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# The impact of cardiac rehabilitation program on anxiety and depression levels after coronary artery bypass graft surgery

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#### SOUHRN

Cíl: Zhodnotit ovlivnění míry deprese a anxiety rehabilitačním programem pro kardiaky po aortokoronárním bypassu. Deprese a anxieta jsou spojeny s horším výsledkem po provedení aortokoronárního bypassu. **Metody:** Do studie jsme zařadili 40 po sobě následujících pacientů po aortokoronárním bypassu, kteří se následně zúčastnili osmitýdenního rehabilitačního programu pro kardiaky (cardiac rehabilitation program, REH). Pacienti byli osobně dotazováni na jejich subjektivní hodnocení míry deprese a anxiety. Se všemi pacienty vyplňoval před absolvováním programu a po něm výzkumný tým dotazníky BDI-II (Beck's Depression Inventory-II) a BAI (Beck's Anxiety Inventory). Hodnoty skóre BDI-II a BAI byly zaznamenány a zjištěné změny byly porovnávány pomocí párového t-testu. Za statisticky významné byly považovány hodnoty p < 0,01. **Výsledky:** Do studie bylo zařazeno 33 mužů (82,5 %) a 7 žen průměrného věku 58,3  $\pm$  8,8 roku. Po absolvování programu REH došlo k významnému poklesu průměrných skóre BDI-II (4,7  $\pm$  4,4;  $\pm$  6,72; p < 0,001). Průměrná skóre BAI po absolvování programu REH se rovněž významně snížila (4,3  $\pm$  5,7;  $\pm$  4,74; p < 0,001). Byla nalezena korelace mezi skóre před programem REH a po jeho absolvování jak v případě deprese ( $\pm$  0,860;  $\pm$  0,001), tak anxiety ( $\pm$  0,631;  $\pm$  0,001).

**Závěr:** Po absolvování rehabilitačních programů pro kardiaky došlo u pacientů po provedení aortokoronárního bypassu ke snížení míry anxiety i deprese. Pro tyto pacienty může být program z psychického hlediska přínosný, protože se mohou dobře vyrovnávat s novými změnami jejich zdravotního stavu.

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#### **ABSTRACT**

**Purpose:** To investigate the role of cardiac rehabilitation program in depression and anxiety levels after coronary artery bypass graft surgery. Depression and anxiety are associated with worse outcome after coronary artery bypass graft surgery.

**Methods:** We enrolled 40 consecutive patients who underwent coronary artery bypass graft surgery. They participated in an eight-week cardiac rehabilitation program (REH). Patients were personally interviewed for assessment of depression and anxiety. A research team member completed Beck's Depression Inventory-II (BDI-II) and Beck's Anxiety Inventory (BAI) for all patients before and after the rehabilitation program. BDI-II and BAI scores were recorded and the changes in the scores were compared using paired *t*-test. *P*-values <0.01 were considered statistically significant.

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L. Pourafkari et al.

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**Results:** Thirty-three male (82.5%) and 7 female patients with an average age of  $58.3 \pm 8.8$  years were studied. Mean BDI-II scores decreased significantly (4.7  $\pm$  4.4, t = 6.72, p <0.001) with participation in REH program. Mean BAI scores also decreased significantly with participation in REH program (4.3  $\pm$  5.7, t = 4.74, p < 0.001). There was a positive correlation between pre-REH and post-REH scores of both depression (r = 0.860, p < 0.001) and anxiety (r = 0.631, p < 0.001).

**Conclusion**: Cardiac rehabilitation programs decreased the levels of anxiety and depression in patients after coronary artery bypass graft surgery. These patients may benefit from this program psychologically and therefore, may cope well with the new changes in their health condition.

#### Introduction

Cardiac rehabilitation programs reduce mortality and hospital readmissions in patients with coronary artery diseases (CAD) [1]. Benefits of cardiac rehabilitation programs are attributed to a combination of different factors. Physiological effects of exercise trainings, better adherence to pharmacotherapy and promotion of psychological health are among the potential contributors to reducing mortality and improvement of modifiable cardiac risk factors by these programs [2–5].

