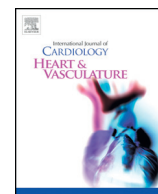


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Effectiveness of mindfulness-based stress reduction program on quality of life in cardiovascular disease patients

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ABSTRACT

Introduction: Cardiovascular disease is one of the most fatal physical illnesses that impose many financial losses on societies every year.

Aim: This study was to investigate the effectiveness of a mindfulness-based stress reduction (MBSR) program on self-efficacy and quality of life in patients with cardiovascular disease.

Material and methods: The samples of this clinical trial were 60 patients who were selected by convenience sampling from patients were diagnosed, clinically interviewed by a cardiologist and randomized to two groups; experimental and control, and then completed *Sherer et al. General Self-Efficacy Scale* and *36-item Short Form Survey* three times; pre-test, post-test, and after 3 months of follow-up. MBSR Program includes the methods that patients learn to calm their minds and body to help them cope with disease that was based on self-efficacy and quality of life. Data analysis was performed by the SPSS v22 using *t*-test and ANOVA.

Results: The results show that the mean pre-test scores of self-efficacy and quality of life of patients were not significantly different between the experimental and control groups ($P > 0.05$). However, the mean scores of the two variables were found to be significantly different between the experimental group and the control group on the post-test and follow-up as the research hypotheses were examined ($P < 0.01$). So that the means of self-efficacy were 60.80 ± 5.91 and 60.40 ± 7.03 and quality of life were 103.80 ± 9.35 and 101.10 ± 9.13 at post-test and 3 months later respectively in experimental group.

Conclusion: Self-efficacy and quality of life of cardiovascular patients could be improved by providing an MBSR program.

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1. Introduction

Cardiovascular disease (CVD) is one of the most fatal physical diseases in the 21st century. Recent research suggests that heart disease is more likely to endanger human life than any other illness and is the main leading cause of death worldwide [1,2]. The study of CVDs is of great importance in terms of psychology, especially health psychology. The results of a number of studies have indicated that these diseases are largely related to the psychological states of patients and these patients also experience severe psychological problems [3].

These symptoms result in intolerance to activity and changes in the patient's lifestyle, affecting his/her quality of life and life satisfaction [4], on the one hand, and leading to feelings of being at risk and impending death due to the various limitations and symptoms that they create, and therefore decreasing life expectancy [5]. The results of various studies have shown that people with high self-efficacy show a greater willingness to participate in challenging behaviors and provide a better interpretation of health behaviors [6,7].

CVDs can affect the patient's quality of life. Quality of life is a broad concept that covers all aspects of life, such as physical, social, and especially health [8]. The results of studies on quality of life have shown that patients with heart failure have lower quality of life than healthy people and even than patients with other physical illnesses [9,10]. Therefore, over the past three decades, quality of life has been considered one of the most important areas of clinical research and also one of the most effective aspects of cardiovascular care. The study of quality of life has therefore been used to detect differences among patients, to predict

Abbreviations: MBSR, mindfulness-based stress reduction; CVD, Cardiovascular disease.

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the outcomes of the disease, and to evaluate therapeutic interventions [11,12].

In recent years, the need for psychological interventions to address the psychological problems of patients with cardiovascular disease has been increasingly considered. For example, relaxation methods and cognitive-behavioral interventions have been used for these patients [13]. Mindfulness-based interventions are also among the new methods known as the *third-wave behavioral therapies* that have been recommended for physical and psychological patients [14]. Meanwhile, mindfulness-based stress reduction (MBSR), first proposed by Kabat-Zinn, is the first method of third-wave psychotherapy, which is often considered the shared output of the novel approaches [15]. MBSR also has been used to treat psychological problems and stress associated with severe physical illnesses with reportedly beneficial effect [16]. The results suggest that mindfulness can mediate between general stress and the stress associated with the disease and its various consequences, and reduce their severity [17–20]. Serve as a mediator variable between some positive attributes such as self-efficacy and positive psychological factors [21]. MBSR has also been used to control factors for CVDs and prevent them. Including MBSR for regulating respiration and heart rate, regulation of blood pressure and prevention of CVDs [22–24], and adjustment of psychological problems such as self-efficacy, stress, anger, depression, anxiety, and sleep disorders [25,26], and improving psychological attributes such as quality of life [27,28].

