STEMedicine

RESEARCH ARTICLE

Online mindfulness training in percutaneous coronary intervention: a randomized clinical trial

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Abstract

***Background*:** Mindfulness training exhibits favorable effects on both psychological and physiological outcomes. We aimed at assessing its effects on post-percutaneous coronary intervention (PCI) patients.
***Methods*:** We recruited 357 patients arranged with PCI and randomized them in a ratio of 1:1 (n = 178 versus n = 179) into a 3-month mindfulness training class in addition to usual care. The primary outcomes were the physiological and health-related quality of life outcomes of patients post-PCI. The secondary outcomes were the psychological outcomes of the patients.
***Results*:** Compared to the control group, the 3-month mindfulness training improved the physiological outcomes including systolic blood pressure, body mass index, total cholesterol level, low-density lipoprotein-cholesterol, and triglyceride levels of patients post-PCI. The psychological outcomes including depression, anxiety, self-efficacy, and stress of these patients were also improved statistically.
***Conclusion*:** Mindfulness training exhibited benefits on both physiological and psychological outcomes of patients post-PCI.

Keywords: *coronary disease*; *mindfulness*; *percutaneous coronary intervention*; *stress disorder*

Received: 11 August 2022; Revised: 3 September 2022; Accepted: 5 September 2022; Published: 10 October 2022

Percutaneous coronary intervention (PCI) has been widely used to treat coronary heart diseases and acute myocardial infarction (1). However, PCI, as an invasive treatment method, tends to trigger negative emotional reactions in patients (2). Previous research has demonstrated that anxiety and depression are common in cardiology patients who have chest pain after PCI, and their physical symptoms are related to their psychological outcomes. Unfortunately, anxiety and depression in patients post-PCI are difficult to cure even if their pathological symptoms are relieved. Therefore, mental intervention is essential for the nursing of patients undergoing PCI.

Increasing evidence has shown that the occurrence of complications after PCI is not only related to physiological factors, such as impaired anticoagulant system and abnormal blood lipid regulation, but also linked to the patient's adverse psychological states (3, 4). It has been reported that the anxiety symptoms before PCI are common, with a prevalence rate of 55.3% (5). Unfortunately, psychological care of patients who have received PCI is always placed in a secondary position in current practice, and many clinicians and nurses lack the related knowledge (6).

Mindfulness is generally defined as being attentive and aware of what is taking place to us or in us at the successive moments of perception, which roots in Buddhist and keeps people's consciousness alive and active (7). Previous research has revealed that mindfulness training and intervention help patients relieve stress and anxiety as well as maintain positive emotions (8). Neurologically, mindfulness training affects electrical activities in the prefrontal cortex of the brain and increases the gray matter density in the left superior temporal gyrus and right hippocampus (9). At the molecular level, mindfulness training reduces the release of pro-inflammatory factors and regulates the activity of histone deacetylase (10, 11). Mindfulness training has become the mainstream psychological intervention method in clinic and has been widely used as the adjuvant management of chronic diseases (12, 13).

Citation: STEMedicine 2022, 3(4): e143 - http://dx.doi.org/10.37175/stemedicine.v3i4.143

Materials and methods

Study design

This study was performed among patients recruited from the Quanzhou First Hospital Affiliated to Fujian Medical University. Participants were randomized in a ratio of 1:1 (n = 178 versus n = 179) using a random sequence generated by the computer and received 3-month mindfulness training in addition to usual care (UC) or UC alone. Physiological and psychological outcomes were evaluated at the baseline time (T0), 3-month (T1, immediately after mindfulness training), and 6-month follow-up (T2, 3 months after mindfulness training). The researchers were blinded to the allocation of experimental groups.

Participants

Adult patients who were previously diagnosed with cardiac diseases (coronary heart disease, myocardial infraction, and ischemic) and arranged with PCI. The exclusion criteria of this study were (1) unwillingness to provide informed consent; (2) inability or unwillingness to use computer or internet; (3) with hearing impairment or dyslexia; (4) with a history of mental illness; (5) with other cardiovascular surgeries scheduled during the study period.