In recent years, the relationship between psychological disorders and CAD has received significant attention [6,7]. Prevalence of depressive symptoms in patients with CAD is substantially higher than in general population [7]. In addition, depression and anxiety disorders may lead to a poor outcome after coronary artery events [8-10]. Although the role of depression in patients with CAD is a matter of controversy, treating severe depressive disorders in this population improves their adherence to the pharmacological treatments and prescribed lifestyle modifications [11,12]. Rothenhausler et al. described a significant improvement in the quality of life after elective coronary artery bypass grafting (CABG). In this study, the frequency of symptoms related to a lower quality of life compared to others [13]. Recent studies on the psychological benefits of rehabilitation programs after myocardial infarction or CABG have demonstrated promising results in reducing anxiety and depressive symptoms [14–16]. Despite this potential benefit, cardiac rehabilitation programs are generally underused in patients with major cardiac diseases [17].

Considering the fact that CAD are the main causes of morbidity and mortality worldwide, identifying potential factors that may improve the prognosis of the disease is of great importance [18]. Moreover, depression and anxiety disorders are gradually emerging as main sources of morbidity in general population [19]. In this study, we investigated the impact of an eight-week cardiac rehabilitation program including both exercise training and educational programs, on depressive and anxiety symptoms after CABG. We hypothesized that the severity of anxiety and depression decreased following this rehabilitation program.

#### **Methods and materials**

#### Study design

The study design was reviewed and approved by the Institutional Review Board Committee at Tabriz University of Medical Sciences. Voluntary written informed consent was obtained from all participating patients. Resear-

chers interviewed all patients to gather demographic information and completed Beck Anxiety Inventory (BAI) and Beck Depression Inventory-II (BDI-II) questionnaires before beginning of the cardiac rehabilitation program [20,21]. One week following the completion of the rehabilitation program, we interviewed the patients and filled out the BAI and BDI-II questionnaires once again. These scores were recorded and compared to those obtained before cardiac rehabilitation program.

## Study sample size determination and power analysis

Sample size was determined using the average of 12.5  $\pm$  8.7 in BDI-II scores reported after CABG surgery by others [22]. Thirty percent reduction in BDI-II scores was considered clinically significant. The required sample size for one-sample comparison of the means with alpha error of 0.05 and power of 0.80 was 28 patients. We enrolled 40 eligible consecutive patients who were referred to an outpatient cardiac rehabilitation program in university clinic after undergoing CABG. The power of the analysis for a sample size of 40 patients was 0.92 for both BDI-II and BAI. Patients younger than 30 years or older than 70 years and patients with a history of pre-morbid depression or anxiety disorders were excluded from the study.

#### Anxiety and depression screening tools

The second edition of Beck Depression Inventory-II was used to evaluate depressive symptoms. This inventory included 21 multiple-choice questions that self-report the severity of depression symptoms. In this questionnaire each answer has a score on a scale value of 0–3. The cutoff points for different categories were as follows: minimal depression 0–13, mild depression 14–19, moderate depression 20–28 and severe depression 29–63. The Beck Anxiety Inventory, also a 21-item self-report multiple-choice questionnaire, was used to assess the severity of symptoms related to anxiety. Similar to BDI-II, each answer in BAI had a score on a scale value of 0–3. The range of total scores was from 0 to 63. The cutoff points for classification are as follows: 0–7 minimal anxiety, 8–15 mild anxiety, 16–25 moderate anxiety, and 26–63 severe anxiety.

#### Cardiac rehabilitation protocol

The cardiac rehabilitation program consisted of supervised exercise training and risk factor modification education. The duration of the program was eight weeks and each session lasted 1 h for three times per week and constituted of warm-up exercises, aerobic training and cool-down exercises. Intensity of exercise was individualized based on pa-

tient's clinical status to achieve 60–85% of maximal heart rate. Each patient was consulted and educated individually about the cardiac risk factors and impact of lifestyle modifications on cardiac diseases. Participants received consultations for dietary and lifestyle modifications and smoking cession, psychological consultations and education about the nature of cardiac diseases.

#### Statistical analysis

Statistical software SPSS (IBM™ ver. 22.0, Chicago, IL) was used for data analysis. Continuous variables were presented as the mean ± standard deviation and categorical variables were stated as frequencies and percentages. Fisher's exact test or Chi-square analysis was done as appropriate to compare the frequencies of categorical variables. Paired sample *t*-test was used to compare the difference of continuous variables before and after cardiac rehabilitation program. Pearson correlation test was used to assess the relationship between continuous variables. *P*-values less than 0.05 were considered statistically significant.