Regarding the above-mentioned, we investigated the effectiveness of an MBSR program in improving the self-efficacy and quality of life of patients with CVDs and then follow up the results 3 months later.

2. Materials and methods

The Sample size of this study was determined 50 with reference to a previous study [29]. Inclusion criteria were ensuring development of vascular disease, which included coronary heart disease, angina, myocardial infarction, stroke and peripheral vascular disease, diagnosed by a cardiologist (Table 1), in this study; having at least completed secondary education to be able to participate in sessions and to perform assignments, and providing written consent to participate in the study, and taking strong antipsychotic drugs. Exclusion criteria consisted of having the history of psychiatric drug use, having the history of receiving psychological treatment in the past 6 months, and the lack of attending more than two consecutive sessions or more than three non-consecutive sessions. The samples of this clinical trial were 60 patients with CVD referring to the clinic were selected using convenience sampling and randomized to two groups of 30 each; experimental and control from patients referring to Imam Ali Specialty Clinic of Ayatollah

Table 1
Baseline characteristics of the study participants (n = 60).

Variable	Interventional group	Control group
	Number (%)	Number (%)
Sex		
Male	15 (50)	15 (50)
Female	15 (50)	15 (50)
Age group		
20–29	5 (16.7)	4 (13.3)
30–39	11 (36.6)	12 (40)
40–49	14 (46.7)	14 (46.7)
Educational level		
Under diploma	9 (30)	8 (26.7)
Diploma	16 (56.3)	15 (50)
Academic	5 (16.7)	7 (23.3)
Type of cardiovascular disease		
Angina	7 (23)	8 (26)
Peripheral vascular disease	6 (20)	5 (16)
Stroke	8 (26)	7 (23)
Myocardial infarction	4 (13)	5 (16)
Coronary heart disease	5 (16)	5 (16)
Smoking patients	0	0

Kashani Hospital, Shahrekord, southwest Iran in 2016. All ethical consideration (according to declaration of Helsinki) was done in this study. The MBSR intervention was performed by a psychologist and data collection and analysis by the researcher so that the study was single-blind. However, according to Kabat-Zinn's comments, the number of people attending MBSR program can be up to 30 [30], but in the present study, in order to *more efficiently* provide the necessary training to the samples of the experimental group, the experimental group was divided into two subgroups of 15 men and 15 women, and interventions were presented in the same way to the two subgroups. Both experimental group and control group received routine medical care and the experimental group also attended 8 sessions of the MBSR program in accordance with the proposed protocol of Kabat-Zinn [30]. Independent variable was the MBSR program and dependent variables were self-efficacy and quality of life. Meanwhile, in order to observe research ethics, after the completion of the study, the control group received a 8-session, intensive MBSR program.

2.1. Sherer et al. General Self-Efficacy Scale

Sherer et al. General Self-Efficacy Scale, developed by Sherer et al. in 1982, has 17 items rated on a 5-point Likert scale from *absolutely agree* to *absolutely disagree*.

The choices of the items 1, 3, 8, 9, 13 and 15 are scored from right to left, and those of the remaining items are scored inversely, so that the maximum and minimum possible scores are 85 and 17, respectively. The results of the study of the psychometric characteristics have shown the appropriateness of these properties for this scale [31]. In the present study, the reliability of this scale was 0.86 according to Cronbach's alpha coefficient.

2.2. 36-item Short Form Survey (SF-36)

SF-36 was developed by Ware and Sherbourne in 1992 in the United States. This scale has 36 items that assess 8 health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. The contents of the program are shown in Table 2.

