggest minimal anxious symptoms, scores of 5-9 suggest mild anxious symptoms, scores of 10-15

suggest moderate anxious symptoms, and scores of 15-21 indicate severe anxious symptoms (Spitzer et al., 2006).

Efficacy Outcomes: Secondary

Starting the Conversation (STC)

STC is a brief and validated dietary assessment designed for health promotion settings (Paxton, Strycker, Toobert, Ammerman, & Glasgow, 2011). It is a broad, 8-item food frequency questionnaire assessing overall dietary patterns. A summary score may be computed by summing all 8 items, with higher scores generally reflecting greater room for dietary improvement. Test-retest reliability is established over a four-month period (r = 0.66). The summary score has demonstrated convergent validity with the National Cancer Institute (NCI) fat screener (r = 0.39). In the present study, participants were asked to consider their food intake patterns over the past two weeks when making their response selections (changed from "over the past few months" in the original measure, due to the short-term nature of the study).

Global Physical Activity Questionnaire (GPAQ)

The GPAQ is a measure of physical activity recommended by the World Health Organization (WHO). The GPAQ measures physical activity behavior at work (including housework), during travel, and during recreational activities. The measure can be scored in a variety of ways, yielding continuous indicators (e.g., MET-minutes/week, time spent in physical activity, minutes spent sitting), or by categorical indicators (e.g., whether one has met a recommended guideline for physical activity levels; World Health Organization, n.d.). A comprehensive psychometric evaluation revealed overall good test-retest reliability across various ways of scoring the measure, as well as concurrent

validity with other physical activity measures (Bull, Maslin, & Armstrong, 2009). For the present study, a summary score of moderate and physical activity across domains (work, travel, recreation) per day was utilized, consistent with other studies (e.g., Herrmann, Heumann, Der Ananian, & Ainsowrth, 2013).

Smoking Cessation Measures

Smoking behavior was assessed for participants who reported having smoked a cigarette over the past month. Smoking was assessed via patient self-report of number of cigarettes per week over the past two weeks. Attitudes towards change were measured using three motivation rulers scored from 0-10 ("How important is stopping smoking to you?" "How ready are you to quit smoking within the next month?" "How confident are you that you will quit smoking within the next month?"). Use of such rulers has demonstrated good convergent validity with other stages of change measures in addition to smoking behavior (Boudreaux et al., 2012). Participants were also asked if they would like a referral facilitated to aid in smoking cessation.

Dieter's Inventory of Eating Temptations-Self-Efficacy (DIET-SE)

The DIET-SE is a scenario-based, self-report measure of self-efficacy in adhering to healthy eating in a variety of situations (Stich, Knäuper, & Tint, 2009). Psychometric properties of the total score are established (test-retest reliability: r = .83; internal consistency: a = .82). The measure also demonstrates appropriate convergent validity with related measures (Stich et al., 2009). Further, there are three available subscales related to common challenges in adhering to healthy eating patterns: high caloric food temptations, social and internal factors, and negative emotional events. Internal consistency for the three subscales ranges from a = .77 to a = .79, and test-re-test

reliability ranges from r = .75 to r = .80 (Stich et al., 2009). The measure is slightly modified for the current study by changing the term "boyfriend or girlfriend" in one item to "significant other" to increase inclusiveness. The present study utilized the total score of the scale, which is calculated by summing responses across all items.

Exercise Confidence Survey (ECS)

The ECS is a 12-item measure of exercise self-efficacy. Each item is scored on a 1-5 Likert scale, with greater scores indicating greater levels of confidence. The measure is adapted (one-item difference) from the original Exercise Self-Efficacy and Exercise Habits Survey (Sallis, Pinski, Grossman, Patterson, & Nader, 1988). The updated scale replaced the item "Get up earlier to exercise" (similar to another item on the survey: "Get up early, even on weekends, to exercise") with "Attend a party only after exercising." Test-retest reliability of the revised measure over a one-week period is established: ICC = .78 (Sallis, n.d.).

Statistical Methodology

Feasibility and acceptability criteria as outlined above were evaluated descriptively via attendance records (feasibility) and responses to the question "Would you recommend this intervention to other patients with coronary artery disease?" (acceptability). With regard to efficacy, a series of four repeated-measures ANOVAs (dependent variables: SEMCD-6, BIPQ, PHQ-9, and GAD-7) were computed to evaluate main hypotheses related to efficacy. Reliable change index scores were also calculated (Jacobson and Truax, 1991; Johnson, Dow, Lynch, & Herrmann, 2006). Secondary efficacy outcomes were analyzed using the same statistical procedures for the following variables: STC, GPAQ, DIET-SE and the ECS. Smoking variable

analyses were omitted because no participants smoked a cigarette within the past month at the time of their Baseline appointment.

RESULTS

Participant Recruitment

Participants were recruited over the course of nine consecutive months in 2018 and 2019. Every patient with stable CAD presenting to the cardiology clinic during recruitment days throughout this period was evaluated for study eligibility. As outlined in the CONSORT diagram (Figure 2), data from 28 participants were available for efficacy analyses. Of the 33 consented participants, five were excluded from efficacy analyses: two IG and one TAU participant dropped out prior to Baseline appointment, one IG participant was withdrawn by the research team after Baseline/Session 1 due to ACS, and one IG participant was excluded due to participation in another lifestyle program with similar intervention targets (e.g., dietary and stress management changes, setting SMART goals). Thus, data from the latter two participants were included in feasibility and acceptability analyses, but not in efficacy analyses.

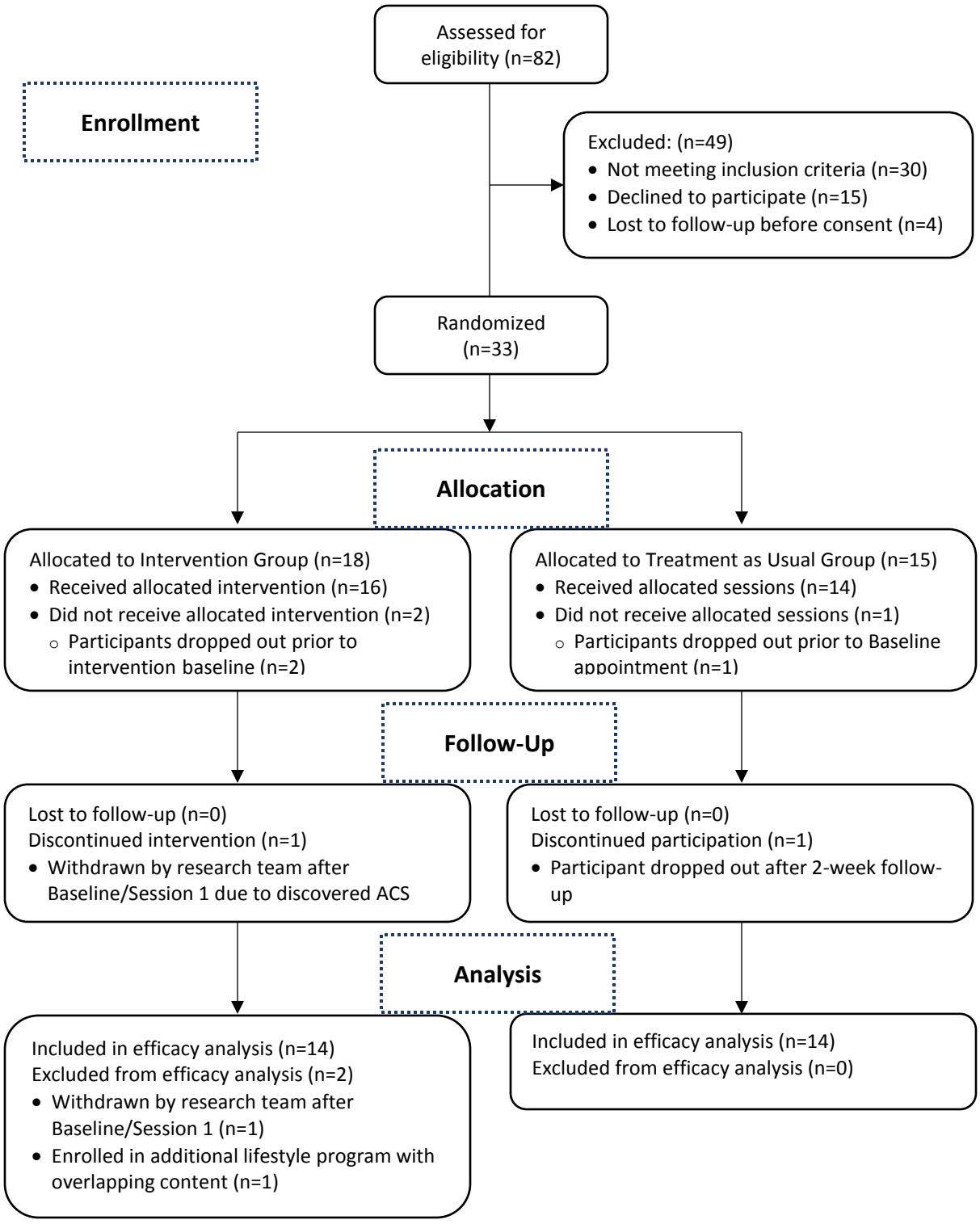


Figure 2. *Consort flow diagram*

Feasibility and Acceptability

Feasibility

Study recruitment and attendance records were examined to identify if the following a priori feasibility criteria were met:

1) At least 60% of referred and eligible patients agree to participate
2) At least 75% of the consented Intervention Group patients complete the study intervention and outcome measurements through 30-day follow-up

Thirty-three out of fifty-two (63.5%) of referred and eligible patients agreed and consented to participation, indicating that that the first study feasibility criteria was met. Patients declined for the following reasons: work schedule (*n*=7), already making lifestyle changes (*n*=2) upcoming medical procedures or appointments (*n*=2), lived out of state (*n*=1), family obligations (*n*=1), and not reported (*n*=2). Additionally, four patients indicated interest in the study, but were lost to follow-up prior to consent.