#### Results

#### Baseline characteristics

The mean age of patients was  $58.3 \pm 8.8$  years. In our sample 33 out of 40 patients (82.7%) were male and seven out of 40 patients (17.5%) were female. Mean body

mass index (BMI) was  $27.8 \pm 4.1 \text{ kg/m}^2$ . The prevalence of diabetes, hypertension and hyperlipidemia was 12%, 45% and 8% respectively. History of smoking was present in 28% of patients and 15% were current smokers. Twenty-two (55.0%) patients were employed and 39 (97.5%) of them were married.

## Anxiety and depression scores before cardiac rehabilitation

Before beginning of cardiac rehabilitation program, mean BAI total score and mean BDI score were  $8.8 \pm 7.4$  (range, 1–37) and  $12.1 \pm 8.7$  (range, 1–40), respectively. According to the BAI scores and anxiety levels, 17 patients (42.5%) reported more than minimal level of anxiety (12 patients 30.0% had mild anxiety, 3 patients 7.5% had moderate anxiety and 2 patients 5.0% had severe anxiety). Table 1 depicts distribution of demographic variables and comorbidity coronary risk factors between patients with more than minimal anxiety symptoms and those with no anxiety. There was no significant difference in demographics, coronary risk factor or medication history between patients with more than minimal anxiety and those with no anxiety.

Based on cutoff points for classification of depression levels, 75% had minimal depression, 12% had mild depression, 8% had moderate depression and 5% had severe depression. Table 2 depicts distribution of demographic variables and comorbidity coronary risk factors between

symptoms and those with no anxiety.							
	Anxiety (n = 17)	No anxiety (n = 23)	Risk (odds ratio)	<i>P</i> -value			

	(n = 17)	(n = 23)	Risk (odds ratio)	<i>P</i> -value
Gender (% male)	13 (76.5%)	20 (87.0%)	0.69 [0.32–1,49]	0.326
Age (y)	58 [31–71]	59 [40–75]	0.96 [0.89–1.04]	0.508
Body mass index (kg/m²)	27.5 [21.4–39.0]	26.8 [23.4–36.4]	1.05 [0.91–1.22]	0.890
Marital status (% single)	0 (0.0%)	1 (4.3%)	Not calculated	0.575
Living place (% rural)	1 (5.9%)	1 (4.3%)	1.16 [0.28–4.75]	0.767
Employment status (% employed)	7 (41.2%)	15 (65.2%)	0.65 [0.36–1.18]	0.117
Education (% college education)	3 (17.6%)	4 (17.4%)	1.00 [0.50-2.04]	0.649
History of smoking	5 (29.4%)	6 (26.1%)	1.08 [0.58–2.00]	0.546
Current smoking	2 (11.8%)	4 (17.4%)	0.84 [0.44-1.59]	0.489
Family history of CAD	3 (17.6%)	8 (34.8%)	0.71 [0.43–1.18]	0.201
Diabetes mellitus	1 (5.9%)	4 (17.4%)	0.68 [0.40–1.16]	0.280
Hypertension	8 (47.1%)	10 (43.5%)	1.06 [0.62–1.83]	0.538
Hyperlipidemia	1 (5.9%)	2 (8.7%)	0.85 [0.37–1.99]	0.615
Beta blockers	12 (70.6%)	15 (65.2%)	1.13 [0.60–2.12]	0.527
ACEI/ARB drugs	8 (47.1%)	9 (39.1%)	1.15 [0.65–2.06]	0.442
Aspirin	15 (88.3%)	19 (82.6%)	0.90 [0.22-3.69]	0.698
Statins	11 (63.7%)	17 (73.8%)	0.62 [0.24–1.59]	0.223
Change in depression scores	4.5 ± 4.8*	4.8 ± 4.2*	Not calculated	0.676
Change in anxiety scores	6.7 ± 8.2*	2.6 ± 1.6*	Not calculated	0.012 <sup>†</sup>

ACEI – angiotensin converting enzyme inhibitor; ARB – angiotensin receptor blocker; CAD – coronary artery disease.

<sup>\*</sup> Significant intragroup difference.

<sup>†</sup> Significant intergroup difference.