Mindfulness training intervention

Participants in the Mindfulness Training group received a 90-day mindfulness intervention course in addition to UC, while patients in the Control group were allocated with UC by their treating cardiologist for 90 days as well. The mindfulness training course started after patients received PCI. Given the convenience, feasibility, and limitations of time and space, mindfulness training classes were given online for patients to learn and direct themselves. The patient received an email with a link to the website which provided text descriptions, video clips, audio tracks with mindfulness exercises, breathing exercises, and information that needed to be filled in at the beginning of the study. The mindfulness training in this study included meditations, self-body scan, mindfulness breathing, mindfulness walking, and yoga exercises. The project was traced and supported by e-mails and intermittent text messages. Participants were asked to slow down and observe things around them with a curious and open attitude. Patients were taught to use their five senses to experience the current feelings, to acquire the spatial sensation of their bodies, and focus their attention on a part of their bodies until they enter a state of complete concentration. Participants were asked to take breath as an observation object, feel the breathing process and changes, and relax their bodies as they breathed. In addition, patients were required to use slow walking or yoga to fully experience their own feelings and the world around them. Their adherence was monitored by finishing the questions during this training online, and their specific answers were not disclosed and not included in the analysis.

Outcomes

The primary outcome was defined as the physiological and health-related quality of life (QoL) outcomes of patients post-PCI. Physiological outcomes were collected at the baseline time (T0), 3 month (T1, immediately after Mindfulness Training), and 6-month follow-up (T2, 3 months after Mindfulness Training). The physiological outcomes, including total cholesterol level, body mass index (BMI), diastolic blood pressure (DBP), low-density lipoprotein-cholesterol (LDL-C) level, systolic blood pressure (SBP), triglyceride level, and high-density lipoprotein-cholesterol (HDL-C) level were measured under the basic operation instructions (14). Given the particularity of the intervention of this research, blindness of patients was impossible. Thus, patients were forbidden to divulge treatment they received to assessors, and all assessors were kept unaware of the grouping of patients.

The secondary outcome was defined as the psychological outcomes of patients post-PCI. Hospital Anxiety and Depression Scale (HADS) was used to evaluate the anxiety and depression levels of participants (15). Perceived Stress Scale (PSS) (16) and Perceived Social Support Scale (PSSS12) (17) were performed, respectively, to evaluate the stress and social support of different patients. Visual Analogue Scale (VAS) ranging from 0 to 100 was utilized to estimate the patients' QoL (18). Short Form Health survey (SF-36) was used to evaluate the mental and physical QoL (19).

Statistical analysis

Chi-square test or Fishers' exact test was used to compare the classification variables. We used one-way ANOVA and a Tukey's post hoc test to analyze the continuous variables, and the contingency table Chi-square test was acquired for the comparison of outcomes among different groups.

Results

Procedure of the study

The recruitment and follow-up of the participants in this trial were shown in Fig. 1. A total number of 712 patients signed up for our study when they were assessed. A total of 357 patients who met the inclusion criteria were randomized as two groups: Mindfulness Training group (178 patients) and Control group (179 patients). Participants in the Mindfulness Training group received a scheduled mindfulness intervention in addition to UC, and patients in the Control group received only UC. Of the initial study population, 303 (84.9%) participants finished all the measurements.