The test-retest reliability of the SF-36 is 0.77 in physical health, 0.77 in mental health, 0.75 in the social relationships dimension, and 0.84 in the environmental health [32]. In this study, the reliability of the SF-36 was evaluated with a pilot study sample and derived 0.82 by using Cronbach's alpha coefficient. Data analysis was performed using the SPSS version 22 on both descriptive and inferential statistics. For descriptive statistics, mean and standard deviation were investigated and for inferential statistics, *t*-test and repeated measures ANOVA were used.

3. Results

The mean age of the participants was 52.06 (10.08) years. Of the 60 patients included in the study, 30 were male, 17 had an education level under high school completion, 31 held high school completion certificate, and 12 had academic education. The patients suffered from angina, peripheral vascular disease, stroke, myocardial infarction, and coronary heart disease.

The *t*-test results in Table 3 show the mean pre-test scores of self-efficacy and quality of life were not significantly different between the experimental and control groups ($P > 0.05$). However, the mean scores of the two variables were found to be significantly different between the experimental group and the control group on the post-test and follow-up as the research hypotheses were examined ($P < 0.01$).

Table 2
Mindfulness-based stress reduction program.

Session no.	Educational content
1	Communicating and conceptualizing, explaining the effect of body and mind on each other, providing explanations on pain, the need for using mindfulness training, providing explanations about the autonomous guidance system (autonomous guidance identification training practice); emphasizing the concept of dependent variables of research (<i>quality of life</i> and <i>self-efficacy</i>).
2	Reviewing the last week's homework, body checkout, feedback and discussing body checkout, meditation exercises, breathing mindfulness exercise.
3	Reviewing the last week's homework, sitting meditation, exercise rehearsal, three-minute breathing space exercises.
4	Reviewing the last week's homework, a five-minute <i>seeing or hearing</i> exercise, a rehearsal of breathing mindfulness, and a body check-up.
5	Reviewing the last week's exercise sessions, breathing exercises, sitting meditation (awareness of breathing, body, sounds, and thoughts), explaining stress and its relationship with pain, examining the awareness of pleasant and unpleasant events with respect to feelings, thoughts and body feelings.
6	Reviewing the last week's homework, vigilant yoga, talking about different views of thoughts or thoughts, sentimental meditation (the presence of minds from voices and thoughts); accepting thoughts and feelings and permitting them to be present.
7	Reviewing the last week's homework, sleep hygiene, repeating the drills of the previous sessions, and providing a list of fun activities.
8	Reviewing the last week's homework, body checkout, summing up sessions, checking out and discussing programs and continuing exercises.

Since the research data were collected in three stages (pre-test, post-test and 3 months later), repeated measures ANOVA was used on one factor for analyzing the research hypotheses.

The results of Box's M test regarding the assumption of equality of covariance matrices were ($P = 0.112$, $F = 1.71$, Box's $M = 10.92$) for self-efficacy scores and ($P = 0.171$, $F = 1.50$, Box's $M = 9.58$) for quality of life scores.

Since the significance level obtained was >0.01 , i.e., default value, it was concluded that the covariance matrices of the mean scores were equal and therefore repeated measures ANOVA could be used.

The results of Mauchly's test of sphericity for self-efficacy ($P = 0.001$ and $MW = 567$) and quality of life ($P = 0.001$ and $MW = 633.0$), show there is a difference between covariances, and therefore there is no pre-condition for the equality of covariances, and Greenhouse-Geisser test was used to investigate intra-subject effects.

The results of Table 4 show there was no significant difference in self-efficacy between the measurements (pre-test, post-test, and 3-month follow-up) ($F = 0.830$, $P = 0.401$), but the interaction effect of measurement time and group on the mean scores was significant ($F = 8.09$, $P = 0.002$). The results from inter-subject effects also show the mean scores of self-efficacy were significantly different between experimental and control groups ($F = 30.49$, $P = 0.001$). The *Eta* coefficient obtained was also 0.345, which indicates that $>34\%$ of the changes in the mean score in the experimental group were related to intervention (MBSR).