Fifteen out of eighteen (83.3%) consented IG patients completed the study intervention and outcome measures through 30-day follow-up, indicating that the second feasibility criteria was also met. For the three participants who did not complete the intervention and measures through 30-day follow-up, two had dropped out of the study prior to starting the CLIMB program (i.e., after consent, but before Baseline/Session 1), whereas one was withdrawn by the research team after the Baseline/Session 1 appointment due to discovered ACS. Therefore, with the exception of one participant, all those who started CLIMB completed the entirety of the program.

Sixteen IG participants completed Session 1, and therefore engaged in module selection. “Healthy Eating” was the module most often selected, followed by “Mood Management” and

"Reducing Stress and Worry" (See Figure 3 for more information). Of note, none of the participants selected the Smoking Cessation Module, as none had smoked a cigarette within the past month at the time of their Baseline appointment. Additionally, three IG individuals had not been cleared for the Physical Activity module, and thus interest in this module may have been greater than reflected in the numbers above. The average session duration for the modules were as follows: 62 minutes for "Healthy Eating", 51 minutes for "Physical Activity", 64 minutes for "Reducing Stress and Worry" and 59 minutes for "Mood Management."

Participants had the option to complete certain research meetings by phone. For IG participants, a total of two participants completed at least one research meeting remotely: one person completed 30-day follow-up questionnaires by phone, and the other completed post-treatment questionnaires by phone. For TAU participants, a total of two individuals completed at least one research meeting remotely: both completed 2-week follow-up questionnaires by phone. Thus, the majority of research meetings were completed in-person.

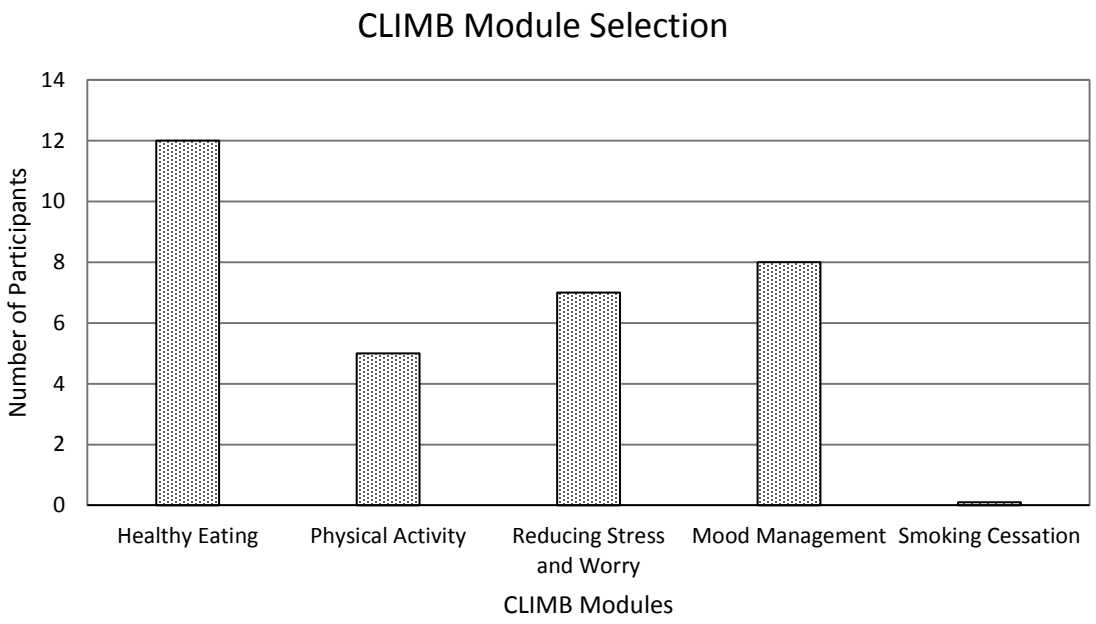


Figure 3. *CLIMB module selection*

Acceptability

Answers to the following question were evaluated to determine if the a priori acceptability criterion was met:

1) At least 80% respond "Yes" to the Yes/No question at post-treatment: "Would you recommend this intervention to other patients with coronary artery disease?"

Fifteen out of 15 (100%) of IG participants who completed post-study questionnaires responded "Yes" to this question, indicating that the a priori acceptability criterion was met.

Efficacy

Participant Characteristics

Demographic characteristics of IG and TAU participants included in efficacy analyses (*N*=28) are outlined in Table 1, and clinical characteristics and baseline medications are outlined in Tables 2 and 3 respectively. Demographic information displayed in Table 1 was obtained via

self-report. Information displayed in Tables 2 and 3 was obtained via medical record, with the exception of the following items from Table 2 which were obtained via self-report: cardiac rehabilitation history, psychiatric history (depression and anxiety), and tobacco use. With regard to substance use, participants were characterized as "Never Smokers" if they had smoked fewer than 100 cigarettes in their lifetimes, "Former Smokers" if they had smoked 100+ cigarettes in their lifetimes but none in the past month, and "Current Smokers" if they had smoked at least one cigarette within the past month (U.S. Department of Health and Human Services, 2017b). All participants with a history of heart failure were compensated at the time of study enrollment.

Between-group differences were evaluated using chi-square and Fisher's exact test for categorical variables, and t-tests for continuous variables. With regard to demographic variables, TAU participants were significantly younger than IG participants, $t(26) = 2.535$, $p = .018$. There were no significant differences with regard to clinical variables. Information for consented participants not included in efficacy analyses is displayed in Table 4.

Table 1. *Participant Demographic Characteristics*

	Total Sample (n = 28)	Intervention Group (n = 14)	Treatment as Usual (n = 14)
Gender			
Male	21 (75.0%)	10 (71.4%)	11 (78.6%)
Female	7 (25.0%)	4 (28.6%)	3 (21.4%)
Age in Years: M(SD)*	66.14 (8.82)	70.00 (7.05)	62.29 (8.94)
Marital Status			
Married	21 (75.0%)	9 (64.3%)	12 (85.7%)
Divorced	4 (14.3%)	2 (14.3%)	2 (14.3%)
Single	2 (7.1%)	2 (14.3%)	0 (0%)
Separated	0 (0%)	0 (0%)	0 (0%)
Widowed	1 (3.6%)	1 (7.1%)	0 (0%)
Race			
Caucasian/White	21 (75.0%)	11 (78.6%)	10 (71.4%)
Latino/a	3 (10.7%)	1 (7.1%)	2 (14.3%)
Asian	3 (10.7%)	1 (7.1%)	2 (14.3%)
African American/Black	1 (3.6%)	1 (7.1%)	0 (0%)
Native American	0 (0%)	0 (0%)	0 (0%)
Pacific Islander	0 (0%)	0 (0%)	0 (0%)
Highest Level of Education			
Graduate Degree	13 (46.4%)	6 (42.9%)	7 (50.0%)
Bachelor's Degree	7 (25.0%)	3 (21.4%)	4 (28.6%)
Associate's Degree	1 (3.6%)	0 (0%)	1 (7.1%)
High school/GED	7 (25.0%)	5 (35.7%)	2 (14.3%)
Employment Status			
Retired	14 (50.0%)	9 (64.3%)	5 (35.7%)
Employed	10 (35.7%)	2 (14.3%)	8 (57.1%)
Part-time employment	4 (14.3%)	3 (21.4%)	1 (7.1%)
Unemployed	0 (0%)	0 (0%)	0 (0%)
Receiving disability	0 (0%)	0 (0%)	0 (0%)

*$p < .05$ for differences between Intervention Group and Treatment as Usual participants

Table 2. *Participant Clinical Characteristics*

	Entire Sample (*n* = 28)	Intervention Group (*n* = 14)	Treatment as Usual (*n* = 14)
BMI[a] M(SD)	29.46 (4.72)	28.76 (3.71)	30.10 (5.56)
H/O ACS			
Yes	14 (50.0%)	8 (57.1%)	6 (42.9%)
No	14 (50.0%)	6 (42.9%)	8 (57.1%)
Current Stable Angina			
Yes	3 (10.7%)	1 (7.1%)	2 (14.3%)
No	25 (89.3%)	13 (92.9%)	12 (85.7%)
H/O Heart Failure			
No	24 (85.7%)	11 (78.6%)	13 (92.9%)
Yes- Preserved LVEF	2 (7.1%)	1 (7.1%)	1 (7.1%)
Yes- Reduced LVEF	2 (7.1%)	2 (14.3%)	0 (0%)
H/O Revascularization			
Stents			
Yes	18 (64.3%)	8 (57.1%)	10 (71.4%)
No	10 (35.7%)	6 (42.9%)	4 (28.6%)
CABG			
Yes	9 (32.1%)	5 (35.7%)	4 (28.6%)
No	19 (67.9%)	9 (64.3%)	10 (71.4%)
H/O Cardiac Rehabilitation			
Yes	10 (35.7%)	6 (42.9%)	4 (28.6%)
No	18 (64.3%)	8 (57.1%)	10 (71.4%)
Hypertension			
Yes	22 (78.6%)	12 (85.7%)	10 (71.4%)
No	6 (21.4%)	2 (14.3%)	4 (28.6%)
Diabetes			
Type 2	12 (42.9%)	5 (35.7%)	7 (50.0%)
Type 1	0 (0%)	0 (0%)	0 (0%)
No	16 (57.1%)	9 (64.3%)	7 (50.0%)
Dyslipidemia			
Yes	27 (96.4%)	14 (100%)	13 (92.9%)
No	1 (3.6%)	0 (0%)	1 (7.1%)
H/O Depression (Treatment or Diagnosis)			
Current	3 (10.7%)	1 (7.1%)	2 (14.3%)
Past	4 (14.3%)	3 (21.4%)	1 (7.1%)
Never	21 (75.0%)	10 (71.4%)	11 (78.6%)
H/O Anxiety (Treatment or Diagnosis)			
Current	3 (10.7%)	1 (7.1%)	2 (14.3%)
Past	1 (3.6%)	0 (0%)	1 (7.1%)
Never	24 (85.7%)	13 (92.9%)	11 (78.6%)
Tobacco Use			
Smoker	0 (0%)	0 (0%)	0 (0%)
Former Smoker	19 (67.9%)	10 (71.4%)	9 (64.3%)
Never Smoker	9 (32.1%)	4 (28.6%)	5 (35.7%)