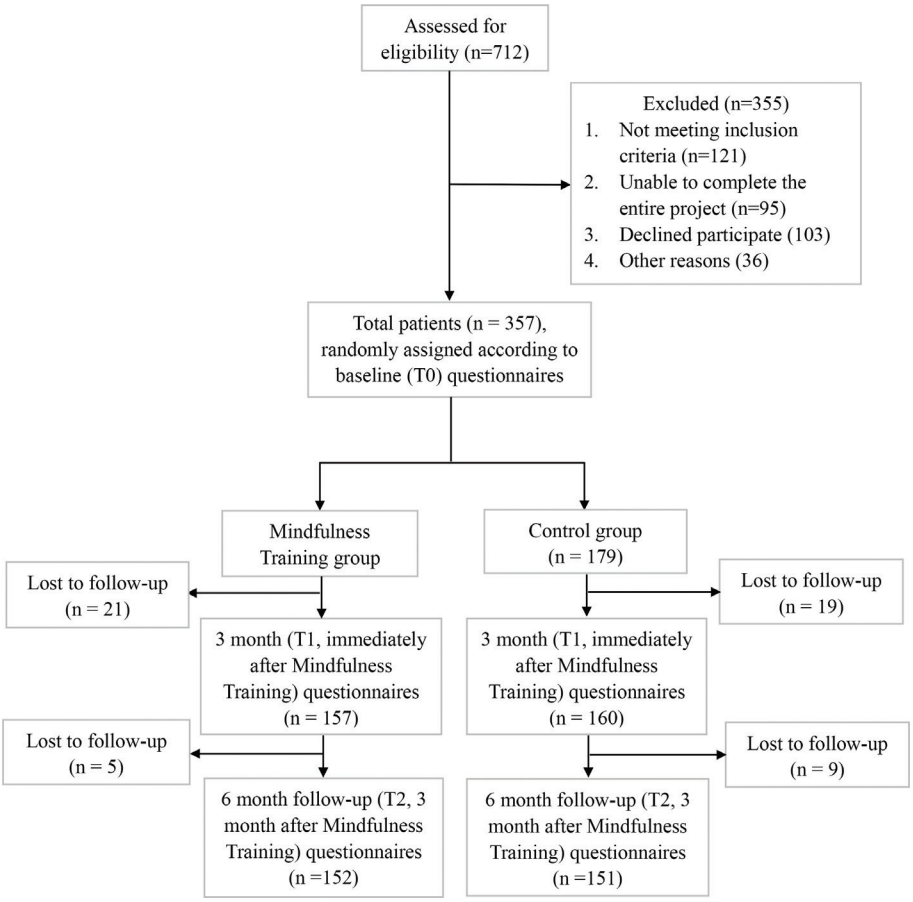

Fig. 1. Flow diagram of the study.

Characteristics of participants

The demographic characteristics of all patients were collected and shown in Table 1. The demographic parameters collected at the T0 (baseline) included age, gender, marital status, educational level, working status, and the clinical characteristics, including hypertension, hyperlipidemia, diabetes, obesity, smoking, and alcohol using medical history. In addition, no significant difference was observed in any of the above characteristics between experimental groups (Table 1).

Physiological outcome analysis

The physiological outcomes of patients with different treatments at different time points were shown in Table 2. The SBP of patients in the Mindfulness Training group decreased immediately after the 3-month mindfulness intervention (P = 0.049) and at the 6-month follow-up (P = 0.033), compared to the control group. Similarly, BMI of participants in the Mindfulness Training group decreased significantly at T1 (P = 0.035) and T2 (P = 0.001). There was also a statistical difference between the total cholesterol levels of patients in the two groups at T1 (P = 0.046) and T2 (P = 0.002). Clinically, BMI, cholesterol levels, and blood pressure are independent risk factors for recurrence in patients with coronary heart disease after treatment. The LDL-C and triglyceride levels of participants in the Mindfulness Training group both decreased at T2 (P = 0.049 and P = 0.040) compared to the Control group.

Psychological outcome analysis

The mindfulness group showed decreased anxiety score on their mean HADS at 3 months (P = 0.030) and 6 months (P = 0.015) compared with the UC group (Table 3). The depression score was also decreased in patients of the Mindfulness Training group at T1 (P = 0.030) and T2 (P < 0.001). In addition, patients in the Mindfulness Training group showed a higher self-efficacy at T1 (P = 0.008) and T2 (P = 0.004) compared with the Control group. Our 3-month mindfulness training also reduced the stress of patients post-PCI at T1 (P = 0.046). However, there was no significant difference in terms of the mental and physical QoL in participants in different groups at any time point.

Discussion

This study aimed at investigating the effects of mindfulness training on the physiological and psychological

Table 1. Baseline demographic and clinical characteristics among all the participants

Demographic characteristics	**Mindfulness Training group (*n* = 152)**	**Control group (*n* = 151)**	***P* value**
Age (years), mean (SD)	52.3 (15.2)	53.1 (14.6)	0.641
Gender, *n* (%)			0.607
Male	67 (44.1)	71 (47.2)	
Female	85 (55.9)	80 (53.0)	
Marital status, *n* (%)			0.536
Currently married	126 (82.9)	121 (80.1)	
Never married/separated/divorced/widowed	26 (17.1)	30 (19.9)	
Educational level, *n* (%)			0.739
Middle or high school	103 (58.0)	105 (64.3)	
≥College	49 (42.0)	46 (35.7)	
Working status, *n* (%)			0.131
Currently working	121 (16.8)	109 (18.2)	
Unemployed/retired/housewife	31 (83.2)	42 (81.8)	
Clinical characteristics, *n* (%)			
Hypertension			0.674
Yes	89 (58.5)	92 (60.9)	
No	63 (41.5)	59 (39.1)	
Hyperlipidemia			0.606
Yes	94 (61.8)	89 (58.9)	
No	58 (38.2)	62 (41.1)	
Diabetes			0.539
Yes	43 (28.3)	38 (25.2)	
No	109 (71.7)	113 (74.8)	
Obesity* (%)	37 (24.3)	40 (26.4)	0.668
Current smoking			0.526
Yes	13 (8.6)	10 (6.6)	
No	139 (91.4)	141 (93.4)	
Current alcohol use			0.681
Yes	83 (54.6)	86 (57.0)	
No	69 (45.4)	65 (43.0)	

