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Randomized controlled trial of a well-being intervention in cardiac patients☆

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ABSTRACT

Objective: Positive psychological well-being interventions have demonstrated promise in improving both psychological and physical health-related outcomes in patients with coronary artery disease (CAD), but evidence of the efficacy of these interventions with individuals with CAD is limited. As such, we developed an eight-week group-based intervention targeting eudaimonic aspects of psychological well-being in a randomized pilot trial. The primary aims of the trial were feasibility and acceptability, and we also explored the intervention's effectiveness on psychological outcomes.

Method: Participants were 40 CAD outpatients randomly assigned to the intervention (n = 20) or an attention-matched control group (n = 20). Feasibility was measured by rates of group session attendance and homework completion, and acceptability was assessed through participant ratings of intervention activities. Additional study outcomes, compared between groups, included psychological well-being, optimism, depression, and positive and negative affect.

Results: The intervention met a priori criteria for feasibility and acceptability. The intervention was also associated with greater improvements in psychological well-being (β = −16.90; 95% Confidence Interval [CI] = −23.36, −10.44; $p < .001$, ES = 1.65), optimism (β = −8.80; 95% CI = −11.17, −6.43; $t = -7.41$; $p < .001$; ES = 2.34), and depression (β = 26.45; 95% CI = 20.97, 31.93; $p < .001$) immediately post-intervention, with sustained effects six weeks later.

Conclusions: These results indicate that the intervention was feasible, well-accepted, and effective in improving clinically relevant psychological outcomes in individuals with CAD. Future work should seek to replicate this work and assess general health-related and cardiac health-specific outcomes.

1. Introduction

Cardiovascular disease is the number one cause of death worldwide [1]. Coronary artery disease (CAD), one type of cardiovascular disease, occurs when coronary arteries are blocked or narrowed. Because patients with existing CAD are at high risk for cardiac-related death, it is critical to promote factors that prevent illness progression and acute cardiac events. Increasingly, it appears that psychological factors, both negative and positive, may play an important role in cardiovascular prognosis [2–4].

For example, negative psychiatric symptoms and syndromes are common in cardiac patients and have been linked with adverse cardiac outcomes. Up to 47% of individuals with heart disease have significant depressive symptoms, and up to 20% have current major depression

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[2]. Depressive symptoms are independently associated with the development and progression of CAD (including acute cardiac events), difficulties with physical functioning and health-related quality of life, and increased risk of mortality [2]. The mechanisms linking depression and adverse cardiac effects likely include physiologic (e.g., inflammation, autonomic nervous system abnormalities) and behavioral factors (e.g., less motivation to engage in health-related behaviors) [2,5,6]. Comorbid anxiety is also associated with lack of improvement in depression over time in persons with heart disease [7]. Anxiety disorders are common in patients with heart disease and associated with higher risk of mortality and other negative health outcomes in patients with CAD, especially those with recent acute events [8,9].

In contrast, positive psychological well-being (e.g., positive affect, optimism) has been associated with superior cardiac health, independent of the adverse effects of depression and anxiety [4]. Psychological well-being is broadly defined as optimal or ideal psychological functioning and has been prospectively linked to decreased risk of developing CAD [10,11] and lower rates of mortality [12]. Such effects may be mediated by increased vagal control [13], lower levels of inflammatory markers [14], and beneficial effects on lipid levels and endothelial function [15–18]. Psychological well-being may have even stronger effects on behavior, and it has been associated with lower rates of smoking, higher rates of physical activity, and healthier diet [4,19–21].

There are numerous different facets of psychological well-being, and there has been increasing study to determine which components are most linked with cardiac health. Eudaimonic well-being refers to fulfilling one's potential and identifying meaningful life pursuits [22,23], and it contains elements that include autonomy, environmental mastery, personal growth, purpose in life, self-acceptance, and positive relationships. This contrasts with hedonic well-being, which is well-being achieved, often more transiently, through the pursuit of pleasure. It appears that eudaimonic aspects of well-being may be substantially more important to health outcomes than hedonic aspects of well-being [24,25]. In terms of cardiac health specifically, there is evidence that eudaimonic well-being in particular is associated with lower cardiovascular risk, including higher high-density lipoprotein (HDL) cholesterol, lower weight, and lower levels of glycosylated hemoglobin [24].