Note. H/O = history of; BMI = body mass index; ACS = acute coronary syndrome; LVEF = left ventricular ejection fraction; CABG = coronary artery bypass grafting

[a]Excludes the missing BMI data for one intervention group participant

Table 3. *Participant Medications*

	Entire Sample (*n* = 28)	Intervention Group (*n* = 14)	Treatment as Usual (*n* = 14)
Aspirin/Other Anti-Platelet			
Yes	27 (96.4%)	13 (92.9%)	14 (100%)
No	1 (3.6%)	1 (7.1%)	0 (0%)
Beta Blockers			
Yes	21 (75.0%)	11 (78.6%)	10 (71.4%)
No	7 (25.0%)	3 (21.4%)	4 (28.6%)
Calcium Channel Blockers			
Yes	4 (14.3%)	0 (0%)	4 (28.6%)
No	24 (85.7%)	14 (100%)	10 (71.4%)
ACE inhibitors and/or ARB inhibitors			
Yes	24 (85.7%)	12 (85.7%)	12 (85.7%)
No	4 (14.3%)	2 (14.3%)	2 (14.3%)
Statin/Other Anti-Cholesterol			
Yes	28 (100%)	14 (100%)	14 (100%)
No	0 (0%)	0 (0%)	0 (0%)
Anti-coagulants			
Yes	5 (17.9%)	2 (14.3%)	3 (21.4%)
No	23 (82.1%)	12 (85.7%)	11 (78.6%)
Anti-diabetes			
Yes	10 (35.7%)	4 (28.6%)	6 (42.9%)
No	18 (64.3%)	10 (71.4%)	8 (57.1%)
Diuretics			
Yes	9 (32.1%)	6 (42.9%)	3 (21.4%)
No	19 (67.9%)	8 (57.1%)	11 (78.6%)

Of note, examination of ACS and revascularization history reveals long-term stability among many study participants. Twenty-five out of 28 participants had a history of revascularization (i.e., CABG and/or stents). Of these individuals, the average time since last coronary revascularization was 5.64 years (*SD* = 5.32). Only two of the 25 (8.0%) had their most recent revascularization within the twelve months prior to study enrollment. Fourteen of the 28 (50.0%) had a history of ACS. Of these fourteen, the average time since last ACS was 7.01 years (*SD* = 5.64). None had had their most recent ACS within the twelve months prior to study enrollment.

Table 4. *Characteristics of Participants Not Included in Efficacy Analyses*

Participant	Group	Age	Gender	Reason
A	IG	70	M	Dropped out before Baseline appointment
B	IG	73	M	Dropped out before Baseline appointment
C	IG	78	M	Withdrawn before collection of post-treatment data due to ACS
D	IG	68	M	Enrolled in additional lifestyle program with overlapping content
E	TAU	66	M	Dropped out before baseline appointment

Data Overview

Missing data were evaluated for each group across time points. Data were evaluated for complete missing data on questionnaires (i.e., no responses) and partial missing data on questionnaires (i.e., incomplete responses). Of note, one TAU participant did not complete Time 3 questionnaires. With the exception of this participant, all missing ECS data (total and partial) was as a result of marking "N/A" to one or multiple items (treated as missing data), rather than leaving responses blank. Regarding complete missing data on questionnaires, group- and time-specific means were utilized to impute total scores (for example, if the ECS total score was missing from an IG participant at Time 2, then the mean score of IG participants at Time 2 was utilized as replacement). Using this method, one TAU participant had ECS total score data imputed at Time 2, and one TAU participant had total scores for all questionnaires imputed at Time 3 (participant dropped out before Time 3)—these were the only two participants with missing data for an entire questionnaire at any time point.

Regarding partially filled out measures, the SEMCD-6 and ECS were the only questionnaires for which participants submitted incomplete responses. Both measures were calculated by taking an average of the items completed by each participant, and thus individual

items were not imputed. For the SEMCD-6, three individuals had partial missing data for at least one time point (i.e., missing at least one item-level response). Missing responses ranged from 2-3 items per individual at any given time point. For the ECS, twenty-one individuals had partial missing data for at least one time point (i.e., an "N/A" response on at least one time point). Partial missing data ranged from 1-7 missing items for an individual at any given time point.

Outliers were evaluated within each group at each time point utilizing an absolute value z-score cut-off of 3.29 (Field, 2013; Tabachnick & Fidell, 2013). No univariate outliers were identified. Normality was evaluated by $Z_{skewness}$ (skew/SE_{skew}) and $Z_{kurtosis}$ (kurtosis/$SE_{kurtosis}$), with values > 3.29 considered non-normal (Tabachnick & Fidell, 2013**)**. Total scores from the GPAQ, SEMCD-6 and PHQ-9 were non-normal for at least one time point. Therefore, transformations were attempted to reduce skew and kurtosis. A square root transformation for the GPAQ total score, a reflect and square root transformation for the SEMCD-6 total score, and a log transformation for the PHQ-9 total score all resulted in normal transformed variables (Tabachnick & Fidell, 2013). Therefore, these three transformed variables were utilized in respective ANOVA analyses. Untransformed variables were utilized for reliable change analyses.

Descriptive Statistics

Following data cleaning, descriptive statistics were performed on untransformed baseline responses for the eight efficacy outcome variables, with results displayed in Table 5. There were no differences observed between groups on these variables, as assessed by t-tests for normal baseline variables (SEMCD-6, BIPQ, GAD-7, STC, DIET-SE, ECS) and Mann Whitney-U tests for non-normal baseline variables (PHQ-9, GPAQ). There were also no significant differences for the transformed baseline SEMCD-6, PHQ-9, and GPAQ variables. At Baseline, all

participants in both groups reported that they had not smoked a cigarette within the past month. Means and standard deviations for dependent variables at all time points are displayed in Appendix F.

Table 5. *Baseline Descriptive Statistics for 2 (Group) X 3 (Time) ANOVAs*

Measure	Total Sample (*n* = 28) M (SD)	Intervention Group (*n* = 14) M (SD)	Treatment as Usual (*n* = 14) M (SD)
SEMCD-6	7.64 (1.68)	7.21 (2.16)	8.07 (.90)
BIPQ	31.86 (10.36)	30.79 (10.70)	32.93 (10.28)
PHQ-9	3.04 (4.21)	3.21 (4.61)	2.86 (3.94)
GAD-7	3.00 (2.54)	3.07 (2.37)	2.93 (2.79)
STC	5.32 (2.28)	5.64 (2.68)	5.00 (1.84)
DIET-SE	28.50 (7.63)	25.79 (6.34)	31.21 (8.06)
GPAQ	63.56 (58.57)	58.61 (57.53)	68.51 (61.34)
ECS	3.91 (.93)	3.77 (.91)	4.05 (.96)

Note. SEMCD-6 = Self-Efficacy for Managing Chronic Disease Scale; BIPQ = Brief Illness Perception Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disoder-7; STC = Starting the Conversation; DIET-SE = Dieter's Inventory of Eating Temptations-Self-Efficacy; GPAQ = Global Physical Activity Questionnaire; ECS = Exercise Confidence Survey

Repeated Measures ANOVAs

Repeated measures ANOVAs were utilized to evaluate changes over the three time points: Time 1 (Baseline), Time 2 (Post-Treatment [IG]/2-week follow-up [TAU]), and Time 3 (30-day follow-up). The average time between Times 1 and 2 was 15.86 days (*SD* = 3.17), and the average time between Times 2 and 3 was 33.56 days (*SD* = 7.56).

A series of four repeated measures ANOVAs was employed to evaluate the primary efficacy variables of interest: SEMCD-6 (transformed), BIPQ, PHQ-9 (transformed), and GAD-7 scores. Study group (IG vs. TAU) was entered as a between-subjects variable, and time was entered as a within-subjects variable. Mauchly's Test of Sphericity was not significant for the SEMCD-6, BIPQ, or PHQ-9, and so tests of within-subjects effects were interpreted with sphericity assumed (Field, 2013). There were no significant between- or within-groups effects, or significant Group X Time interactions for the SEMCD-6, BIPQ, or PHQ-9 at the .05 alpha level.

For the GAD-7, Mauchly's Test of Sphericity was significant, $\chi^2(2) = 10.247$, $p = .006$, and the Greenhouse-Geisser estimate was less than .75, and so tests of within-subjects effects were estimated using the Greenhouse-Geisser estimation (Field, 2013). There was a significant within-subjects effect of time, $F(1.497, 38.914) = 3.855$, $p = .041$, partial $\eta^2 = .129$, but no significant between-group effect or Group X Time interaction. Given the significant within-subjects effects, within-subjects contrasts were evaluated for differences in GAD-7 scores (inclusive of all participants) across time. Contrasts revealed a significant difference between Times 1 and 2, $F(1, 26) = 5.041$, $p = .033$, partial $\eta^2 = .162$, and between Times 1 and 3, $F(1, 26) = 4.262$, $p = .049$, partial $\eta^2 = .141$. No significant contrasts were found between Time 2 and 3 ($p = .720$). The mean scores at respective time points were: Time_1 $M = 3.00$ ($SD = 2.54$), Time_2 $M = 1.96$ ($SD = 1.95$), Time_3 $M = 1.85$ ($SD = 1.82$).