Data were expressed as mean (SD) or *n* (%).
*Obesity was defined when the BMI was ≥30 kg/m^2. BMI, body mass index.

outcomes of patients post-PCI. As one of the main technologies for coronary diseases, PCI has certain shortcomings. Population undergoing PCI are often troubled by poor psychological and psychological outcomes. Accumulating evidence has demonstrated that the rate of coronary restenosis after PCI is relatively high (20). Other complications induced by negative psychological reactions post-PCI seriously affect the QoL of patients with coronary heart diseases (21). In addition, the risk factors of PCI for cardiovascular disease treatment, such as personality and emotion alteration, have not been eliminated. Previous research has demonstrated that psychological counseling or intervention in patients undergoing PCI can improve the patient's mood and regulate their autonomic nerve function, thereby alleviating myocardial ischemia and reducing the occurrence of arrhythmia (22). The hypercoagulability of patients with coronary heart diseases tends to be effectively relieved with the reduction of anxiety and other negative emotions, and the deformability of their red blood cells is also attenuated (23). Therefore, it is of great significance to design reasonable psychological intervention therapy for PCI patients and explore its effects.

In this study, we hypothesized that mindfulness training was a positive psychological intervention for patients after PCI. Participants in this trial were randomized in a ratio of 1:1 (n = 178 versus n = 179) and received 3-month mindfulness training in addition to UC or UC alone. We reported for the first time that mindfulness training could effectively reduce the SBP of patients undergoing PCI and help obese patients lose weight (Table 2). More

Table 2. Changes in physiological outcomes over time

Physiological outcomes		Mindfulness Training group (*n* = 152)	Control group (*n* = 151)	*P* value
Systolic blood pressure (mmHg)	Baseline (T0)	125.3 (16.1)	125.7 (19.6)	0.846
	3-Month follow-up (T1)	123.9 (13.9)	127.6 (18.4)	0.049
	6-Month follow-up (T2)	125.9 (18.1)	130.3 (17.6)	0.033
	P value (T0 and T1)	0.418	0.386	
	P value (T0 and T2)	0.76	0.033	
Diastolic blood pressure (mmHg)	Baseline (T0)	70.1 (10.5)	70.4 (10.9)	0.807
	3-Month follow-up (T1)	68.8 (9.7)	68.9 (8.8)	0.925
	6-Month follow-up (T2)	69.6 (8.9)	68.3 (10.3)	0.241
	P value (T0 and T1)	0.263	0.189	
	P value (T0 and T2)	0.655	0.086	
BMI (kg/m^2)	Baseline (T0)	26.1 (4.3)	25.9 (4.5)	0.693
	3-Month follow-up (T1)	25.8 (4.0)	26.8 (4.2)	0.035
	6-Month follow-up (T2)	25.6 (3.6)	27.0 (3.9)	0.001
	P value (T0 and T1)	0.529	0.073	
	P value (T0 and T2)	0.273	0.024	
Total cholesterol (mmol/L)	Baseline (T0)	4.61 (0.73)	4.74 (0.69)	0.112
	3-Month follow-up (T1)	4.52 (0.68)	4.68 (0.71)	0.046
	6-Month follow-up (T2)	4.45 (0.65)	4.71 (0.81)	0.002
	P value (T0 and T1)	0.267	0.457	
	P value (T0 and T2)	0.044	0.729	
LDL-C (mmol/L)	Baseline (T0)	2.73 (1.01)	2.69 (1.03)	0.733
	3-Month follow-up (T1)	2.68 (0.61)	2.71 (0.74)	0.700
	6-Month follow-up (T2)	2.56 (0.73)	2.74 (0.85)	0.049
	P value (T0 and T1)	0.602	0.846	
	P value (T0 and T2)	0.094	0.646	
HDL-C (mmol/L)	Baseline (T0)	1.15 (0.30)	1.14 (0.34)	0.786
	3-Month follow-up (T1)	1.19 (0.50)	1.20 (0.25)	0.826
	6-Month follow-up (T2)	1.21 (0.33)	1.18 (0.34)	0.436
	P value (T0 and T1)	0.398	0.082	
	P value (T0 and T2)	0.098	0.307	
Triglyceride (mmol/L)	Baseline (T0)	1.50 (1.05)	1.53 (1.13)	0.811
	3-Month follow-up (T1)	1.45 (0.89)	1.59 (1.15)	0.237
	6-Month follow-up (T2)	1.39 (1.09)	1.65 (1.10)	0.040
	P value (T0 and T1)	0.655	0.648	
	P value (T0 and T2)	0.371	0.351	