In addition, the results of Table 4 show that for quality of life, the measurement time (pre-test, post-test and 3-month follow-up) was significantly different ($F = 15.74$, $P = 0.001$) and measurement time interaction was significantly different ($F = 21.72$, $P = 0.001$).

Table 3
Mean and standard deviation of self-efficacy and quality of life scores in the experimental and control groups on pre-test, post-test, and 3-month follow-up.

Dependent variable	Group	Pre-test	Post-test	3 months later
Self-efficacy	Experimental group	53.82 ± 10.59	60.80 ± 5.91	60.40 ± 7.03
	Control group	53.20 ± 9.22	50.30 ± 7.48	49.63 ± 6.58
<i>P</i> -value		0.717	0.001	0.001
Quality of life	Experimental group	90.76 ± 7.21	103.80 ± 9.35	101.10 ± 9.13
	Control group	88.80 ± 6.96	87.83 ± 8.95	87.80 ± 7.85
<i>P</i> -value		0.231	0.001	0.001

Thus, the results of the above table indicate that the mean scores of experimental and control groups at different times of measurement are significantly different. The results from the inter-subjects effects also showed that the mean scores of quality of life were significantly different between the experimental and control groups ($F = 37.49$, $P = 0.001$). The *Eta* coefficient was obtained 0.345, which indicates that over 39% of the changes in the mean scores in the two group were related to intervention (MBSR). The results show the mean scores of self-efficacy and quality of life are not significantly different between the experimental and control groups ($P < 0.05$). Although in the follow-up phase, the mean score of quality of life in the experimental group decreased, but there was still a significant difference from the mean score of quality of life in the control group.

4. Discussion

The results of this study indicated that the presentation of an MBSR program led to a stable improvement of the scores of self-efficacy and quality of life in the experimental group on the post-test and 3-month follow-up. In fact, the results of our study showed that the mean scores of self-efficacy and quality of life on post-test and follow-up were higher in the experimental group than in the control group. In addition, we observed that the mean scores of self-efficacy and quality of life on pre-test were not significantly different between the experimental group and the control group, but on post-test and follow-up, a significant difference was observed.

Eta coefficient for self-efficacy was 0.345 and 39.22 for quality of life, indicating that $>34\%$ and 39% of the changes in the mean scores of self-efficacy and quality of life, respectively, in the experimental group were due to the MBSR program. Our findings are consistent with other studies [14,33–36] reporting that mindfulness-based interventions are effective to reduce psychological symptoms of distress in severe physical and mental patients. The results of this study are also consistent with the results of studies on the efficacy of MBSR on various cardiovascular disease risk factors. The studies in which the effectiveness of MBSR in regulating respiration, heart rate, and blood pressure was investigated, include the studies of Ditto et al. [37] and Dellizonna et al. [38], in preventing cardiovascular diseases, include the studies of Sullivan et al. [33], Blom et al. [39], Azam et al. [31], and Momeni et al. [25], and in modulating psychological problems such as stress, anger, depression, anxiety, and sleep disorders include the studies of Bohlmeijer et al. [26] and Momeni et al. [25], and in improving positive psychological characteristics such as quality of life include the studies of Zwisler et al. [28], Sullivan et al. [33], and Azam et al. [31]. These studies have shown that mindfulness can provide conditions for change by refining cognitive-affective-behavioral cycles (albeit different from the cognitive-behavioral therapy). Since self-efficacy is a cognitive variable and is directly related to how one perceives oneself and to the possibility of disease improvement, then mindfulness-based interventions provide the conditions for improving cognitive variables, including self-efficacy, by creating a positive re-evaluation, including self-efficacy. In fact, mindfulness-based interventions, by relying on affective circles, cause a person to reduce catastrophic thinking by positive re-evaluation, and thus positive re-evaluation and mindfulness will improve each other constantly and mutually, and create the dynamics of a spiral upward that acts opposite to downward spiral [40,41].

Table 4
Summary of intra- and inter-subject effects on self-efficacy and quality of life in patients with cardiovascular diseases.