A series of four repeated measures ANOVAs was then utilized to evaluate secondary efficacy outcomes: STC, DIET-SE, GPAQ (transformed), and ECS scores. Mauchly's Test of Sphericity was not significant for the STC, GPAQ, and ECS, and so tests of within-subjects effects were interpreted with sphericity assumed (Field, 2013). There were no significant between- or within-subjects effects, or significant Group X Time interactions for the STC, GPAQ, or ECS.

For the DIET-SE, Mauchly's Test of Sphericity was significant, $\chi^2(2) = 6.463$, $p = .040$ and the Greenhouse-Geisser estimate was above .75, and so within-subjects effects were estimated using the Huyn-Feidt estimation (Field, 2013). There was a statistically significant main effect for Group, $F(1, 26) = 6.037$, $p = .021$, partial $\eta^2 = .188$, such that collapsed across time, TAU scores were higher than the IG scores. Indeed, visual inspection of plotted means illustrated that TAU scores started higher than IG scores and remained higher over time (See

Table 15 in Appendix F for means over time). However, there was no significant within-subjects effect or Group X Time interaction.

Reliable Change

Reliable change cut-offs were then calculated to evaluate for changes between Time 1 and Time 2, and between Time 1 and Time 3. Reliable change cut-offs were calculated via the following formula: $1.96(S_{diff})$, whereby S_{diff} is the standard error of difference between the two scores (Iverson, 2018, Jacobson & Truax, 1991). Jacobson and Truax describe that S_{diff} can be calculated by utilizing the following equation: $\sqrt{(2[SE]^2)}$ whereby SE is the standard error of measure. SE can be calculated utilizing the following equation: $SD\sqrt{(1-r_{12})}$ whereby r_{12} reflects the test-retest reliability of the measure. While test-re-test reliability is most often utilized in this calculation, internal consistency is also sometimes used (Iverson, 2018; Busch, Wagener, Gregor, Ring, & Borrelli, 2011). Multiplying S_{diff} by 1.96, yields a cut-off that can be employed to evaluate whether there has been reliable change on the measure.

Per the formulas above, calculation of reliable change requires knowledge of a scale's reliability (test-re-test or internal consistency) and standard deviation—see Table 6 for values utilized in the present study. Reliability estimates were obtained from previously published research. In particular, test-retest reliabilities were utilized, with the exception of the SEMCD-6 for which only internal consistency could be obtained satisfactorily. Standard deviation estimates were obtained from Baseline study data (i.e., Baseline data from IG and TAU participants included in efficacy analyses).

Table 6. *Reliable Change Cut-Offs*

Measure	Citation	Reliability	SD	Reliable Change "Cut-Off"
SEMCD-6	Lorig, et al.(2001)	.91	1.68	±1.40
BIPQ	Hallegraef et al. (2013)	.72	10.36	±15.20
PHQ-9	Kroenke et al. (2001)	.84	4.21	±4.67
GAD-7	Spitzer et al. (2006)	.83	2.54	±2.90
STC	Paxton et al., (2011)	.66	2.28	±3.69
DIET-SE	Stich et al. (2009)	.83	7.63	±8.72
GPAQ	Herrmann, et al. (2013)	.82	58.57	±68.88
ECS	Sallis (n.d.)	.78	0.93	±1.21

Note. SEMCD-6 = Self-Efficacy for Managing Chronic Disease Scale; BIPQ = Brief Illness Perception Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disoder-7; STC = Starting the Conversation; DIET-SE = Dieter's Inventory of Eating Temptations-Self-Efficacy; GPAQ = Global Physical Activity Questionnaire; ECS = Exercise Confidence Survey

Reliable change was evaluated at the group level using group means, and the cut-offs displayed in Table 6. For example, the IG group mean on the SEMCD-6 was 7.21 at Time 1, and 7.86 at Time 2; the difference between these scores is .65 points which does not meet the 1.40 cut-off, and thus does not indicate reliable change. Employing this method, neither group exhibited reliable change (favorable or unfavorable) on any measure between Times 1 and 2, and/or between Times 1 and 3. Then, data was pooled across groups to test for reliable change across the entire sample. Again, no reliable change was observed on any measure between Times 1 and 2, and/or between Times 1 and 3. See Table 15 in Appendix F for group and sample means at each time point.

Reliable change for each individual was then evaluated between Times 1 and 2, and between Times 1 and 3. Participants required original total score data (i.e., not mean-replaced) for a measure at both time points in order for reliable change to be assessed. As described above, one TAU participant had a mean-replaced ECS total score at Time 2, and one TAU participant had mean-replaced total scores on every measure at Time 3. Thus, for the former participant, reliable change was not evaluated for the ECS from Time 1 to Time 2; for the latter, reliable changes were not evaluated for any questionnaire from Time 1 to Time 3.

Changes over time were characterized as "favorable" if the differences between scores met the reliable change cut-off (last column of Table 6) and indicated improvement over time. For example, higher scores on the SEMCD-6 indicate higher self-efficacy (a favorable outcome). Therefore, if a participant scored a 4 at Time 1 and an 8 at Time 3, the resulting difference of 4 (8-4=4) meets the 1.40 cut-off and represents improvement over time ("favorable change"). Changes over time were characterized as "unfavorable" if the differences in scores met the cut-off and indicated worsening symptoms. For example, higher scores on the PHQ-9 indicate higher level of depressive symptoms (an unfavorable outcome). Therefore, if a participant scored a 4 at Time 1 and a 9 at Time 3, the resulting change score of 5 falls above the 4.67 threshold and represents worsening symptoms ("unfavorable change"). See Table 7 for results for IG individuals, and Table 8 for results of TAU individuals. Cell values represent the number of individuals experiencing favorable change/no change/unfavorable change on each of the specified measures.

Table 7. *Intervention Group Reliable Change Results Calculated By Individual*

	Time 1—Time 2			Time 1—Time 3		
Measure	Favorable Change	No Change	Unfavorable Change	Favorable Change	No Change	Unfavorable Change
SEMCD-6	7	4	3	5	8	1
BIPQ	0	14	0	0	14	0
PHQ-9	1	12	1	1	13	0
GAD-7	3	11	0	2	11	1
STC	0	14	0	1	13	0
DIET-SE	0	12	2	2	11	1
GPAQ	3	9	2	3	10	1
ECS	1	13	0	0	14	0

Note. SEMCD-6 = Self-Efficacy for Managing Chronic Disease Scale; BIPQ = Brief Illness Perception Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disoder-7; STC = Starting the Conversation; DIET-SE = Dieter's Inventory of Eating Temptations-Self-Efficacy; GPAQ = Global Physical Activity Questionnaire; ECS = Exercise Confidence Survey

Table 8. *Treatment as Usual Group Reliable Change Results Calculated By Individual*

	Time 1—Time 2[a]			Time 1—Time 3[b]		
Measure	Favorable Change	No Change	Unfavorable Change	Favorable Change	No Change	Unfavorable Change
SEMCD-6	1	12	1	0	12	1
BIPQ	1	13	0	1	12	0
PHQ-9	1	13	0	1	12	0
GAD-7	5	8	1	4	8	1
STC	1	13	0	0	13	0
DIET-SE	2	12	0	0	13	0
GPAQ	0	13	1	4	8	1
ECS	0	13	0	0	13	0

Note. SEMCD-6 = Self-Efficacy for Managing Chronic Disease Scale; BIPQ = Brief Illness Perception Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disoder-7; STC = Starting the Conversation; DIET-SE = Dieter's Inventory of Eating Temptations-Self-Efficacy; GPAQ = Global Physical Activity Questionnaire; ECS = Exercise Confidence Survey

[a]Thirteen out of fourteen participants had complete ECS data for Time 1—Time 2 calculation

[b]Thirteen out of fourteen participants had complete Time 1—Time 3 data

The IG and TAU group were then compared using Fisher's Exact Test to identify potential between-group differences in the likelihood of experiencing favorable change on each measure. Specifically, participants were coded as having either experienced favorable change or no favorable change over the specified time points (i.e., participants experiencing "no favorable change" from Time 1 to Time 2 had either experienced "no change" or "unfavorable change" between those time points). Results revealed that a higher proportion of IG participants as compared with TAU participants exhibited favorable change on the SEMCD-6 from both Time 1 to Time 2 (p = .033), and from Time 1 to Time 3 (p = .041). Indeed, from Time 1 to Time 2, 7/14 (50.0%) of IG participants exhibited an increase in self-efficacy scores, as compared with 1/14 (7.1%) of the TAU group. From Time 1 to Time 3, 5/14 (35.7%) of the IG participants demonstrated an increase in SEMCD-6 scores, as compared with 0/13 (0%) TAU participants exhibiting reliable change on this measure. There were no other significant differences in likelihood of favorable change from Time 1—Time 2 or from Time 1—Time 3. Fisher's Exact Test was then utilized to identify group-differences in likelihood of experiencing unfavorable

change, again with participants coded as having either experienced unfavorable change or no unfavorable change over the specified time points (i.e., participants experiencing "no unfavorable change" from Time 1 to Time 2 had either experienced "favorable change" or "no change" between those time points). There were no between-group differences on these calculations at the .05 alpha level.