While observational studies linking psychological well-being and cardiac health are promising, this line of work raises the question of whether such aspects of well-being are inherent or whether they can be actively modified in an intervention among patients with heart disease. There is evidence to suggest that behavioral interventions have a moderate effect on increasing psychological well-being [26]. A specific type of behavioral intervention, positive psychological interventions, which utilize systematic, deliberate activities to promote well-being, have been found consistently effective in improving well-being in healthy persons. For example, a meta-analysis in over 5000 healthy participants found that these interventions increase well-being and decrease depression [27]. A more recent meta-analysis of positive psychological interventions similarly indicates that these interventions have a significant effect on psychological well-being in clinical samples [28]. There has been less investigation in persons with cardiovascular disease, though initial studies have found that such interventions do appear to improve positive affect and, in some cases, health-related outcomes, in persons with heart disease [29–33]. While this preliminary evidence is promising, more investigation is warranted [4], and, importantly, no intervention for cardiac patients has specifically targeted eudaimonic well-being despite its prominent links to superior health outcomes. Furthermore, the vast majority of studies that have looked at positive psychological interventions have done so within predominantly Western samples [34,35]. While the last decade has seen an increase in non-Western samples in positive psychological research, much of the studies are considered to be of lower quality [34], and there is still a question of whether the effects of these interventions can generalize to non-Western populations.

Accordingly, we developed and studied an eight-week group-based well-being-focused intervention targeting eudaimonic aspects of well-being in a randomized pilot trial among Persian individuals diagnosed with CAD. The primary aims of the project were feasibility and acceptability of the well-being intervention, and we also explored the intervention's effectiveness on psychological outcomes, compared to an attention matched control condition.

2. Method

This study was a randomized controlled trial of an eight week well-being intervention among Persian outpatients with CAD. The primary study outcomes were feasibility and acceptability of the intervention. Secondary outcomes included psychological well-being, depression, optimism, positive affect, and negative affect, compared between groups. The study did not have any funding sources and was approved by the local ethics review committee of Isfahan Azad University under the supervision of the national ethics committee. The study was also registered in a publicly available clinical trials database (reference number CTRN: IRCT20171010036693N2, “Study of the feasibility and effectiveness of well-being therapy on psychological well-being, optimism, positive and negative affects and depression in coronary patients”). After voluntarily attending an introductory informational presentation, all interested and eligible participants completed full informed consent prior to study procedures. All procedures and assessments were completed at Sahib Al-Zaman Hospital of Shahreza. CONSORT guidelines [36] were used in the design and reporting of this clinical trial (see Supplementary Table 1 for CONSORT Checklist).

2.1. Participants

The sample was randomly selected from all cardiac patients with a definitive diagnosis of coronary artery disease referred to Sahib Al-Zaman Hospital between June and August 2017. Inclusion/exclusion criteria were specifically made broad to allow the study of a wide range of cardiac patients, increasing external validity. Specifically, inclusion criteria were diagnosis of coronary artery disease, as confirmed by medical record, which was reviewed under the supervision of the team cardiologist, and the ability to complete the informed consent process. Patients were excluded from participation if they were currently receiving any psychiatric or psychological treatment, including psychiatric medication. However, patients with untreated anxiety or depressive symptoms were not excluded, given that the intervention had the potential to provide benefit to these patients and to increase generalizability. Sample size was determined by number of available, eligible patients and study team resources.

2.2. Study assessments

The study trainer in collaboration with hospital staff from the Cardiac Department enrolled patients. The study trainer held a M.A. degree in Psychology, was trained directly by the intervention designer, and had prior experience delivering positive psychological interventions. The study trainer met with the intervention designer to resolve all questions and also piloted the study procedures in part to a different group of CAD patients in the presence and under the supervision of the intervention designer. During the present study, the study trainer received supervision both before and after each session, which is also how fidelity of intervention delivery was assessed. After enrollment, information regarding demographic and medical information was collected. After completion of baseline questionnaires, participants were then randomly assigned to either the experimental condition or an attention-matched control group by the study trainer using concealed cards to ensure blinding of study staff and participant until baseline assessments were completed; assignments/cards were made via random number generator.

Study assessments were performed in both the intervention and control groups at three time points: baseline (pre-intervention), one week after the 8-week intervention (post-test) and six weeks after post-test (follow-up). Study staff performing assessments for study outcomes and those performing statistical analyses were blinded to group assignment of individual participants during the course of the study. There was no evidence of harm or unintended effects in ether the intervention or control groups.

2.3. Study interventions

2.3.1. Introductory session

Before beginning the eight-session intervention, potential participants (alone, or with loved ones) attended in an introductory session. In this introductory session, individuals were informed about the importance of mental health in cardiac rehabilitation and the role of psychological factors on heart disease prognosis. Details about the stages of the study, the time and date of assessments, and completion of self-assessment and rating questionnaires were reviewed with participants. Eligible outpatients who expressed willingness to participate were then enrolled and registered (contact information of both patients and spouses were obtained) at the end of this initial introductory session by a study coordinator. Participants were also provided with a schedule of sessions. Throughout the course of the study, participants were reminded about assessments via text messaging and phone calls.

