



# A randomized trial of a brief behavioral health lifestyle program for outpatient cardiology clinics

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## Abstract

Research on lifestyle programs for patients with coronary artery disease (CAD) has largely recruited from hospitals and/or recruited following acute coronary syndrome. By contrast, this study evaluated a 3-session behavioral health program for patients with stable CAD treated in an outpatient cardiology clinic. Thirty-three patients were randomized to the behavioral lifestyle intervention or to Treatment as Usual (TAU). A priori feasibility and acceptability criteria were met, and reliable change analyses revealed that at post-treatment and 30-day follow-up, significantly more intervention participants than TAU participants exhibited increased self-efficacy compared with baseline.

## Keywords

behavioral health, brief treatment, cardiac psychology, coronary artery disease, ischemic heart disease, lifestyle program

## Introduction

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, 2017). Coronary artery disease (CAD), also commonly referred to as coronary heart disease 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, 2017). Lifestyle changes in areas such as healthy eating, physical activity, weight management, stress management, and smoking cessation are essential for both the management (e.g. Fihn et al., 2012) and prevention (e.g. Arnett et al., 2019) of cardiovascular disease.

A number of lifestyle programs to help patients manage CAD have been developed and

evaluated, and these programs have had diverse foci with various emphases on diet, physical activity, and stress management. In general, lifestyle modification programs targeting diet and exercise have often been associated with reduced physical risk markers such as atherosclerotic burden (Jhamnani et al., 2015), and comprehensive lifestyle programs involving health behavior change as well as stress reduction have often yielded positive results for improved physical health and psychological variables (e.g. Billings,

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2000; Koertge, et al., 2003; Lisspers et al., 1999). For example, one comprehensive program with a focus on diet, moderate exercise, stress management, and social support demonstrated improvements in cardiac-related health behaviors (diet, exercise, stress management), quality of life, and physiological markers (lower plasma lipids, blood pressure, weight, higher exercise capacity) over the course of 1-year follow-up (Koertge et al., 2003).

By contrast, interventions with a primarily psychological focus have yielded mixed results. For example, a meta-analysis found that psychological interventions were associated with reduced psychological symptoms (small/moderate effect) and reduced cardiac mortality (small effect), but were not associated with total mortality, subsequent revascularization, or non-fatal myocardial infarction/“MI” (Whalley et al., 2014). One recent study found that adding stress management training to cardiac rehabilitation was associated with reduced stress levels after treatment, in addition to lower rates of clinical events (18% for intervention group vs. 33% for control group) such as all-cause mortality, fatal or non-fatal MI, stroke/TIA, unstable angina requiring hospitalization, and/or coronary or peripheral artery revascularization over the 5-year follow-up period (Blumenthal et al., 2016). Thus, it could be that stress management interventions are most effective when combined with a focus on lifestyle change.

Support for comprehensive risk reduction programs is not limited to clinical research trials. Engagement in cardiac rehabilitation programs is recommended by the American Heart Association and the American College of Cardiology Foundation for individuals with history of acute coronary syndrome (ACS) and/or immediately post percutaneous coronary intervention (PCI) or coronary artery bypass grafting/“CABG” (Smith et al., 2011). However, 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 approach to increase accessibility and acceptability of services is via brief treatment protocols which 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 behavioral health treatment for cardiac patients 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). Importantly, patients often receive lifestyle intervention and related information after an ACS, and indeed, recruitment for both brief and longer lifestyle programs has largely occurred in hospital settings and/or following an ACS or coronary procedure (e.g. Black et al., 1998; Carney et al., 2004; Lisspers et al., 1999; Mayou et al., 2002; McLaughlin et al., 2005). By contrast, the present study evaluated the feasibility, acceptability, and efficacy of a brief behavioral health lifestyle program titled “CLIMB” (Cardiac Lifestyle Intervention for Maintaining Healthy Behaviors”) designed for implementation in outpatient cardiac care, and 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. Results of this study are intended to inform development of interventions for brief secondary prevention in outpatient cardiology.