Physical Activity: Additional Analyses

For physical activity, in addition to computing how many individuals met the reliable change cut-off at given time points, we additionally examined how many individuals met a cut-off of 150 minutes of physical activity per week. This number was derived from physical activity recommendations for stable CAD (Fihn et al., 2012), which suggest a minimum of 30 minutes of moderate-intensity aerobic physical activity, 5 days per week (which averages to 150 minutes/week). While these recommendations are for moderate-intensity activity in particular, we additionally included patient-reported vigorous-intensity activity in overall weekly estimates. As with the reliable change analyses, only individuals with complete GPAQ data (not mean-replaced) were included in these calculations for the relevant time points. Tables 9 and 10 display results for IG and TAU participants, respectively. Results suggest that most participants, per self-report, were meeting the 150-minute/week cut-off at Baseline.

Table 9. *Intervention Group Results for Physical Activity Cut-off*

	Time 1	Time 2	Time 3
Meeting Moderate+Vigorous Physical Activity Cut-off ($\geq$150 minutes/week)	10	11	12
Not Meeting Moderate+Vigorous Physical Activity Cut-off (<150 minutes/week)	4	3	2

Table 10. *Treatment as Usual Group Results for Physical Activity Cut-off*

	Time 1	Time 2	Time 3[a]
Meeting Moderate+Vigorous Physical Activity Cut-off (≥150 minutes/week)	12	10	9
Not Meeting Moderate+Vigorous Physical Activity Cut-off (<150 minutes/week)	2	4	4

[a]*Thirteen out of fourteen participants had complete Time 3 data*

Next, changes over time were identified with regard to whether individuals met the 150 minutes/week cut-off. In particular, participants were coded for "favorable change," "no change," or "unfavorable change" between Times 1 and 2, and between Times 1 and 3. Favorable change indicated that a participant switched from not meeting the 150 minute/week cut-off at Time 1, to meeting the cut-off at the subsequent evaluated time point. "Unfavorable change" indicated that the participant switched from meeting the 150 minutes/week cut-off at Time 1, to not meeting it at the next evaluated time point. "No change" indicated that no favorable or unfavorable change took place between the two time points (e.g., if a participant met the recommendations at Time 1 and continued to meet them at Time 2, this would be marked as "no change"). Results for IG participants are displayed in Table 11, and results of TAU participants are displayed in Table 12. Fisher's Exact Test was then utilized to examine group-differences in likelihood of experiencing favorable change over time, with participants coded as having either experienced favorable change or no favorable change (as with the reliable change analyses, "no favorable change" was inclusive of participants experiencing "no change" or "unfavorable change" between the specified time points). A second set of Fisher's Exact Tests was then employed to evaluate group-differences in the likelihood of experiencing unfavorable change over time, again with participants coded as having either experienced unfavorable change or no unfavorable change over the specified time points (i.e., participants experiencing "no

unfavorable change" from Time 1 to Time 2 had either experienced "favorable change" or "no change" between those time points).

Two IG individuals exhibited favorable change from Time 1 to Time 2, and three exhibited favorable change from Time 1 to Time 3. By contrast, no TAU individuals exhibited any favorable change from Time 1 to Time 2, or from Time 1 to Time 3; however, Fisher Exact Tests revealed that these between-group differences in likelihood of favorable change were not significant at the .05 alpha level. Similarly, Fisher's Exact Tests were not significant for between-group differences in likelihood of unfavorable change from Time 1 to Time 2, or from Time 1 to Time 3.

Table 11. *Intervention Group Changes in Meeting Physical Activity Cut-off*

	Favorable Change	No Change	Unfavorable Change
Time 1—Time 2	2	11	1
Time 1—Time 3	3	10	1

Table 12. *Treatment as Usual Group Changes in Meeting Physical Activity Cut-off*

	Favorable Change	No Change	Unfavorable Change
Time 1—Time 2	0	12	2
Time 1—Time 3[a]	0	11	2

[a]*Thirteen out of fourteen participants had complete Time 3 data*

Program Development and Satisfaction with Care Questionnaires

In addition to the results from the ANOVA and reliable change analyses, information was gathered through the Program Development Questionnaire and Satisfaction with Care Questionnaires. These measures were administered at Post-Treatment for all IG participants. Table 13 summarizes the Program Development Questionnaire. Results reveal self-reported changes in lifestyle domains since starting the CLIMB program: over 70% of participants indicated that they made changes in terms of healthy eating, over 70% reported changes in

physical activity, and over 50% reported changes in stress and mood management. Results also provided valuable feedback that may be used to inform future iterations of brief lifestyle programs in outpatient cardiac care. For example, most participants reported that receiving two lifestyle modules was “just right” in the program. See Table 13 for additional information.

Table 13. *Program Development Information (N=14)*

Question	Results: *n* (%)
1. Have you made any changes regarding the way you manage your lifestyle and health behaviors as a result of the intervention?	Yes: 14 (100%) No: 0 (0%)
2. To what extent do you agree or disagree with the following statement: "I have made changes in terms of healthy eating since starting the CLIMB program."	Strongly disagree: 0 (0%) Disagree: 1 (7.1%) Neither agree nor disagree: 2 (14.3%) Agree: 7 (50.0%) Strongly agree: 4 (28.6%)
3. To what extent do you agree or disagree with the following statement: "I have made changes in terms of physical activity since starting the CLIMB program."	Strongly disagree: 1 (7.1%) Disagree: 1 (7.1%) Neither agree nor disagree: 2 (14.3%) Agree: 7 (50.0%) Strongly agree: 3 (21.4%)
4. To what extent do you agree or disagree with the following statement: "I have made changes in terms of stress and mood management since starting the CLIMB program."	Strongly disagree: 0 (0%) Disagree: 0 (0%) Neither agree nor disagree: 6 (42.9%) Agree: 6 (42.9%) Strongly agree: 2 (14.3%)
5. Would you have wanted to participate in:	More modules: 4 (28.6%) Fewer modules: 0 (0%) Two was "just right": 10 (71.4%)
6. Would you liked to have had time to review the information provided in this program with behavioral health provider and your cardiologist jointly?	Yes: 2 (14.3%) No Preference: 6 (42.9%) No: 6 (42.9%)
7. With regard to the provided information, would you have preferred: to have received the information by telephone exclusively?	Yes: 0 (0%) No Preference: 3 (21.4%) No: 11 (78.6%)
8. With regard to the provided information, would you have preferred: to have received the handouts, without any additional contact with the behavioral health provider?	Yes: 0 (0%) No Preference: 3 (21.4%) No: 11 (78.6%)
9. What other topics would you like to be covered? Are there any other module topics that you would have liked to be available?	Yes: 0 (0%) No: 14 (100%)
10. To what extent do you agree or disagree with the following statement: "I would be interested in attending a peer support group for patients making lifestyle changes related to chronic disease."	Strongly disagree: 3 (21.4%) Disagree: 3 (21.4%) Neither agree nor disagree: 5 (35.7%) Agree: 3 (21.4%) Strongly agree: 0 (0%)

Table 14 summarizes the Satisfaction with Care Questionnaire. Importantly, 100% of participants agreed or strongly agreed that they were satisfied with the behavioral health lifestyle intervention (Question 1), 92.9% (all but one person) agreed or strongly agreed that the sessions and material were helpful to their cardiac care (Question 3), and 71.4% reported that they felt more favorably toward their cardiac team following the program (Question 5).

Table 14. *Participant Satisfaction (N=14)*

Question	Results: *n* (%)
1. To what extent do you agree or disagree with the following statement: "I was satisfied with the behavioral health lifestyle intervention I received."	Strongly disagree: 0 (0%) Disagree: 0 (0%) Neither agree nor disagree: 0 (0%) Agree: 4 (28.6%) Strongly agree: 10 (71.4%)
2. To what extent do you agree or disagree with the following statement: "I was satisfied with the behavioral health provider who delivered the intervention."	Strongly disagree: 0 (0%) Disagree: 0 (0%) Neither agree nor disagree: 0 (0%) Agree: 2 (14.3%) Strongly agree: 12 (85.7%)
3. To what extent do you agree or disagree with the following statement: "The sessions and material I received were helpful to my cardiac care."	Strongly disagree: 0 (0%) Disagree: 0 (0%) Neither agree nor disagree: 1 (7.1%) Agree: 4 (28.6%) Strongly agree: 9 (64.3%)
4. Would you recommend this intervention to other patients with coronary artery disease?	Yes: 14 (100%) No: 0 (0%)
5. Has your perception of your cardiac care team changed?	I feel more favorably toward my team: 10 (71.4%) No changes: 4 (28.6%) I feel more unfavorably toward my team: 0 (0%)

DISCUSSION

Study results support the feasibility and acceptability of a brief lifestyle program for patients living with stable coronary artery disease. 63.5% of referred and eligible patients elected to participate in the study, and 83.3% of IG participants completed the program through 30-day follow-up—meeting study a priori feasibility criteria. Overall, such results demonstrate patient interest in brief programs to help maintain healthy behaviors pertinent to cardiac health. The high percentage of participants completing the program suggests that brief lifestyle programs implemented in outpatient cardiac care are promising in terms of high patient attendance, low attrition, and high satisfaction. Indeed, such outcomes are consistent with previous literature in which brief behavioral health treatment in integrated care settings has been well-attended as compared with non-co-located behavioral health treatment (e.g., Bartels et al., 2004).

While most eligible patients ultimately enrolled in the study, a sizeable minority declined participation—most commonly due to work schedule. Although patients were made aware that sessions could be completed by telephone, many individuals still cited work concerns as a barrier to engagement. Nevertheless, our results indicate that offering telephone appointments was not sufficient to ensure program feasibility for all employed patients living with CAD. Appointments for the present study were limited to the clinic hours of 8:00 AM-5:00 PM for both in-person and telephone sessions. Additional options, such as evening or weekend appointments, may have further facilitated feasibility for patients and is recommended for future programs.