2.3.2. Well-being intervention

In the intervention condition, participants received a novel well-being-based intervention, designed by the research team, during eight group sessions (weekly, 90 min), held in September and October 2017. Sessions were run on two successive days each week such that participants who missed a given session could participate in the same session the following day. The frame and content of the intervention sessions were created by the study team leader(GRN) based on the existing literature focused on eudaimonic principles [24,37–39] and in consultation with study team cardiologists to ensure appropriate customization to the population.

The content of the sessions is outlined in Table 1. Each session covered a different topic. During the first session, the importance of psychological factors in cardiovascular health was discussed in more detail, and patients were introduced to the concept of psychological well-being as well as ways to self-monitor well-being. The second session was dedicated to considering and engaging in “optimal experiences” and pleasant activities that elicit well-being. During this second session, patients were also encouraged to identify thoughts and beliefs that could negatively affect their psychological well-being and to consider what specific aspects of psychological well-being were particularly impacted by these thoughts and beliefs.

The remaining six sessions covered specific dimensions of psychological well-being that encompass positive functioning and eudaimonic well-being: autonomy, environmental mastery, personal growth, purpose in life, self-acceptance, and positive relationships. The focus was not only on presenting these dimensions but also on identifying specific impairments that participants might have in each dimension. Each session was dedicated to improvement in each of these dimensions and its components to achieve balanced optimal functioning [38]. In order to promote improvement and balance across the dimensions, most sessions presented two categories of relevant technique for promoting a given dimension: techniques to be used broadly in daily life and techniques focused on cardiac health specifically. In each session, participants were asked to complete at least one exercise, preferably one that was specifically matched to their impairment or area of difficulty within each well-being dimension.

Across all eight sessions, each session had a general agenda that consisted of nine stages (see Supplementary Table 2). These included detailed explanations of specific exercises that were presented to participants prior to homework assignments. Participants were provided with a new section of the treatment manual each week that detailed the weekly topic and the exercises that were assigned to promote the week's specific dimension of well-being. Participants would then complete the various exercises related to well-being dimensions at home or at work between sessions. In the following group session, participants were encouraged to describe their well-being exercises to fellow group members. The study trainer leading the group would also ask participants to report on their psychological well-being both before and after the exercise and to reflect on how performing the particular exercise may have impacted their psychological well-being in between sessions. An emphasis was placed on cultivating skills that could be used for long-term well-being promotion; in other words, participants were asked to focus on how they might incorporate these skills into their daily lives with the goal of continued use after the intervention was completed.

2.3.3. Control condition

An attention-matched control group was used. Participants randomized to this condition attended eight weekly 90-minute sessions focused on extended education about cardiovascular illness and modification of risk factors. These sessions were developed in consultation with a cardiologist and were led by the same staff as the intervention group to prevent interventionist-specific effects. Each weekly session involved education on a certain topic followed by a group discussion. Topics included the process of atherosclerosis, risk factors for cardiac disease, medications and side effects, and general lifestyle modification. Later sessions also focused on healthy diet, safe physical activity, and smoking cessation. Time was allotted during each session for questions following the education portion. Group discussion focused on the particular topic that was presented and also on potential barriers to cardiac recovery and lifestyle medication more broadly. Participants in this condition also received an introductory session similar to the intervention group, and once the study was completed, control group participants could elect to participate in the intervention condition.

2.4. Study outcomes

2.4.1. Aim #: to assess the feasibility and acceptability of the well-being intervention

Feasibility was assessed through two metrics: (1) rate of group session attendance, and (2) rate of homework completion for exercises assigned the previous session (i.e., participants were asked, “Did you do the last week's exercise?” and were provided with a list of relevant exercises). Both of these metrics were recorded as percentages.

Based on previous research [29,40], acceptability was assessed using a five-point Likert scale to assess three different dimensions: (1) ease of the exercise (“How easy was it to do?” with choices including “very hard,” “hard,” “moderate,” “easy,” and “very easy”); (2) utility of the exercise (“How useful was this exercise for you?” with five similar choices ranging from not useful to very useful); and (3) likelihood of continuation post-intervention (“How much is it possible to keep doing it after completing this course?” with five choices choice ranging from very unlikely to very likely). The ratings were collected through a brief questionnaire at the beginning of each session. Scores on these three dimensions were averaged for an overall acceptability/utility rating and were interpreted according to a five-point Likert scale ranging from “very poor” to “very good.”

2.4.2. Aim #2: to explore between-group differences in psychological outcomes

The following self-report measures were administered by blinded study staff at baseline, post-test (nine weeks after baseline, one-week post-intervention), and follow-up (six weeks after post-test, 15 weeks after baseline). All measures were administered in Persian.