## **Method**

### ***Participants***

Participants included patients with stable CAD, being treated by a board-certified cardiologist at an outpatient college of medicine faculty practice. 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 3 months, no coronary revascularizations within the past 3 months, and no planned revascularizations.

Exclusion criteria included:

- 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 any current mental health diagnosis involving psychotic symptoms 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 2 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 significant valvular disease.

Stable CAD criteria were informed by previous studies conducted with CAD patients (e.g. Braunwald et al., 2004; Fox et al., 2003). Adults unable to consent and prisoners were also not eligible for the study. Individuals were identified for study inclusion via medical chart review and patient interaction during regularly scheduled medical appointments with the cardiologist. Interested individuals then spoke with the principal investigator to complete study

screening and to complete the written informed consent process if desired. All study data were collected at the outpatient college of medicine faculty practice from which participants were recruited.

### *Study procedures*

The study protocol was reviewed and approved by the University of Central Florida Institutional Review Board (approval number: SBE-18-14085) and HIPAA Compliance Officer. Data storage followed clinic IT Security guidelines. Participants were randomly assigned to either the CLIMB Group (CG) or to the Treatment as Usual (TAU) group via a random number generator, with an equal chance of being assigned to either group. Of note, while there were two research “groups” (conditions), the CLIMB intervention was delivered in individual format. The principal investigator generated the random allocation sequence, enrolled participants, and assigned participants to the interventions. Thus, this trial was an unblinded, parallel, randomized design. The ClinicalTrials.gov identifier is NCT03629158.

*Description of the intervention.* CLIMB consisted of three sessions taking place over the course of 2 weeks. Immediately (same day) following baseline assessment, participants completed Session 1 of the program. During Session 1, participants received feedback regarding their baseline questionnaires, completed a values exercise to increase 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 elective modules (“Healthy Eating,” “Physical Activity,” “Reducing Stress and Worry,” “Mood Management,” and “Smoking Cessation Education”). See Figure 1 (Supplemental Material) for additional information. This format allowed for selection of material the participant expressed the most interest in 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 was reviewed and relevant behavioral goals were made for each session. Common elements among modules included review of behavioral goals, psychoeducation, identifying and problem-solving barriers to health behavior change, and making behavioral goals. The principal investigator served as the interventionist who delivered the CLIMB program for all CG participants.

**Study protocol.** CLIMB Group (CG): CG participants completed a baseline appointment consisting of an intake form and questionnaires. After baseline, CG participants participated in the 3-session CLIMB program. Participants completed questionnaires at four timepoints: baseline (before Session 1), post-treatment (immediately following Session 3), 30-day follow-up, and 3-month follow-up. With the exception of baseline and Session 1, participants were permitted to complete appointments (CLIMB Session 2, CLIMB Session 3, 30-day follow-up, and/or 3-month follow-up) by telephone if they were unable to attend in-person within one calendar week after the specified session date or within three business days prior to the specified time point.

Treatment as Usual (TAU): The TAU group continued to receive their usual medical care while they completed research questionnaires at the following times points: at baseline, at 2-week follow-up (2 weeks after baseline), and at 30-day follow-up (30 days after 2-week follow-up). After this point, they were given the option to participate in the CLIMB program. Baseline always occurred at the clinic. Participants were permitted to complete 2-week and 30-day follow-up questionnaires either in-person or by telephone. They did not complete a 3-month follow-up appointment.

### Study outcome measures

**Feasibility and acceptability.** A priori criteria for feasibility were: (1) at least 60% of referred and

eligible patients agree to participate (Horton et al., 2013) and (2) at least 75% of the consented intervention group (CG) patients complete the study intervention and outcome measurements through 30-day follow-up (Horton et al., 2013). The a priori criterion for acceptability was: (1) at least 80% respond “Yes” to the Yes/No question administered at post-treatment: “Would you recommend this intervention to other patients with coronary artery disease?” (Jones et al., 2017). This question was administered as part of the “Satisfaction with Care” questionnaire developed for this study.