Data were expressed as mean (SD).
BMI, body mass index; LDL, low-density lipoprotein cholesterol; HDL, high-density lipoprotein cholesterol.

importantly, mindfulness training could reduce the cholesterol levels of patients with coronary heart diseases and reduce their symptoms of hyperlipidemia (Table 2), thereby effectively protecting their cardiovascular system. Our research also revealed the impact of mindfulness training on the psychological factors of patients undergoing PCI. Mindfulness training effectively reduced the anxiety and depression among the participants and reduced the pressure on patients from diseases and surgical interventions from the perspective of short-term and long-term effects. In particular, mindfulness training significantly improved the participants' sense of self-efficacy, suggesting that the individual's effectiveness in dealing with internal and external environmental events has been improved.

Mindfulness is defined as mental awareness and selfless distraction, which emphasizes consciously and uncritically focusing on the present (24). As a non-drug mental therapy, mindfulness treatment has achieved significant results in clinical applications. Accumulating evidence has demonstrated that mindfulness can improve patients' psychological adaptability, reduce anxiety and depression levels, correct sub-health conditions, relieve

Table 3. Changes in psychological outcomes over time

Physiological outcomes		Mindfulness Training group (*n* = 152)	Control group (*n* = 151)	*P* value
Anxiety score (HADS)	Baseline (T0)	5.9 (2.6)	5.6 (2.9)	0.344
	3-Month follow-up (T1)	5.2 (3.0)	6.0 (2.6)	0.014
	6-Month follow-up (T2)	5.1 (3.1)	6.1 (3.0)	0.005
	P value (T0 and T1)	0.030	0.207	
	P value (T0 and T2)	0.015	0.142	
Depression score (HADS)	Baseline (T0)	5.3 (2.9)	5.5 (3.0)	0.556
	3-Month follow-up (T1)	4.9 (2.7)	5.6 (2.9)	0.030
	6-Month follow-up (T2)	4.6 (3.0)	6.0 (3.1)	<0.001
	P value (T0 and T1)	0.214	0.769	
	P value (T0 and T2)	0.039	0.155	
Total score (HADS)	Baseline (T0)	10.0 (4.5)	9.9 (4.6)	0.848
	3-Month follow-up (T1)	9.5 (5.1)	10.4 (4.9)	0.024
	6-Month follow-up (T2)	8.8 (5.9)	10.8 (5.4)	0.014
	P value (T0 and T1)	0.365	0.101	
	P value (T0 and T2)	0.047	0.387	
Self-efficacy	Baseline (T0)	2.7 (0.6)	2.8 (0.5)	0.116
	3-Month follow-up (T1)	2.8 (0.7)	2.6 (0.6)	0.008
	6-Month follow-up (T2)	2.9 (0.5)	2.7 (0.7)	0.004
	P value (T0 and T1)	0.182	0.002	
	P value (T0 and T2)	0.002	0.154	
Mental QoL (SF-36)	Baseline (T0)	50.2 (9.9)	50.6 (10.3)	0.731
	3-Month follow-up (T1)	51.9 (10.4)	50.1 (9.6)	0.118
	6-Month follow-up (T2)	52.8 (9.8)	50.7 (10.8)	0.077
	P value (T0 and T1)	0.145	0.663	
	P value (T0 and T2)	0.022	0.934	
Physical QoL (SF-36)	Baseline (T0)	45.3 (12.2)	45.5 (13.4)	0.892
	3-Month follow-up (T1)	45.6 (13.1)	46.0 (11.8)	0.780
	6-Month follow-up (T2)	45.4 (12.1)	46.2 (13.3)	0.584
	P value (T0 and T1)	0.836	0.731	
	P value (T0 and T2)	0.943	0.649	
Quality of life (VAS)	Baseline (T0)	75.2 (12.9)	74.3 (11.6)	0.524
	3-Month follow-up (T1)	75.9 (13.1)	74.9 (12.1)	0.491
	6-Month follow-up (T2)	76.3 (11.2)	75.3 (11.4)	0.442
	P value (T0 and T1)	0.639	0.660	
	P value (T0 and T2)	0.428	0.451	
Stress (PSS)	Baseline (T0)	22.3 (7.5)	22.0 (7.8)	0.733
	3-Month follow-up (T1)	20.4 (8.3)	22.3 (8.2)	0.046
	6-Month follow-up (T2)	20.1 (7.9)	21.3 (7.8)	0.184
	P value (T0 and T1)	0.037	0.745	
	P value (T0 and T2)	0.013	0.436	
Social support (PSSS12)	Baseline (T0)	69.1 (11.0)	71.0 (12.6)	0.163
	3-Month follow-up (T1)	71.7 (11.6)	69.5 (12.3)	0.110
	6-Month follow-up (T2)	72.1 (9.9)	68.8 (10.9)	0.006
	P value (T0 and T1)	0.046	0.296	
	P value (T0 and T2)	0.013	0.106	