Source			Sum of squares	df	Mean square	Value F	Significance level
Self-efficacy	Intra-subject effects	Time	88.81	1.39	63.63	0.830	0.401
		Group × time	865.43	1.39	620.05	8.09	0.002**
	Inter-subject effects	Constant	540,766.42	1	540,766.42	6457.42	0.001**
Group		2553.80	1	2553.80	30.49	0.001**	
Quality of life	Intra-subject effects	Time	1200.93	1.46	820.92	15.74	0.001**
		Group × time	1657.77	1.46	1133.20	21.73	0.001**
		Group	156,856.05	1	156,856.05	12,028.60	0.001**
	Inter-subject effects	Constant	4877.60	1	4877.60	37.40	0.001**
		Group	4877.60	1	4877.60	37.40	0.001**

** $P < 0.05$.

It is also known that the effect of MBSR can be stable and last even up to 15 months after treatment, and by self-regulating pain, leads to changes in negative body image, inhibition of pain response, mood disorder, and psychological syndromes including anxiety and depression even after 15 months of treatment [42], which can be attributed to self-regulation of emotion and the creation of the positive cycles mentioned above [41]. According to the literature, spiritual problems are the main cause of heart disease, and programs that target such problems can have a positive effect on the mental and emotional state of patients with CVDs [27]. Mindfulness-based interventions can have a positive effect in improving the factors associated with cardiovascular functions, due to their impact on the lifestyle and the emotional and spiritual health of individuals, as emphasized by Ornish, the leading researcher and the architect of the healthy lifestyle of the heart [43]. In fact, given the fact that CVD patients experience severe stress and anxiety due to specific conditions of the disease, knowledge about the feelings, emotions, and bodily sensations caused by such stress and anxiety can help patients cope with their conditions while feeling to have higher self-efficacy, and thus improve their quality of life. In other words, through mindfulness-based drills, an extensive awareness is created in people that facilitate the adoption and ability of interpretation of stressful situations, which reduces mental and emotional distresses.

The efficacy of MBSR in treating cardiovascular disease is based on the patient's automatic thoughts; the patient must have the necessary skills, attention, concentration, and observation to be able to utilize the various therapeutic functions of mindfulness in a structured and combined way to improve his/her quality of life, while increasing feelings of control over the disease and improving self-efficacy.

The use of mindfulness-based interventions will increase selective and sustainable attention and awareness, thereby reducing negative processes, which in turn reduces emotional vulnerability, which in turn contributes to improving the quality of life and life expectancy.

As previously mentioned, the MBSR is based on emotional self-regulation training programs and is aimed at reducing emotional responsiveness to stress and its consequences. Thus, the MBSR provides patients with the opportunity to develop their own self-efficacy by using their mindfulness skills and appropriate metaphors and analogies to develop their behavioral capabilities for self-control as a method of self-efficacy. In other words, people learn to improve self-regulation and focus on the internal resources of health and integrity, and to differentially observe their inner states. In fact, how patients' cognitive evaluation of a situation influences their behavior and inner reactions, and also how they develop outcome expectations (as one of the most important dimensions of self-efficacy) as an outcome of their personal experiences by practicing mindfulness and its applications in the living environment, help them further adapt to their living environment and improve their quality of life.

5. Limitation

The follow-up study seems to have been performed only after 3 months from the last intervention session, which is not a sufficient interval to sustain the MBSR results.

Therefore, studies with longer intervals of in follow-up, e.g., at least 6 months or one year, are necessary.

In addition, mindfulness-based education, used in this study, is a general educational protocol that is commonly used for problems due to stress and other psychological factors related to serious physical illnesses, such as heart disease.

Therefore, it is necessary to use a more specific protocol for these patients in the future research.

6. Conclusion

Self-efficacy and quality of life of cardiovascular patients could be improved by providing an MBSR program. Therefore, it is recommended to apply this therapy, as providing counseling to the cardiovascular patients for improving their health dimensions.

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Conflict of interest

There is no conflict of interest regarding this work.

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