Psychological well-being, the primary Aim #2 outcome, was assessed

Table 1
Psychological well-being intervention for cardiac patients.

Week	Session topic	Session objectives	Examples of techniques used
1	Psychological factors in cardiovascular health	Importance of psychological factors in cardiovascular health Psychological well-being and its dimensions and the importance of self-monitoring well-being	Report in a structured diary the circumstances surrounding periods of experiencing well-being, rated on a 0–100 scale
2	Optimal experiences	Identifying and engaging in optimal experiences and pleasant activities to promote well-being Identifying thoughts/beliefs impeding well-being	Identify 'well-being moments' and report them to group Identify activities or situations that promoted psychological well-being and share with the group Identify thoughts and beliefs leading to premature interruption of well-being Identify and note irrational or automatic thoughts related to dimensions of psychological well-being
3	Environmental mastery	Wisdom Self-determination Optimal experience	Self-determination technique for daily life – Problem solving: *Identify one problem or issue in the next week.* *List the possible solutions (options)* *Evaluate the options* *Select an option or options* *Checking the obstacles* *Implementing solutions* *Evaluating and learning* Self-determination technique for cardiac health: *In the next week, complete one task related to cardiac health that has been concerning you. For example, buy a blood pressure cuff if you do not have one and try to monitor and control your blood pressure*
4	Personal growth	Meaning Post-traumatic growth Benefit finding Intrinsic motivation	Post-traumatic growth technique for daily life: *Identify, record, and report to the group the inconvenient events and failures of your life that made you grow and made you stronger* Post-traumatic growth technique for cardiac health: *During the next week, think about the positive changes that have occurred after the diagnosis of heart disease and report to group at the next session*
5	Purpose in life	Goals Hope Passion Optimism	Optimism technique for daily life: *Use optimistic explanatory style and replace pessimistic thoughts with optimistic thoughts (ABC model)* Optimism technique for cardiac health: *Use positive imagery and expectations for cardiac health in the future during meditation practice*
6	Autonomy	Leadership Locus of Control Bravery	Locus of control technique for daily life: *During the next week, report on one good thing that has occurred because of personal efforts as opposed to chance or luck* Locus of control technique for cardiac health: *Prepare a statement illustrating how your cardiac health-related behaviors are within your control, not chance or external factors*
7	Self-acceptance	Self esteem Positive reframing	Self-esteem technique for daily life: *Choosing self-compassion instead of self-criticism in challenging situations in daily life* Self-esteem technique for cardiac health: *Practice mindfulness to recognize thoughts about inferiority due to complications of heart disease and learn to challenge these thoughts*
8	Positive relations	Empathy Generosity Altruism Forgiveness Gratitude	Gratitude technique for daily life: *Keep a daily gratitude journal: Record 3–5 things for which you are grateful. Make the list personal and try to think of different things each day* Gratitude technique for cardiac health: *Complete a gratitude letter to your doctor, nurse, or spouse for their care of you and deliver it to them or read it for them*

using Ryff's psychological well-being brief scale (1989, 1995). This questionnaire consists of 18 items that capture aspects of eudaimonic psychological well-being, with answer choices ranging from 1 ("completely wrong") to 6 ("completely true") on a 6-point Likert scale [37,41]. Ryff [37] reported good validity (0.93), and prior work has also shown adequate reliability (0.72) and validity (0.77) for the Persian version of the scale [42]. Cronbach's alpha for the current sample indicated moderate reliability (0.64).

Depression was assessed using the Beck Depression Inventory-II (BDI-II) [43], which contains 21 items measuring depressive symptoms over the preceding two weeks. The range of scores is between 0 and 63. Ghassemzadeh et al. reported high internal consistency of its Persian version ($\alpha = 0.87$) and acceptable test-retest reliability ($r = 0.74$) in an Iranian sample [44]. Cronbach's alpha for the current sample indicated adequate reliability (0.81).

Positive and negative affect were measured using the Positive and

Negative Affect Schedule (PANAS) [45]. This scale consists of 20 items (10 measuring positive affect, 10 measuring negative affect) and has been utilized in multiple prior studies of patients with heart disease [46] and in Iranian samples [47]. This scale has demonstrated adequate convergent and discriminant validity and reliability [45]. Cronbach's alpha in the current sample indicated adequate reliability (0.92).