L. Pourafkari et al. 435

Table 2 – Distribution of demographic variables and comorbidity coronary risk factors between patients with more than minimal depressive symptoms and those with no depression.

depressive symptoms and those with no depressi	511.			
	Depression (n = 10)	No depression (n = 30)	Risk (odds ratio)	<i>P</i> -value
Gender (% male)	9 (90.0%)	24 (80.0%)	0.44 [0.05–4.22]	0.428
Age (y)	60 [52–71]	58 [31–75]	1.04 [0.95–1.14]	0.508
Body mass index (kg/m²)	27.6 [21.7–39.0]	26.7 [24.6–36.2]	0.99 [0.83–1.18]	0.890
Marital status (% single)	0 (0.0%)	1 (3.3%)	Not calculated	0.750
Living place (% rural)	2 (20.0%)	0 (0.0%)	Not calculated	0.058
Employment status (% employed)	4 (40.0%)	18 (60%)	0.82 [0.56–1.19]	0.231
Education (% college education)	2 (20.0%)	5 (16.7%)	1.06 [0.64–1.76]	0.572
History of smoking	1 (10.0%)	10 (33.3%)	0.76 [0.56–1.03]	0.154
Current smoking	0 (0.0%)	6 (20.0%)	Not calculated	0.155
Family history of depression	3 (30.0%)	8 (26.7%)	1.04 [0.69–1.58]	0.568
Diabetes mellitus	0 (0.0%)	5 (16.7%)	Not calculated	0.217
Hypertension	3 (30.0%)	15 (50.0%)	0.82 [0.58–1.16]	0.233
Hyperlipidemia	0 (0.0%)	3 (10.0%)	Not calculated	0.411
Beta blockers	6 (60.0%)	21 (70.0%)	0.96 [0.62–1.51]	0.604
ACEI/ARB drugs	5 (50.0%)	12 (40.0%)	1.18 [0.82–1.71]	0.311
Aspirin	9 (90.0%)	25 (83.3%)	Not calculated	0.557
Statins	7 (70.0%)	21 (70.0%)	1.00 [0.64–1.57]	0.667
Change in depression scores	8.2 ± 6.5*	3.5 ± 2.7*	Not calculated	0.049⁺
Change in anxiety scores	5.6 ± 10.1*	3.9 ± 3.4*	Not calculated	0.729

ACEI – angiotensin converting enzyme inhibitor; ARB – angiotensin receptor blocker.

Table 3 – Linear regression model constructed for changes in BAI scores as the dependent variable. Pre-rehabilitation state of anxiety, social and coronary risk factors along with current medication history were used as independent variables. The presence of anxiety prior to the rehabilitation program was the only independent predictor of decreases in anxiety scores.

	Coefficients				95.0% confidence interval	
Model	В	Std. error	t	<i>P</i> -value	Lower bound	Upper bound
Constant	-11.273	5.482	-2.056	0.054	-22.747	0.202
Gender (male = 0, female =1)	0.169	1.925	0.088	0.931	-3.860	4.198
College education	1.868	1.813	1.031	0.316	-1.926	5.663
Employment	-1.493	1.360	-1.098	0.286	-4.339	1.354
Rural living place	3.444	2.541	1.356	0.191	-1.873	8.762
History of smoking	0.745	1.515	0.492	0.628	-2.426	3.917
Family history of CAD	0.300	1.605	0.187	0.854	-3.059	3.659
Diabetes mellitus	-2.038	1.935	-1.053	0.305	-6.089	2.013
Hypertension	-2.409	1.690	-1.426	0.170	-5.945	1.127
Hyperlipidemia	0.503	2.078	0.242	0.811	-3.847	4.852
Body mass index (kg/m²)	0.283	0.166	1.705	0.104	-0.064	0.630
Beta blockers	-2.481	1.684	-1.473	0.157	-6.006	1.044
ACEI/ARB drugs	1.278	1.801	0.709	0.487	-2.492	5.048
Aspirin	1.046	3.186	0.328	0.746	-5.622	7.715
Statins	3.095	2.070	1.495	0.151	-1.238	7.428
Pre-rehab anxiety	-2.868	1.339	-2.142	0.045*	-5.671	-0.065

ACEI – angiotensin converting enzyme inhibitor; ARB – angiotensin receptor blocker; CAD – coronary artery disease. \*Significant p-value.

<sup>\*</sup> Significant intragroup difference.