Regarding acceptability, 100% of IG participants responded “Yes” to the question “Would you recommend this intervention to other patients with coronary artery disease?” — meeting the a priori acceptability cut-off of 80%. Indeed, such results align with previous

literature regarding patient satisfaction with integrated behavioral health services (e.g., Chen et al., 2006). All IG participants either agreed (28.6%) or strongly agreed (71.4%) that they were satisfied with the behavioral health lifestyle intervention they received.

The modules offered in CLIMB were consistent with many lifestyle areas emphasized by the American Heart Association and the American College of Cardiology (Fihn et al., 2012). While "Healthy Eating" was the module most often selected, participants expressed interest in all modules except "Smoking Cessation Education"—likely because none of the participants had smoked a conventional cigarette within the last month. Participants were given an opportunity to provide feedback on the Program Development Questionnaire if there were other topics they would have been interested in; ultimately, no other topics were identified, further highlighting the relevance of the modules selected for this study. Nevertheless, other behavioral health targets such as sleep and medication adherence are particularly important for cardiac patients, and thus may serve as the basis for additional or alternate modules in future programs (Bosworth, Blalock, Hoyle, Czaijowski, & Voils, 2018; Hall, Brindle, & Buysse, 2018). Further, a weight management module may be considered for longer programs, as weight loss was a goal cited by many participants as they completed CLIMB.

The most promising treatment outcome was the increase in self-efficacy for managing CAD (measured by the SEMCD-6) experienced by IG participants, supporting study Hypothesis 1. Indeed, 50.0% exhibited a reliable increase in scores between Times 1 and 2, and 35.7% exhibited reliable favorable change between Time 1 and Time 3. By comparison, only 7.1% of TAU participants exhibited reliable favorable change between Times 1 and 2, and none exhibited reliable favorable change between Times 2 and 3. These results are encouraging given the long-term stability exhibited by our study sample. Thus, a 3-session program was effective in

increasing patient confidence in managing their cardiac disease, despite having *been* managing CAD for many years. Self-efficacy is an important component of many models of health behavior change (e.g., Theory of Planned Behavior, Transtheoretical Model), and empirical evidence indeed illustrates that improvements in self-efficacy often precede meaningful changes in health behavior (Ajzen & Madden, 1986; Bandura, 1977, Prochaska & Velicer, 1997; Sheeran et al., 2016). Thus, it is possible that increasing patient confidence may have cascading health effects as they continue management of this long-term disease.

While study Hypothesis 1 was supported, other study Hypotheses were not supported. In general, results of parametric analyses were inconclusive, and unfortunately underpowered.[*] One exception might be that the GAD-7 ANOVA revealed a significant main effect for Time. This result suggests that contact with a behavioral health provider in general (regardless of study group) may have helped contribute to reduced anxiety levels among study participants. Of course, results must also be interpreted within the context of meaningful change. While there was a statistically significant decrease in scores, changes over time did not meet the threshold for reliable change—possibly because participants generally exhibited low levels of anxiety, even at Baseline (mean Baseline GAD-7 score for study sample was 3.00, which is considered "minimal range"). Future research may evaluate to what extent contact with a behavioral health provider helps reduce anxiety among patients at varying levels of distress. For example, it is possible that patients in higher levels of distress will experience greater changes in symptoms.

[*]Footnote: Power analysis using G*Power software indicated 52 participants were needed to detect between-group differences with a conventional large effect size of f = .40 (Cohen, 1969; Cohen 1988; Faul, Erdfelder, Buchner, & Lang, 2009)

One surprising result was the significant between-groups difference on the DIET-SE, with TAU participants exhibiting significantly higher scores collapsed across time as compared with IG participants. Despite randomization, TAU scores were higher than IG scores at Baseline by approximately five points and remained higher over time. Given the lack of Group X Time interaction, these between-group differences were likely a product of initial values versus differing rates of improvement or worsening symptoms between groups.

Regarding the Program Development Questionnaire, 100% of IG participants reported that they had made changes regarding the way they manage "lifestyle and health behaviors a result of the intervention." Over half of participants indicated that they had made changes in terms of healthy eating, physical activity, and/or mood management since starting the CLIMB program. Of note, these responses were obtained at post-treatment (immediately following Session 3) to maximize feedback in case of subsequent attrition. As a result, it is possible that these responses did not reflect further changes that could have occurred following the Session 3 module (e.g., if a participant chose "Physical Activity" for Session 3, then subsequent changes may not have been reported until 30-day follow-up).

Limitations and Future Directions

While the present study provides important and promising information regarding the feasibility and acceptability of brief lifestyle interventions in outpatient cardiac care, the findings should be considered preliminary due to small sample size. For this reason, ANOVAs were likely underpowered to detect significant effects. Indeed, Bonferroni corrections were not employed, despite multiple analyses, to help avoid Type 2 error. Additionally, mean replacement was utilized for two individuals to impute missing that that was not missing at random. Thus, there is the potential that results for ANOVAs (though not reliable change analyses) were biased

by such estimations. While adequately powered replication studies with robust strategies for missing data are undoubtedly needed, it is also important to note that mean differences between groups were often quite small (see Table 15), and it is very possible that that even adequately powered ANOVAs would result in null results for some variables.

Another limitation of the study included the age disparity between groups, despite random assignment. In particular, the TAU participants were younger on average as compared with IG participants, and it is possible that this difference confounded efficacy results. For example, the observed improvements in self-efficacy among IG participants could have, in part, been related to older age. Overall, the promising feasibility and acceptability results, in conjunction with the limitations of the current sample, further support the need for future larger-N studies in this area which would allow for analyses stratified by age.

Results must additionally be interpreted with consideration of generalizability to other outpatient clinics. The primary provider for the CLIMB program was a doctoral student, with a flexible schedule to meet participant needs within the hours of clinic operations. Thus, program scheduling was likely more accommodating than would be the case in a typical outpatient clinic. Additionally, our study sample was not necessarily representative of other outpatient clinics. For example, 75% of participants included in efficacy analyses had received higher education (i.e., beyond high school), and 46% had a masters, professional, or doctoral degree. Further, while many participants were former smokers, not one had smoked a conventional cigarette within the last month at Baseline. Most people, at least by self-report, were engaging in at least 150 minutes of physical activity per week. Women made up only 25% of this sample; in part, this may be because our study employed an age cut-off, and women are diagnosed with CAD, on average, later in life as compared with men. For example, one international study found that women were

diagnosed with MI, on average nine years after men (six years after men among the North American sample; Yusuf, et al. 2004). Our sample was also predominantly Caucasian. It is unclear to what extent our results would generalize to a more diverse population in terms of race and gender, and future research is needed in this regard.

As discussed above, this study additionally had limitations regarding outcome measures. Unfortunately, objective data for physical activity (e.g., by accelerometers) was unavailable, and our eating questionnaire lacked the rigor of many others used to evaluate diet, particularly regarding the DASH plan (e.g., Dixon et al., 2007; Harsha et al., 2004). Other physiological measures related to cardiac health such as cholesterol and blood pressure readings may provide additional objective measurement.

Another important limitation in measurement were demand characteristics that may have influenced participant responses. Importantly, the primary provider for the study administered study outcome measures. It is possible that participants, consciously or unconsciously, adjusted their responses to reflect better maintenance of healthy behaviors. Similarly, participant reports of satisfaction with the program may have been inflated. Some participants completed questionnaires by telephone, in which case responses were dictated to the research team member verbally rather then entered into the computer directly (e.g., during telephone appointments or due to technical issues). It is possible that this method of administration in particular could have influenced participant responses.

Future research may benefit from inclusion of a measure of general stress, such as the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983) which has been utilized in previous cardiology research (e.g., Blumenthal et al., 2016). Average Baseline PHQ-9 and GAD-7 scores (3.04 and 3.00 respectively) for the present study suggested minimal levels of

depression and anxiety among participants; however, qualitatively participants often commented that their levels of perceived stress were higher than such scores indicated. Inclusion of a general measure of stress may able to better capture changes in general distress and coping over time. Relatedly, future iterations of this program should be evaluated with patients who experiencing elevated levels of distress, whether manifesting as symptoms of anxiety, depression or difficulty coping with perceived stress more generally. It is possible that changes in self-efficacy observed in the present study will be particularly impactful for such a population.

In general, the observed levels of depression in the current study were lower than would be expected given the comprehensive literature linking depression and coronary artery disease (e.g., Bush et al., 2005; Thombs et al., 2005). Indeed, estimates of depression among those who have experienced MI have often met or exceeded 20% (e.g., Bush et al., 2005; Thombs et al., 2005). However, much of this literature has evaluated patients immediately post-MI and followed patients up to one-year post-cardiac event (e.g., Lauzon et al., 2003; Lesperance, Frasure-Smith, & Talajic, 1996). By contrast, the average time since ACS in the present study was 7.01 years, and many of our participants had never experienced an ACS. Future research is needed regarding the long-term course of depression after MI, as well as the course of depressive symptoms among those with stable CAD, but without history of ACS and/or revascularization. Indeed, it is likely that there are many variables that affect individual trajectories in depressive symptoms (e.g., optimism) in the years surrounding an MI (Galatzer-Levy & Bonanno, 2014).

While the present study evaluated cigarette use and offered a corresponding Smoking Cessation Education module, e-cigarette use was not evaluated (though reported by one participant). Given the rising prevalence of e-cigarettes and concerns regarding the effects of nicotine on the cardiovascular system, this module may require adaptation as research emerges

on the relationship between e-cigarettes and heart disease (Bold, Krishnan-Sarin, & Stoney, 2018).

Lastly, it is important to note that study efficacy analyses may not have captured all gains made by participants. Some gains were reported in qualitative fashion to research members. For example, participants reported reduced alcohol use, elimination of whole-milk products, weight loss, reduced anxiety about physical activity, improved ability to cope with stress, increased hope for the future, and more. Such results highlight the many ways in which a brief lifestyle program may have a meaningful impact for patients.