Dispositional optimism was assessed using the well-validated Life Orientation Test-Revised (LOT-R). This 10-item scale includes four filler items and six active items (scored from 1 to 5; three reverse-scored, total score 6–30) to derive the total optimism score. The item has been used in numerous prior studies in patients with heart disease [46,48]. Internal consistency of the Persian version of the scale has been reported as $\alpha = 0.74$ with adequate convergent and discriminant validity [49]. Cronbach's alpha in the current sample indicated moderate reliability (0.61).

2.5. Data analysis

Descriptive statistics (percentages, means and standard deviations [SD]) were used to summarize baseline participant characteristics and scores on the psychological self-report measures. Even though participants were randomly assigned to intervention versus control group, exploratory tests of between-group differences on baseline characteristics were performed including chi-square and independent sample *t*-tests to provide information on potential baseline differences between groups.

Descriptive statistics were used to calculate the proportion of sessions attended (out of eight total) and assignments completed (also out of eight) to measure feasibility. Acceptability was assessed through examining means (and SD) for the ratings of ease, utility, and likelihood of continuation that were collected during each session. Based on prior studies of positive psychology interventions for cardiac patients [29,31,40], a priori thresholds for adequate scores on these measures were that 1) more than half of participants would have attendance rates of 62.5% or greater (5 of 8 sessions), 2) a majority of patients would complete 70% or more of study exercises/assignments (6 or more out of 8 exercises), and 3) mean ratings of ease, utility, and likelihood of continuation would be at least 3.5 out of 5.

To assess between-group differences on psychological outcomes, we used mixed effects regression models for each outcome at each study time point. Psychological well-being was the main Aim #2 outcome with the nine-week (i.e., one-week post-intervention) timepoint representing the main study time point, and the 15-week follow-up time point as an exploratory outcome. Effect sizes were also calculated for each outcome variable by dividing the mean difference between timepoints by the pooled standard deviation. All analyses were performed using Stata version 15.1 (College Station, TX), and all statistical tests were two-tailed; an alpha level of 0.05 was used to denote significance.

3. Results

See Fig. 1 for the study flow diagram. One hundred twenty-one cardiac patients were initially approached, with 46 agreeing to participate in the study. Six patients were excluded either for current use of psychiatric medication or for inability to participate in the study procedures, resulting in 40 participants who were randomized (20 to the intervention, 20 to the control condition). Baseline patient characteristics are presented in Table 2. Overall, the mean age of participants was 58.6 (SD = 5.9), and 45% were women. The majority were married, employed or self-employed, and had multiple cardiac risk factors.

In terms of psychological outcome measures, the baseline mean score for psychological well-being was 37.6 (SD = 4.0), with higher scores indicating better well-being; this mean score was lower than the mean score reported by Soleimani Khashab et al. in an Iranian University sample [42]. The mean BDI-II score was 46.7 (SD = 6.7), in the severe depression range. Baseline mean scores for PANAS positive affect (M = 18.6, SD = 3.7) and negative affect (M = 22.9, SD = 7.9) indicated relatively low levels of both positive and negative affect at baseline. Finally, participants' mean baseline LOT-R score was 11.58 (SD = 3.80), lower than Western population age-normed means (approximately 14.6) [50]. Tests of between-group differences at baseline did not reveal any significant differences between the intervention and control group. Follow-up data was obtained from all 40 (100%) patients at nine weeks (i.e., one-week post-intervention) and 15 weeks.

In terms of feasibility (Aim #1), the mean number of sessions completed by participants in the intervention condition was 7.1 (SD = 0.83) out of 8, with 100% of participants completing at least 6 out of 8 sessions. In addition, 100% of participants in the intervention group completed over 70% or more of the exercises (i.e., at least 6 of 8). Regarding acceptability, combined mean ratings for ease, utility, and likelihood of continuing the exercises, summed across all eight weeks, was 3.75 (SD = 0.91), above the a priori threshold of 3.5/5 for acceptability.

Regarding between-group differences (Aim #2), the intervention was associated with significantly greater improvements in psychological well-being (Ryff scale) at nine weeks ($\beta = -16.90$; 95% Confidence Interval [CI] = −23.36, −10.44; $t = -5.21$; $p < .001$; ES = 1.65) and at 15 weeks ($\beta = -22.05$; 95% CI = −28.62, −15.48; $t = -6.68$; $p < .001$; ES = 2.11), compared to the control condition (see Table 3). Regarding the secondary psychological outcomes, the intervention was similarly associated with a significantly greater improvement in depression (BDI-II) at nine weeks ($\beta = 26.45$; 95% CI = 20.97, 31.93; $t = 9.61$; $p < .001$; ES = −3.04) and 15 weeks ($\beta = 26.40$; 95% CI = 20.82, 31.98; $t = 9.43$; $p < .001$; ES = −2.98) and optimism (LOT-R) at nine weeks ($\beta = -8.80$; 95% CI = −11.17, −6.43; $t = -7.41$; $p < .001$; ES = 2.34). No significant differences on either positive or negative affect (PANAS) at week nine or week 15 were observed between the intervention and control groups.