**Psychological measures.** **Self-Efficacy for Managing Chronic Disease Scale (SEMCD-6)**: The SEMCD-6 is a six-item measure of self-efficacy for managing chronic illness (Lorig et al., 2001; Ritter and Lorig, 2014). Each item is scored on a Likert scale of 1 to 10, with higher scores indicating greater levels of self-efficacy (example item: *How confident do you feel that you can keep the fatigue caused by your disease from interfering with the things you want to do?*). The overall score is the mean of the six items. The overall score has a high internal consistency (Cronbach’s  $\alpha = 0.88\text{--}0.91$ ), and evidence suggests that the scale is one-dimensional in structure (Lorig et al., 2001; Ritter and Lorig, 2014). This measure has been used in other brief interventions for patients with cardiopulmonary conditions (e.g. Hundt et al., 2018).

**Brief Illness Perception Questionnaire (BIPQ)**: The BIPQ is a nine-item measure evaluating overall patient perceptions of illness (Broadbent et al., 2006). Scores on the first eight items may be summed for a total score, with higher scores representing more threatening views of illness. Research has demonstrated that less threatening illness perceptions among cardiac patients are associated with better quality of life (e.g. Janssen et al., 2013).

**Patient Health Questionnaire-9 (PHQ-9)**: The PHQ-9 is a 9-item self-report measure of depressive symptoms (Kroenke et al., 2001). Item scores represent frequency with which symptoms are present, ranging from 0 (*not at*

all) to 3 (*nearly every day*). Summed scores range from 0 to 27 with higher scores representing more severe depressive symptoms (Kroenke et al., 2001).

### **Generalized Anxiety Disorder-7 (GAD-7):**

The GAD-7 is a 7-item self-report measure of anxious symptoms (Spitzer et al., 2006). Item scores represent frequency of experienced symptoms, ranging from 0 (*not at all*) to 3 (*nearly every day*). Summed scores range from 0 to 21 with higher scores representing more severe symptoms (Spitzer et al., 2006).

### **Statistical methodology**

Reliable change indices were computed for psychological variables between Time 1 (baseline) and Time 2 (post-treatment [CG]/2-week follow-up [TAU]), and between Time 1 and Time 3 (30-day follow-up) at the group and individual level. Reliable change was calculated via the following formula:  $1.96(S_{\text{diff}})$ , whereby  $S_{\text{diff}}$  is the standard error of difference between the two scores (Iverson, 2018; Jacobson and Truax, 1991). Jacobson and Truax describe that  $S_{\text{diff}}$  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 or internal consistency of the measure (Busch et al., 2011; Iverson, 2018). The specific equation used was:  $1.96\sqrt{2[SD\sqrt{(1-r_{12})}]^2}$ .

Multiplying  $S_{\text{diff}}$  by 1.96, yields a cut-off that can be employed to evaluate whether there has been reliable change on the measure. Test-retest reliabilities were utilized from previously published research, available from authors upon request, with the exception of the SEMCD-6 for which only internal consistency ( $\alpha = 0.91$ ; Lorig et al., 2001) could be obtained satisfactorily. Standard deviation estimates were obtained from pooled baseline study data for all participants included in Treatment Outcome analyses. Changes over time were characterized as “favorable change” if the differences between scores met the reliable change cut-off and indicated improvement over time. Changes over time were

characterized as “unfavorable change” if the differences in scores met the cut-off and indicated worsening symptoms. If differences over time did not meet the reliable change cut-off, this was characterized as “no change.”