CLIMB in Clinical Practice: What's Next?

Overall, the implementation of CLIMB as a research protocol within a clinical setting was successful. Feasibility and acceptability were established, and preliminary treatment outcome results were promising—particularly regarding improved patient self-efficacy in managing their CAD.

With so many individuals living with CAD, it is important to consider treatments that are accessible to patients, and feasible with regard to clinic implementation. The brief and flexible nature of CLIMB lends itself to many possibilities in terms of clinical practice. For example, CLIMB, or similar programs, may be considered as part of a tiered approach to behavioral health in cardiology—such an approach has the potential to be cost-effective while providing the appropriate level of care to patients (Rozanski, 2014). Brief behavioral health programs may serve as a good "first step" for patients needing assistance with lifestyle change. Indeed, the present study suggests that the brief nature of CLIMB is appropriate for many patients, at minimum in providing and/or reinforcing important lifestyle information and helping patients to "get back on track" with their health goals. At minimum, those providing CLIMB to patients

should be licensed clinical providers (or supervised by a licensed clinical provider), given that cardiac populations often have significant medical and psychological comorbidities. Indeed, clinical training in medical settings, and with cardiac patients in particular, will aid individuals in working with this population most effectively. Training in health behavior change will also likely facilitate successful implementation of CLIMB.

For some patients, of course, three sessions will not be sufficient to meet behavioral health needs. In such cases, a cardiologist may suggest patients may start with the CLIMB program, and then be referred to specialty providers such as a cardiac psychologist or nutritionist as needed. Other services, such as cardiac rehabilitation, may also be warranted. For patients with elevated symptoms (e.g., clinical depression) a specialty referral may be required more immediately.

As a research protocol, CLIMB emphasized the individual needs of patients in various ways (e.g., module selection, individual health behavior feedback, personalized goals). Nevertheless, within the context of a research protocol there are elements of uniformity that may be limiting in clinical practice. For example, in the present study each patient participated in exactly two lifestyle modules. Perhaps increased flexibility in the number of modules patients receive and/or allowing patients to repeat modules would improve program effectiveness in a clinical setting. Of course, modules may be added or removed depending on the population of the clinic in which the program is implemented.

Overall, this study suggests a bright future for integrated cardiology care teams which include behavioral health services. Clinical psychologists are in a unique position to develop treatments and programs to target modifiable and psychological risk factors for patients with

cardiac disease. For the psychologist looking to help patients make healthy lifestyle changes, there's no better place to start, than the heart.

APPENDIX A: INSTITUTIONAL REVIEW BOARD APPROVAL

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Chelsea H Wiener, Bernard Joseph Gros, MD, Cerissa L Blaney, Jeffrey Cassisi**

Date: **August 13, 2018**

Dear Researcher:

On 08/13/2018 the IRB approved the following modifications / human participant research until 08/12/2019 inclusive:

Type of Review:	Submission Response for UCF Initial Review Submission Form; Expedited Review Category #6 and #7 Adult Participants; n=100
Project Title:	Brief behavioral health intervention program for patients with stable coronary artery disease
Investigator:	Chelsea H Wiener
IRB Number:	SBE-18-14085
Funding Agency:	
Grant Title:	
Research ID:	N/A

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

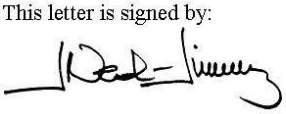
If continuing review approval is not granted before the expiration date of 08/12/2019, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

This letter is signed by:



Signature applied by Jennifer Neal-Jimenez on 08/13/2018 10:40:13 AM EDT

Designated Reviewer

Registration of Clinical Trials

*Clinical Trials Registration - All **applicable** clinical trials are required by law to register in the ClinicalTrials.gov registry by 21 days after the first patient is enrolled. For additional information about clinical trial registration, see http://prsinfo.clinicaltrials.gov

* For industry-sponsored, multi-center trials, the industry sponsor is responsible for trial registration. Before enrolling study subjects the HMC/PSU principal investigator should ensure the industry sponsor has registered the trial.

* For investigator-initiated trials, the lead principal investigator is responsible for trial registration.

*Applicable clinical trials that must be registered are: 1) controlled clinical investigations of drugs and biologics, other than Phase 1 investigations, of a product subject to FDA regulation; and 2) controlled trials of devices with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance.

*Registration required in order to publish - Clinical trials that are research studies that prospectively assign human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes require registration in a public registry in order to be considered for publication according to a policy of the International Committee of Medical Journal Editors (ICMJE). Details of the ICMJE requirement are described at the ICMJE website at http://www.icmje.org

For assistance with these requirements, contact Jane Gentilini, Office of Research & Commercialization, Contracts & Grants, at 407-882-1452.

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Chelsea H Wiener** and Co-PIs **Bernard Joseph Gros, Cerissa L Blaney, and Jeffrey Cassisi**

Date: **August 29, 2018**

Dear Researcher:

On 08/29/2018 the IRB approved the following modifications human participant research until 08/12/2019 inclusive:

Type of Review:	IRB Addendum and Modification Request Form
Modification Type:	Added Study Personnel: Daniel Paulson and Krystal Morrison; administrative changes to flyer; uploaded revised protocol
Project Title:	Brief behavioral health intervention program for patients with stable coronary artery disease
Investigator:	Chelsea H Wiener
IRB Number:	SBE-18-14085
Funding Agency:	
Grant Title:	
Research ID:	N/A

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

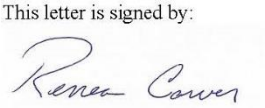
If continuing review approval is not granted before the expiration date of 08/12/2019, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

This letter is signed by:



Signature applied by Renea C Carver on 08/29/2018 04:22:17 PM EDT

Designated Reviewer

APPENDIX B: CARDIAC RESEARCH FORM

Cardiac Research Questionnaire

Completed by research staff in collaboration with participant

ID:

Demographic Information

Age:

Sex:
M
F
Other (describe) _____

Marital Status:
Single
Married
Divorced
Separated
Widowed
Other (describe) _____

Race:
Caucasian/White
African American/Black
Latino/a
Asian
Native American
Pacific Islander
Other (describe) _____

Highest Level of Education:
High school/GED
AA
BA/BS
Graduate Degree (MS, MA, PhD, JD, MD, etc.)
Other (describe) ____

Employment Status:
Employed
Unemployed
Part-time employment
Receiving disability
Retired

Clinical Information

Height:

Weight:

BMI:

Previous Cardiac Events

Have you ever been diagnosed with any of the following?

Acute myocardial infarction	Y	N	Number:
Stable angina	Y	N	
Unstable angina	Y	N	
Heart failure	Y	N	
Other cardiac event:	Y	N	Describe:

Coronary Artery Disease Treatment and Procedure History:

Have you ever received the following treatment?

Percutaneous Coronary Intervention	Y	N	# received _____
(Coronary angioplasty)			time since last intervention (mos):
Stents	Y	N	# received _____ time since last intervention (mos):
If known, specify (circle) history of:	bare metal stents	drug-eluting stents	both
Coronary Bypass Surgery	Y	N	# received _____ time since last surgery (mos):
Cardiac Rehabilitation	Y	N	time since last cardiac rehab (mos):
Other Cardiac Treatment	Y	N	Please describe: _____

Has anyone ever recommended you to follow a specific diet for cardiovascular disease?

If so, what diet?

Current medical conditions:

Have you ever been diagnosed with any of the following?

Hypertension (high blood pressure)

Y N

Diabetes

Y (Type 1) Y (Type 2) N

Hyperlipidemia or high cholesterol?

Y N

Other current medical conditions (Describe):

Current medications

Aspirin	Y	N
Beta blockers	Y	N
Calcium channel blockers	Y	N
ACE inhibitors and/or ARB inhibitors	Y	N
ADP inhibitors	Y	N
Statin or other cholesterol-lowering drug	Y	N
Anti-coagulants	Y	N
Anti-diabetes medication	Y	N

NSAIDs Y N
(prescribed or OTC physician-directed)

List all medications (including those endorsed above):

<u>History of psychiatric diagnoses:</u>

Have you ever been diagnosed with or treated for depression?

Y (Current) Y (Past) N

Have you ever been diagnosed with or treated for anxiety?

Y (Current) Y (Past) N

Have you ever been diagnosed with or treated for panic attacks?

Y (Current) Y (Past) N

Have you ever been diagnosed with or treated for any other psychiatric disorder?