Data were expressed as mean (SD).

HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form Health survey; QoL, Quality of Life; VAS, Visual Analogue Scale; PSS, Perceived Stress Score; PSSS12, Perceived Social Support Scale.

pain, and improve patients' immunity (25). In recent years, a large number of studies have demonstrated that mindfulness decompression therapy improves the mental health level, emotional regulation ability, self-behavior management, and QoL of patients with multiple diseases, and it can be used as an adjuvant treatment for physiological problems caused by multiple diseases (26). Park et al. performed a randomized controlled trial and demonstrated that 6-week mindfulness decompression therapy could alter the gene expression of cancer tissues in breast cancer patients, thereby improving patient prognosis (11). Johns et al. showed that mindfulness decompression therapy reduced cancer-related fatigue in cancer patients (27). It is reported that mindfulness training can effectively reduce the mid-term anxiety of diabetic patients, enhance their health management capabilities, improve patient compliance, and exert a significant effect on controlling mid- and long-term blood sugar levels (28). In addition, a randomized controlled experiment on 127 patients with arthritis also demonstrated the relieving effect of mindfulness training on chronic pain (29). In another study, the mindfulness training group was significantly better than the control group in terms of joint stiffness, self-efficacy, mindfulness level, and pain level (29). Similar to these previous findings, we also confirmed the positive effects of mindfulness training intervention on patients with coronary heart diseases in this study. We speculate that the effects of mindfulness training in the recovery of patients after PCI are similar to its function in the treatment of cancer and other chronic diseases. Therefore, mindfulness training has the potential to play a beneficial role in the care of PCI patients.

Due to the limitation of resources and time, we adopted the method of online teaching in this study. Considering the different understanding and execution abilities of different patients, it was very likely that some participants had not fully implemented our mindfulness training. Although we designed a questionnaire containing multiple questions to assess participants' learning about the mindfulness courses, existing deviations might still affect the accuracy of our research. The adherence of participants was monitored by finishing the questions during the training online, and their specific answers were not disclosed and not included in the analysis. However, our means of assessing patient compliance were still limited. In addition, we mainly evaluated the influence of mindfulness training on physiological indexes such as blood pressure and blood lipid. Considering that some patients had multiple chronic diseases at the same time and were taking different drugs, these physiological characteristics were inevitably disturbed by factors other than mindfulness training. We hope that the diet and exercise in UC and changes in the patient's mental state may exclude the influence of other factors and reflect the effectiveness of mindfulness training.

In conclusion, we hereby report that online mindfulness training is feasible in patients who underwent PCI and shows positive effects on their physiological and psychological outcomes. Physiologically, the 3-month mindfulness training improved the physiological outcomes, including SBP, BMI, total cholesterol level, LDL-C, and triglyceride levels of patients. Psychologically, our mindfulness training effectively reduced the patient's anxiety and depression levels and improved the patient's self-efficacy. We will try to design more effective mindfulness training methods and to expand the role of mindfulness training in the management of other chronic diseases in future research.

Acknowledgments

None.

Conflict of interest and funding

The authors declare that they have no conflicts of interest and funding.

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