Changes in psychological outcome measures between Times 1 and 2, and between Times 1 and 3 were compared between the two groups. It was hypothesized that CG participants would report greater self-efficacy in managing disease over time as compared with TAU participants (Hypothesis 1), CG participants would report less threatening illness perceptions over time as compared with TAU participants (Hypothesis 2), CG participants would report greater decreases in depressive symptomatology over time as compared with TAU participants (Hypothesis 3), and that CG participants would report greater decreases in anxious symptomatology as compared with TAU participants (Hypothesis 4). Secondary analyses included evaluation of treatment outcomes among CG participants at 3-month follow-up.

## **Results**

### **Participant recruitment**

Participants were recruited over the course of nine consecutive months in 2018 and 2019. Data collection was terminated based on consensus among study collaborators due to pragmatics of clinic resources (e.g. clinic patient flow), which also determined the final sample size. Every patient with stable CAD presenting to the cardiology clinic during recruitment days was evaluated for study eligibility. The CONSORT diagram in Figure 2 (Supplemental Material) outlines participant flow through 30-day follow-up. Of note, one CG participant was withdrawn by the research team after baseline/Session 1 due to ACS, and one CG participant was excluded from analyses 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 assessing a priori feasibility and acceptability



**Table 1.** Participant satisfaction.

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 Disagree: 0 Neither agree nor disagree: 0 Agree: 4 Strongly agree: 10
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 Disagree: 0 Neither agree nor disagree: 0 Agree: 2 Strongly agree: 12
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 Disagree: 0 Neither agree nor disagree: 1 Agree: 4 Strongly agree: 9
4. Would you recommend this intervention to other patients with coronary artery disease?	Yes: 14 No: 0
5. Has your perception of your cardiac care team changed?	I feel more favorably toward my team: 10 No changes: 4 I feel more unfavorably toward my team: 0

Table includes only those CLIMB Group participants included in Treatment Outcome analyses (n = 14)

criteria but not in treatment outcome analyses of psychological variables. Another three participants (2 CG, 1 TAU) dropped out prior to baseline appointments. The five consented individuals not included in treatment outcome analyses were between 66 and 78 years of age and all male.

*Feasibility and acceptability*

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 criterion was met. Fifteen out of eighteen (83.3%) consented CG patients completed the study intervention and outcome measures through 30-day follow-up, indicating that the second feasibility criterion was also met. Fifteen out of 15 (100%) of CG participants who completed post-study questionnaires responded “Yes” to the question “Would you recommend this intervention to other patients with coronary artery disease?” indicating that the a priori acceptability criterion was met. Other responses from the Satisfaction with Care

Questionnaire are displayed in Table 1 and provide further support for the acceptability of the program.

*Post-treatment and 30-day follow-up treatment outcomes*

*Participant characteristics.* Demographic and clinical characteristics of participants included in post-treatment and 30-day follow-up analyses (N = 28) are outlined in Tables 2 and 3 respectively (both available in Supplemental Material). 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 CG participants, *t*(26) = 2.535, *p* = 0.018. There were no other significant differences between groups.

Of note, examination of ACS and revascularization history revealed 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 had their most recent revascularization within the 12 months prior to study enrollment. Of the fourteen individuals with history of ACS, the average time since last ACS was 7.01 years ( $SD = 5.64$ ). None had their most recent ACS within the 12 months prior to study enrollment.

**Descriptive statistics.** Missing data was addressed using group- and time-specific means. Using this method, Time 3 total score data was imputed for the TAU participant who dropped out before Time 3. The only other missing data for other participants were individual items on the SEMCD-6, which were not imputed as the total score was calculated by taking a mean of completed items.

The raw group means and standard deviations of study variables at the four time points are available in Table 4 (Supplemental Material). Between-group differences on baseline psychological variables were assessed via *t*-tests for normal baseline variables and Mann Whitney-U tests for the non-normal baseline variable (i.e. PHQ-9). No differences between groups were observed. Of note, baseline depressive and anxious symptoms, on average, fell within the “minimal” range for the sample (i.e. 3.04 for PHQ-9 and 3.00 for GAD-7).