4. Discussion

The current study explored the feasibility and acceptability of a novel eight-week, in-person, group-based psychological well-being intervention for individuals with CAD who had substantial depressive symptoms. The intervention appeared to be both feasible and acceptable in this cohort, surpassing all a priori thresholds in these domains. In addition, consistent with the results of recent meta-analyses [26,28], the intervention was associated with greater improvements in psychological well-being at nine and 15 weeks, compared to the control group, with large between-group effect size differences. Secondary analyses indicated that compared to the control group, the intervention was also associated with greater improvements in depression and optimism immediately post-intervention, with the effect for depression maintained at the 15-week follow-up time point.

These findings are generally consistent with similar intervention studies for cardiac patients, most of which have found such interventions to be feasible, well-accepted, and associated with improvements in psychological outcomes [30,31]. For instance, Celano et al. [30] examined a 10-week phone-based positive psychology-based intervention in individuals with heart failure in a single-arm trial. The authors found the intervention to be feasible, acceptable, and associated with improved psychological and health behavior outcomes. A recent larger, randomized controlled trial found that an eight-week optimism training program was effective in patients with CAD compared to an attention-matched education control condition, leading to improvements in psychological outcomes at eight and 16 weeks [40]. This current work confirms these findings and extends such work by showing efficacy in a cohort of cardiac patients with substantial depression, a population at very high risk for adverse outcomes [2].

Compared to past positive psychological intervention studies that focused on specific psychological targets (e.g., optimism, gratitude, etc.), this intervention also uniquely focused on eudaimonic constructs

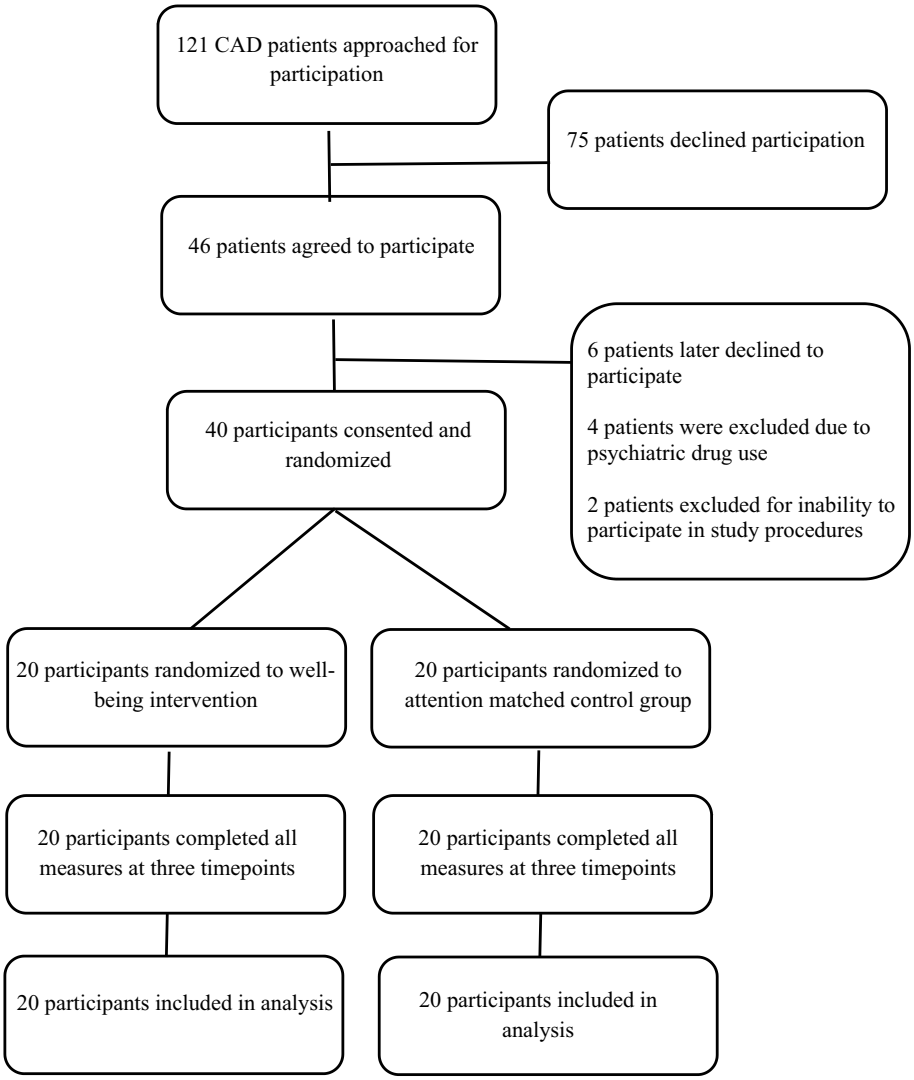

Fig. 1. Study flow diagram.