Y (Current) Y (Past) N

*Specify:

**Have you ever experienced any psychiatric hospitalizations?*

*Y N

*Number:

*Most Recent (mos):

*Describe:

Substance Use

Tobacco: Current smoker Former smoker Never Smoked

Current smoking patterns:

Cigarettes/week:

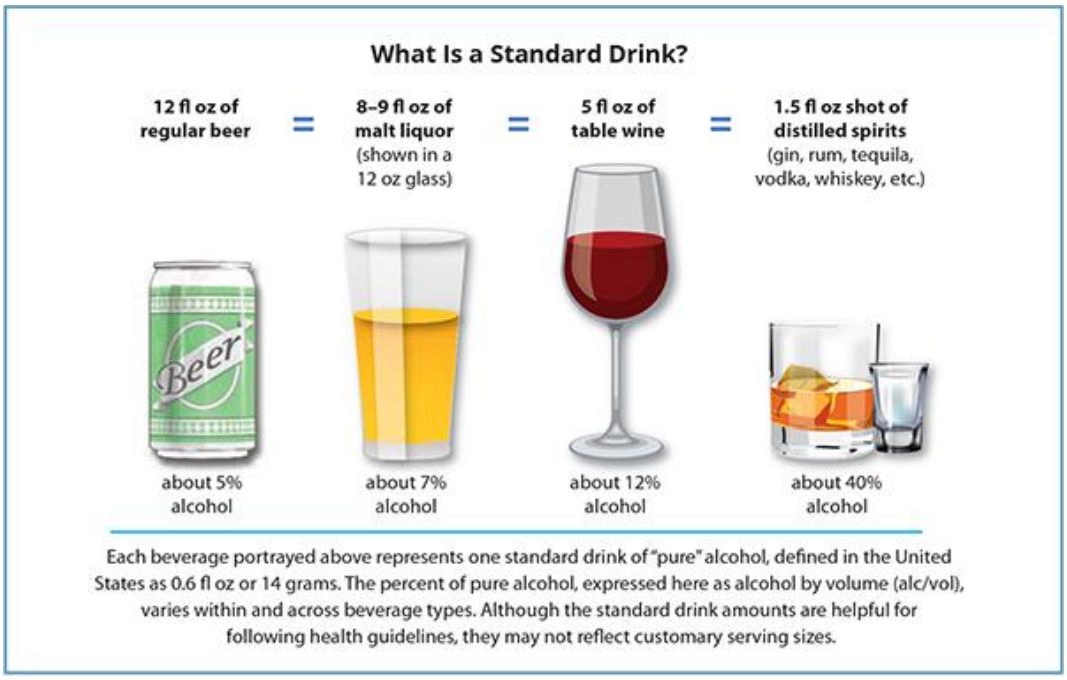
Alcohol Use:

Drinking days/month (in the last month):

Avg. # standard drinks on drinking days in the last month *(show* NIAAA *image on back page)*:

*Other illicit drugs (cocaine, opiates, etc.)/prescription drug abuse (taking more or differently than directed, taking someone else's medications, etc.):

*Indicates information not entered in Qualtrics



From: https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/what-standard-drink

APPENDIX C: MODULE DESCRIPTIONS

Healthy Eating
The healthy eating module introduces the Dietary Approaches to Stop Hypertension (DASH) eating plan from the National Heart, Lung, and Blood Institute (U.S. Department of Health and Human Services, 2003, 2006). Recommendations from the American Heart Association for heart-healthy eating are discussed. Participants are provided with tips for how to reduce sodium and fat (particularly saturated fat and *trans* fat) from diet. Participant barriers to implementing dietary changes are identified and problem-solved. At the end of the session, participants make a behavioral goal related to dietary change.

Physical Activity
This module focuses on physical activity guidelines provided from a task force consisting of the American College of Cardiology Foundation, the American Heart Association, and other medical associations (Fihn et al., 2012). A walking plan is introduced to help meet recommended guidelines. Barriers to implementing physical activity recommendations are identified and problem-solved. At the end of session, participants make a behavioral goal related to physical activity changes.

Reducing Stress and Worry
This module focuses on promoting awareness of the relationships between stress and negative emotions with CAD. Information is provided regarding the cognitive-behavioral therapy model, and the relationship between thought patterns and mood is discussed. Discussion is tailored to each participant's individually identified stressors. Participants engage in an activity to challenge negative thought patterns. At the end of session, participants make a goal regarding monitoring thought processes and challenging negative thoughts.

Mood Management
This module focuses on promoting awareness of the relationships between stress and negative emotions with CAD. Information is provided regarding the cognitive-behavioral therapy model, and the importance of regularly engaging in pleasant and valued activities to promote stress and mood management is emphasized. Discussion is tailored to each participant's individually identified stressors. At the end of session, participants make a behavioral goal regarding increasing engagement in pleasant and valued activities.

Smoking Cessation Education
This module focuses on the relationship between smoking and CAD. Participant smoking behavior is reviewed, and participants engage in a decisional balance exercise to identify costs and benefits of smoking vs. quitting/reducing. Participants are provided with general information on smoking cessation, in addition to available resources in the state of Florida for smoking cessation (http://tobaccofreeflorida.com/). At the end of session, participants make a behavioral goal related to smoking patterns.

APPENDIX D: PROGRAM DEVELOPMENT QUESTIONNAIRE

Please answer the following questions regarding your experience in the CLIMB program.

1. Have you made any changes regarding the way you manage your lifestyle and health behaviors as a result of the intervention?

   Yes No

   Describe:

2. To what extent do you agree or disagree with the following statement:
   "I have made changes in terms of healthy eating since starting the CLIMB program."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

3. To what extent do you agree or disagree with the following statement:
   "I have made changes in terms of physical activity since starting the CLIMB program."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

4. To what extent do you agree or disagree with the following statement:
   "I have made changes in terms of stress and mood management since starting the CLIMB program."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

5. To what extent do you agree or disagree with the following statement:
   "I have made changes in terms of smoking cessation since starting the CLIMB program."

   1 = Strongly disagree

2 = Disagree
3 = Neither agree nor disagree
4 = Agree
5= Strongly agree

6. There were five modules to choose from in this study. Which modules did you select?
   Healthy Eating
   Physical Activity
   Reducing Stress and Worry
   Mood Management
   Smoking Cessation Education

7. Would you have wanted to participant in:
   More modules Fewer modules Two was "just right"

8. How many sessions would have been ideal?

9. Which module was most helpful for you?

   Healthy Eating
   Physical Activity
   Reducing Stress and Worry
   Mood Management
   Smoking Cessation Education

10. Would you liked to have had time to review the information provided in this program with behavioral health provider and your cardiologist jointly?

    Yes No Preference No

11. With regard to the provided information, would you have preferred:
    a. To have received the information by telephone exclusively?
       Yes No Preference No

       If Yes, why:

    b. To have been provided with an option to receive the handouts without any additional clinical contact with the behavioral health provider?

Yes: Describe

No: Describe

12. What other topics would you like to be covered? Are there any other module topics that you would have liked to be available?

    Yes (Describe):
    No

13. Since beginning your participation in CLIMB, have you met with another member of the behavioral health team to continue managing your coronary artery disease?

    Yes
    No

14. Since beginning your participation in CLIMB, have you started any new treatment for psychological concerns (medication, therapy, etc.)?

    Yes
    No

15. To what extent do you agree or disagree with the following statement:
    I would be interested in attending a peer support group for patients making lifestyle changes related to chronic disease.

    1 = Strongly disagree
    2 = Disagree
    3 = Neither agree nor disagree
    4 = Agree
    5= Strongly agree

APPENDIX E: SATISFACTION WITH CARE QUESTIONNAIRE

Please answer the following questions regarding your experience in the CLIMB program.

1. To what extent do you agree or disagree with the following statement:
   "I was satisfied with the behavioral health life intervention I received."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

2. To what extent do you agree or disagree with the following statement:
   "I was satisfied with the behavioral health provider who delivered the intervention."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

3. To what extent do you agree or disagree with the following statement:
   "The sessions and material I received were helpful to my cardiac care."

   1 = Strongly disagree
   2 = Disagree
   3 = Neither agree nor disagree
   4 = Agree
   5= Strongly agree

4. Would you recommend this intervention to other patients with coronary artery disease?
   Yes
   No

5. Has your perception of your cardiac care team changed?

   1 = I feel more favorably toward my team
   2 = No changes
   3 = I feel more unfavorably toward my team

6. We invite your feedback! Please provide us with any additional information that would be helpful as we continue to improve our program for future patients!
   [Free Text]

APPENDIX F: DEPENDENT VARIABLE MEANS AND STANDARD DEVIATIONS

Table 15. *Means and Standard Deviations of Dependent Variables*

	Total Sample			Intervention Group			Treatment as Usual		
Measure	Time 1	Time 2	Time 3	Time 1	Time 2	Time 3	Time 1	Time 2	Time 3
SEMCD-6	7.64 (1.68)	8.09 (1.46)	8.14 (1.38)	7.21 (2.16)	7.86 (1.73)	8.14 (1.64)	8.07 (.90)	8.32 (1.16)	8.13 (1.13)
BIPQ	31.86 (10.36)	29.25 (10.26)	31.13 (11.97)	30.79 (10.70)	28.64 (9.59)	30.64 (11.34)	32.93 (10.28)	29.86 (11.22)	31.62 (12.98)
PHQ-9	3.04 (4.21)	2.18 (2.76)	2.21 (2.43)	3.21 (4.61)	2.36 (2.34)	2.57 (2.62)	2.86 (3.94)	2.00 (3.21)	1.85 (2.25)
GAD-7	3.00 (2.54)	1.96 (1.95)	1.85 (1.82)	3.07 (2.37)	2.00 (1.62)	1.93 (1.73)	2.93 (2.79)	1.93 (2.30)	1.77 (1.97)
STC	5.32 (2.28)	4.86 (2.24)	4.89 (2.04)	5.64 (2.68)	5.29 (2.46)	4.79 (2.36)	5.00 (1.84)	4.43 (1.99)	5.00 (1.75)
DIET-SE	28.50 (7.63)	29.57 (8.19)	31.02 (7.82)	25.79 (6.34)	25.57 (7.63)	28.43 (8.98)	31.21 (8.06)	33.57 (6.82)	33.62 (5.65)
GPAQ	63.56 (58.57)	65.75 (63.68)	89.52 (79.14)	58.61 (57.53)	73.83 (74.29)	84.87 (71.59)	68.51 (61.34)	57.67 (52.56)	94.18 (88.53)
ECS	3.91 (.93)	4.07 (.65)	4.03 (.73)	3.77 (.91)	4.07 (.57)	3.87 (.80)	4.05 (.96)	4.07 (.74)	4.18 (.64)

Note. SEMCD-6 = Self-Efficacy for Managing Chronic Disease Scale; BIPQ = Brief Illness Perception Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disoder-7; STC = Starting the Conversation; DIET-SE = Dieter's Inventory of Eating Temptations-Self-Efficacy; GPAQ = Global Physical Activity Questionnaire; ECS = Exercise Confidence Survey

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