**Reliable change.** 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 ( $SD = 7.56$ ). Reliable change cut-offs for study variables were calculated as detailed in the “Statistical Methodology” section, and resulted in the following variable cut-offs: SEMCD-6 ( $\pm 1.40$ ), BIPQ ( $\pm 15.20$ ), PHQ-9 ( $\pm 4.67$ ), and GAD-7 ( $\pm 2.90$ ). Reliable change was evaluated at the group level ( $n = 14$  for each group) using group means, and these cut-offs. Change over time in group means was evaluated and classified as “favorable change,” “unfavorable change,” or “no change” as described in the “Statistical Methodology”

section above. Employing this method, neither group exhibited reliable change on any measure between Times 1 and 2, and/or between Times 1 and 3.

Reliable change for each individual was 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 at the individual level. Similar to the group analysis, reliable change for each individual on each measure was classified as “favorable change,” “unfavorable change,” or “no change” as described above. Fisher’s Exact Test was then used to evaluate between-group differences in the likelihood of experiencing “favorable change” versus “no favorable change” (i.e. “no favorable change” including individuals who experienced “no change” or “unfavorable change”) as well as “unfavorable change” versus “no unfavorable change” (i.e. “no unfavorable change” including individuals who experienced “favorable change” or “no change”). With regard to favorable change, results revealed that a higher proportion of CG participants as compared with TAU participants exhibited favorable change on the SEMCD-6 from both Time 1 to Time 2 ( $p = 0.033$ ), and from Time 1 to Time 3 ( $p = 0.041$ ). Indeed, from Time 1 to Time 2, 7/14 of CG participants exhibited an increase in self-efficacy scores, as compared with 1/14 of the TAU group. From Time 1 to Time 3, 5/14 of the CG participants demonstrated an increase in SEMCD-6 scores, as compared with 0/13 of TAU participants exhibiting reliable change on this measure (See Table 5 in Supplemental Material for more information). There were no other significant differences in likelihood of favorable change from Time 1 to Time 2 or from Time 1 to Time 3 at the .05 alpha level, and no between-group differences on any measures for likelihood of unfavorable change over time.

**3-month follow-up.** Following completion of primary randomized analyses, reliable change analyses were conducted between baseline and 3-month follow-up for CG participants. Of the

15 CG participants who completed the CLIMB program through 30-day follow-up, two individuals were lost to follow-up prior to completing 3-month follow-up questionnaires (one of whom would have been excluded from analyses due to enrollment in another lifestyle program—see above), and one dropped due to family obligations and travel. Therefore, twelve participants attended the 3-month follow-up appointment. The average time from post-treatment to 3-month follow-up for these twelve individuals was 86.83 days ( $SD = 20.23$ ). Reliable change was evaluated at the group level with no observed reliable change from Time 1 (baseline) to Time 4 (3-month follow-up) on any measure.

Reliable change for each individual was evaluated between Time 1 and Time 4 using the same criteria described above. Inspection of SEMCD-6 scores supported primary analyses, as 5/12 participants exhibited favorable change from baseline to 3-month follow-up (6 experienced “no change” and 1 experienced “unfavorable change”).

## Discussion

Study results support the feasibility and acceptability of a brief lifestyle program for patients living with stable CAD. Thirty-three out of fifty-two (63.5%) of referred and eligible patients elected to participate in the study, and fifteen out of eighteen (83.3%) of CG participants completed the program through 30-day follow-up—meeting study a priori feasibility criteria. 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 all CG participants responded “Yes” to the question “Would you recommend this intervention to other patients with coronary artery disease?”, and all either Strongly Agreed or Agreed that they were satisfied with the program.