(e.g., purpose, fulfilling one's potential) utilizing Ryff's well-being dimensions [38]. Though a therapy ("Well-Being Therapy") partially based on these dimensions has been successfully delivered in group format [51], the current study is the first to deliver and examine a eudaimonia-focused program in cardiac patients. Our findings may be particularly important given that prior work has found these eudiamonic constructs to be substantially more associated with health outcomes (including biomarkers of health) than hedonic well-being (e.g., happiness, pleasure) [24]. This study also adds to the small yet growing literature suggesting that these types of interventions are feasible and acceptable in non-Western populations [31,40].

Interestingly, while strong intervention effects were found for psychological well-being, depression, and optimism, no significant effects were observed for positive or negative affect. One potential explanation for this finding may be related to the nature of the intervention. The purpose of the intervention was not necessarily to change momentary affective experience, but it instead specifically focused on eudaimonic principles and overall psychological well-being, constructs that are not necessarily correlated with positive or negative affect [37]. Psychological well-being, depression, and optimism may be less transient and more enduring compared to positive and negative affect as measured by the PANAS, which examines moment-to-moment state affective constructs, and the intervention's focus on these former targets may explain its specific effects on these outcomes, with lesser effects on momentary affect. Furthermore, there may also be cultural differences in the construct, expression of, or insight into positive and negative emotions, particularly since scores for both positive and negative emotions were fairly low at baseline and showed minimal changes throughout.

It is also worth noting that the effect sizes found for psychological well-being and depression were larger than what has typically been reported previously [28]. This could be the result of social desirability or cultural tendencies given that the participants were aware the intervention was designed to improve well-being.

The observed improvements in psychological well-being, sustained beyond the intervention period, could have beneficial cardiac effects. Psychological well-being has been consistently and independently linked with superior cardiac health, likely due in large part to beneficial effects on cardiac health behaviors such as increased physical activity, improved diet, and reduced cigarette smoking [4,52]. Indeed, some prior studies of positive psychological interventions have found potential benefits in overall adherence and/or physical activity [53,54], and the intervention in this study could similarly have beneficial effects on cardiac health behavior and overall heart health. Such a program could be utilized as part of clinical care, for example as an adjunct to cardiac rehabilitation and prevention programs, the current gold standard for improving cardiac health [55,56]. Indeed, adjunctive mental-health-related programs have been linked to superior outcomes in cardiac rehabilitation [57], but—despite the independent links between

Table 2
Demographic information.

	Control group (n = 20)	Well-being treatment (n = 20)
Age: Mean (SD)	60.35 (6.70)	56.85 (4.39)
Sex		
Male	8 (40)	14 (70)
Female	12 (60)	6 (30)
Education		
Illiterate	6 (30)	6 (30)
Elementary	6 (30)	6 (30)
Guidance school to diploma	3 (15)	4 (20)
Bachelor's degree	2 (10)	4 (20)
Master's degree or doctorate	3 (15)	0 (0)
Marital status		
Married	16 (80)	12 (60)
Single	0 (0)	2 (10)
Divorced	0 (0)	3 (15)
Widowed	4 (20)	3 (15)
Employment status		
Employed	5 (25)	4 (20)
Self-employed	4 (20)	3 (15)
Housewife	5 (25)	7 (35)
Unemployed	0 (0)	1 (5)
Retired	6 (30)	5 (25)
Diabetes	5 (25)	5 (25)
High blood pressure	12 (60)	11 (55)
Hyperlipidemia	8 (40)	12 (60)
History of depression	6 (30)	7 (35)
Tobacco use	2 (10)	2 (10)
Alcohol use	1 (5)	1 (5)
Opiate use	0 (0)	0 (0)
Baseline self-report psychological measures: Mean (SD)		
Depression (BDI-II, range 0–63)	45.0 (7.57)	48.4 (5.36)
Positive affect (PANAS, range 0–40)	17.8 (3.78)	19.5 (3.41)
Negative affect (PANAS, range 0–40)	22.0 (9.21)	23.8 (6.34)
Optimism (LOT-R, range 6–30)	11.4 (4.18)	11.8 (3.47)
Well-being (Ryff's, range 18–108)	38.3 (3.54)	36.8 (4.32)

Note. All figures are N (%) unless otherwise specified.

well-being and cardiac outcomes—such programs do not currently focus on this concept in a systematic manner. The fact that such marked improvement in psychological well-being was observed after just eight 90-minute group sessions suggests that improvement in well-being can be achieved efficiently.