<sup>&</sup>lt;sup>†</sup> Significant intergroup difference.

patients with more than minimal depressive symptoms and those with no depression. There was no significant difference in demographics, coronary risk factor distribution and medication history between patients who reported more than minimal depressive symptoms compared to those who had none.

## Anxiety and depression scores after cardiac rehabilitation

After completing the cardiac rehabilitation program, mean BAI total score and mean BDI total score were  $4.7 \pm 5.6$  (range, 1-37) and  $7.5 \pm 7.7$  (range, 1-40), respectively. Based on cutoff points for classification of anxiety levels, 86% of patients had minimal anxiety, 12% had mild anxiety, and 2% had severe anxiety. Among those with more than minimal anxiety symptoms, 13 out of 17 patients (64%) improved regarding anxiety severity subclasses. Changes in anxiety scores were significant between patients who had more than minimal anxiety.

Based on cutoff points for classification of depression levels, 88% had minimal depression, 8% had mild depression, and 5% had severe depression.

There was no significant correlation between anxiety scores and depression scores after cardiac rehabilitation, r = 0.2740, n = 40, p = 0.087.

## Comparison of anxiety and depression scores before and after cardiac rehabilitation

Comparison of anxiety scores before and after cardiac rehabilitation revealed statistically significant decline in BAI score (8.8  $\pm$  7.4 vs. 4.7  $\pm$  5.6, p-value <0.001). There was a positive correlation between the two scores before and after rehabilitation, r = 0.631, n = 40, p <0.001. Patients who had higher scores before rehabilitation scored higher after rehabilitation.

The comparison of depression scores before and after cardiac rehabilitation also revealed statistically significant decline in BDI score (12.1  $\pm$  8.7 vs. 7.5  $\pm$  7.7, p-value <0.001). There was also a positive correlation between two scores before and after rehabilitation, r = 0.8600, n = 40, p < 0.001. Patients who had higher BDI scores before rehabilitation scored higher after rehabilitation.

Linear regression models were constructed for changes in BAI and BDI-II scores as the dependent variable and are shown in Tables 3 and 4.

#### Discussion

According to our results, in patients with new onset anxiety and depressive symptoms after undergoing CABG, participation in an eight-week cardiac rehabilitation program decreases both anxiety and depressive symptoms [7,22].

Anxiety and depressive symptoms are prevalent in patients with major cardiac events [7]. Although premorbid anxiety and depressive disorders predispose patients to coronary diseases [10], the emergence of new onset depression and anxiety after myocardial infarction or CABG is also associated with a poor outcome [9,23]. Despite the

Table 4 – Linear regression model constructed for changes in BDI-II scores as the dependent variable. Pre-rehabilitation state of depression, social and coronary risk factors along with current medication history were used as independent variables. The presence of depression prior to the rehabilitation program was an independent predictor of decreases in depression scores along with history of hypertension and being employed (p-values are marked with asterisks). There was a strong trend of increasing depression scores in patients with history of smoking and use of ACEI/ARB.

	Coefficients				95.0% confidence interval	
Model	В	Std. error	t	<i>P</i> -value	Lower bound	Upper bound
Constant	8.484	8.535	0.994	0.333	-9.446	26.414
Gender (male = 0, female = 1)	-0.745	2.092	-0.356	0.726	-5.141	3.651
College education	1.091	1.988	0.549	0.590	-3.086	5.267
Employment	-5.109	1.543	-3.311	0.004*	-8.351	-1.868
Rural living place	5.181	3.018	1.717	0.103	-1.160	11.523
History of smoking	3.154	1.586	1.989	0.062	-0.177	6.486
Family history of CAD	0.789	1.595	0.495	0.627	-2.561	4.140
Diabetes mellitus	-2.554	2.258	-1.131	0.273	-7.297	2.189
Hypertension	-4.284	1.930	-2.219	0.040*	-8.339	-0.229
Hyperlipidemia	-4.046	2.288	-1.768	0.094	-8.853	0.761
Body mass index (kg/m²)	-0.029	0.184	-0.158	0.876	-0.417	0.358
Beta blockers	-2.141	1.959	-1.093	0.289	-6.256	1.975
ACEI/ARB drugs	4.317	2.194	1.967	0.065	-0.293	8.928
Aspirin	-4.134	3.435	-1.204	0.244	-11.350	3.082
Statins	1.308	2.225	0.588	0.564	-3.367	5.982
Pre-rehab depression	-8.091	1.975	-4.097	0.001*	-12.240	-3.942