The most promising treatment outcome was the increase in self-efficacy for managing CAD experienced by CG participants, supporting study Hypothesis 1. Thus, a 3-session program was effective in increasing patient confidence in managing their cardiac disease, despite patients 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 and Madden, 1986; Bandura, 1977; Prochaska and Velicer, 1997; Sheeran et al., 2016). Self-efficacy for managing chronic disease was also recently found to predict improvement in depression following engagement in a brief CBT protocol for those with cardiopulmonary conditions (Hundt et al., 2018). Thus, it is possible that increasing patient confidence may have cascading health effects as patients continue management of this long-term disease.

Average baseline PHQ-9 and GAD-7 scores (i.e.  $<5$ ) for the present study suggested minimal levels of depression and anxiety, which likely influenced the null results related to Hypotheses 3 and 4. In general, the observed levels of depression in the current study were lower than would be expected given the comprehensive literature linking depression and CAD (e.g. Thombs et al., 2005). However, much of this literature has evaluated patients immediately post-MI and followed patients up to 1-year post-cardiac event (e.g. Lauzon et al., 2003; Lesperance et al., 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.

Future iterations of this program should be evaluated with patients who are experiencing elevated levels of distress, whether manifesting as symptoms of anxiety or depression or experiencing 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. Additionally, it is important to note the possibility that experiencing some level of distress (e.g. a slightly anxious patient) may serve as motivation for health-promoting behaviors (e.g. more conscientious adherence to medications), further supporting the need for future research in this area.

### *Limitations*

Study results must be interpreted with consideration of generalizability, as our study sample was small and not necessarily representative of other outpatient clinics. For example, 21/28 participants included in the primary Treatment Outcome analyses had received higher education (i.e. beyond high school). Further, while many participants were former smokers, not one had smoked a conventional cigarette within the month prior to baseline (and thus none selected the Smoking Cessation Education Module). 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. 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 CG participants, and it is possible that this difference confounded study results. Overall, the promising feasibility, acceptability, and self-efficacy results, in conjunction with the limitations of the current sample, further support the need for future studies with larger samples in this area.

Study limitations in measurement are also worth noting. There was one interventionist for the study who delivered the CLIMB program, and therefore it was not possible to evaluate the effect of the interventionist versus the intervention itself. Additionally, the primary interventionist 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 and/or inflated their responses regarding program satisfaction.

Within both groups, some participants completed follow-up measures in-person, whereas others did so over the phone. Therefore, there were circumstances in which responses were dictated to the research team member verbally rather than entered into the computer directly (e.g. during telephone appointments or due to technical issues). It is possible that this method of administration could have additionally influenced participant responses. Future research with a larger study sample (participants and interventionists) may allow for evaluation of interventionist effects and results stratified by the format of intervention and questionnaire delivery (in-person vs. telephone). Additionally, other physiological measures related to cardiac health such as cholesterol and blood pressure readings may provide additional objective measurement and will be essential in future studies.

### *Clinical implications*

Overall, the implementation of CLIMB as a research protocol within a clinical setting was successful, and this program helps address a recognized need for developing integrated behavioral health into specialty cardiac clinics (Dornelas and Sears, 2018). Feasibility and acceptability were established, and preliminary treatment outcome results were promising with regard to improved patient self-efficacy in managing CAD. Additionally, it is important to note that study 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 behavioral health treatment may have a meaningful impact for patients in cardiology clinics. As noted above, inclusion of physiological outcome variables will be a vital next step

in research evaluating the impact of brief lifestyle programs and/or behavioral health treatment in outpatient cardiology care.

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). Other areas 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 et al., 2018; Hall et al., 2018). While low-intensity (fewer than or equal to five sessions) weight management interventions have not translated into clinically meaningful weight loss for patients, a weight management module may be considered for longer programs (U.S. Department of Health and Human Services, 2013).

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

this study suggests that future research on behavioral health programs integrated into outpatient cardiology clinics is warranted.

### Data availability statement

Data for the present study are not publicly available. Supplemental material includes means and standard deviations for study variables at all time points.

### Declaration of conflicting interests

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### Supplemental material

Supplemental material for this article is available online.

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