This study had some important strengths, namely the randomized design, an attention matched control group, the use of well-validated measures, and the construction of an intervention that is not only applicable to patients with CAD but also culturally relevant. Regarding the latter, the vast majority of Iranians also identify as Muslims, and well-being concepts such as purpose in life is frequently mentioned in Islamic texts including the Quran [58]. Furthermore, the sample that was used in many ways is representative of cardiac patients who are seen for care in hospital settings, i.e., men and women, aged approximately 60, with multiple cardiac risk factors.

The study also had several limitations. These include the fact that

Table 3
Between-group differences in change from baseline on study outcome measures at 9 weeks and 15 weeks.

Measure	Coefficient	95% CI	t	p	ES
Baseline to 9 weeks					
Primary outcome measure					
Well-being (Ryff)	−16.90	−23.36, −10.44	−5.21	< .001	1.65
Secondary psychological measures-3.0					
Depression (BDI-II)	26.45	20.97, 31.93	9.61	< .001	−3.04
Positive affect (PANAS)	−3.20	−6.70, 0.30	−1.82	.073	0.58
Negative affect (PANAS)	0.75	−4.20, 5.70	0.30	.764	−0.10
Optimism (LOT-R)	−8.80	−11.17, −6.43	−7.41	< .001	2.34
Baseline to 15 weeks					
Primary outcome measure					
Well-being (Ryff)	−22.05	−28.62, −15.48	−6.68	< .001	2.11
Secondary psychological measures					
Depression (BDI-II)	26.40	20.82, 31.98	9.43	< .001	−2.98
Positive affect (PANAS)	1.10	−2.15, 4.35	0.67	.502	−0.21
Negative affect (PANAS)	0.70	−4.09, 5.49	0.29	.772	−0.09
Optimism (LOT-R)	2.65	−0.22, 5.52	1.84	.070	−0.58

Note. CI = Confidence Interval. BDI-II = Beck Depression Inventory – 2nd Edition; PANAS = Positive Affect Negative Affect Schedule; LOT-R = Life Orientation Test, Revised. Results of between-group differences in change from baseline to 9 weeks or 15 weeks are from mixed effects regression models.

the intervention was conducted at a single site, with a relatively small sample size, and administered to participants who were both able and willing to complete the in-group sessions and between-session homework. Over half (62%) of individuals initially approached declined to participate, which may have artificially skewed the results in terms of lack of attrition and higher levels of feasibility and acceptability in the sample of those who were willing to participate. In addition, data on severity of CAD and possible medical comorbidities beyond diabetes, high blood pressure, and hyperlipidemia was not collected. As such, it not apparent whether these results will generalize to other sites or other patient cohorts. Future studies should consider how interventions such as these can appeal to more qualifying individuals and how motivation and adherence can be encouraged in those who are prone to discontinuing. It will be worth considering how the recruitment process can be improved as well, perhaps providing detailed written explanation of the studies ahead of time, providing renumeration for participation, or more heavily involving family. In addition, the lack of longer follow-up measurements may limit our understanding of how enduring the effects are. While qualitative information was gathered only informally during this study, future work that focuses on qualitative data may also provide more information on how both recruitment and similar interventions can be improved.

It is also possible that the lack of attrition among those who agreed to participate was at least partly due to the fact that Iranian and Muslim values align well with positive psychological well-being concepts. Whereas more traditional Western psychological interventions focus on the individual, positive psychological interventions, and perhaps particularly those delivered in a group format specifically, often include activities that require interaction and emphasize positive relations with others, which may appeal more to the collectivist communities [59] and collectivistic nature of the Iranian culture. Therefore, the same intervention delivered in a setting where cultural values differ more significantly may not have demonstrated the same degree of adherence and feasibility.

Finally, cardiac health behaviors were not measured, and therefore, it cannot be known whether the observed improvement in psychological well-being was associated with greater improvements in health behaviors or health outcomes. Future work should examine this possibility by measuring both objective behaviors and health outcomes.

In sum, this initial examination of a psychological well-being intervention for individuals with CAD found that this intervention was feasible, well-accepted, and associated with improvements in psychological well-being, depression, and optimism. Future work should replicate this work in other samples, other settings, and other delivery methods (e.g., online or telephone) to increase external validity and improve reach and applicability to different types of patients. Furthermore, future work would also benefit from incorporating general health-related and cardiac health-specific outcomes to determine the possible public health impact.

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Declaration of Competing Interest

None.

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None to report.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.genhosppsych.2019.06.005.

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