L. Pourafkari et al.

fact that the complex pathophysiological interactions between mental disorders and coronary diseases are not well understood [12,24], the evidence confirms the beneficial effects of therapy for psychiatric disorders on prognosis of cardiac diseases and quality of life [6,26]. However, therapeutic approach to management of psychiatric disorders after cardiac events is a matter of controversy [6,17,25]. Psychological consulting [26], pharmacotherapy with antidepressants [27], pharmacotherapy with statins [28] and exercise training [29] are studied individually or in combination with promising results [30]. Nevertheless, mental disorders after major cardiac events are still under diagnosed [11].

Cardiac rehabilitation programs after myocardial infarction or CABG are designed mainly to improve cardiovascular symptoms. However, such programs may also impact mental well-being and quality of life in patients [29]. Szczepanska-Gieracha et al. evaluated the efficacy of an early 3-week cardiac rehabilitation regarding the reduction of negative psychological symptom after CABG in 50 patients. In their study, mean scores of anxiety and depression decreased significantly after cardiac rehabilitation program [31]. Our study revealed the same results regarding the change in anxiety and depressive symptoms. They also showed that overall efficacy of the program was lower in patients with anxiety and depression. In their study, anxiety-depression scores before cardiac rehabilitation correlated with scores after the program [31], which is also consistent with our results. In other words, despite a decrease in severity of the symptoms, patients with higher levels of anxiety or depression before engaging in cardiac rehabilitation programs had higher levels of symptoms after completing the program. This fact suggests that patients with more severe symptoms may require further interventions in addition to cardiac rehabilitation programs.

According to our results, there was no significant correlation between anxiety and depression scores either before or after the cardiac rehabilitation. This is in contrast to the study by Szczepanska-Gieracha et al. [31]. In one study conducted by Rymaszewska et al., level of anxiety was measured in 53 CABG candidates, before and after surgery. The results revealed that the level of anxiety decreases after cardiac surgery; however, the change was smaller for depression [22]. This indicates the need for more precise investigation of different subgroups of mental disorders in patients with coronary diseases, in future studies. The prevalence of depression in our sample was 25%, which is consistent with previously reported data [7,31]. The mean BDI score in our study was 12, which is lower than another report from our country with means of 19 [32]. Sharif et al. compared the efficacy of cardiac rehabilitation program with educational program alone. Although anxiety symptoms were not significantly different between two groups, their study revealed same results as our study in terms of improving anxiety and depressive symptoms after cardiac rehabilitation [32].

An early intervention to improve the psychological disorders, besides traditional coronary risk factors is highly emphasized in recent years [6,25]. As demonstrated in our study, an eight-week course cardiac rehabilitation program including both exercise training and educational programs significantly reduced anxiety and depre-

ssion levels after CABG. Reduction of mortality in depressed patients after myocardial infarction is achieved by effective treatment of depression [33]. However, different therapeutic methods for improvement of psychological disorders in patients with cardiac diseases are proposed [6,24,25]. In one meta-analysis, efficacy of antidepressants and psychotherapies in reduction of depressive symptoms is compared with cardiac rehabilitation programs. The results revealed that cardiac rehabilitation is superior to antidepressants and psychotherapies for reducing total mortality risk [25]. In one study published by Milani and Lavie mild improvements in levels of fitness after cardiac rehabilitation were associated with reduction in depressive symptoms and the excess mortality accompanying these symptoms [4]. In our study, a supervised exercise training accompanying other components of cardiac rehabilitation program was used to evaluate the outcomes and we concluded that improvement in mental well-being was significant.

#### Conclusion

An eight-week cardiac rehabilitation program including exercise and educational components significantly reduces depressive and anxiety scores in patients after coronary artery bypass graft surgery.

#### Limitations

Our study included the patients who accepted to participate in cardiac rehabilitation therapy. But the patients who refused to participate in the program may differ in baseline characteristics. We should also note that participants were screened two times without further long-term follow-up.

#### **Conflict of interest**

No conflict of interest.

#### **Funding body**

None.

#### **Ethical statement**

I declare, on behalf of all authors that the research was conducted according to Declaration of Helsinki.

#### Informed consent

I declare, on behalf of all authors that informed consent was obtained from all patients participating in this study.

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