













The effect of home-based cardiac rehabilitation on depression score in patients with ischemic heart disease: A longitudinal clinical trial study

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Original Article

Abstract

BACKGROUND: Depression is common in patients with cardiovascular disease (CVD). Home-based cardiac rehabilitation (HBCR) is a program that alleviates depression. This study aimed to determine and compare HBCR programs and usual care (UC) effects on depression control in patients with ischemic heart disease (IHD).

METHODS: This clinical trial study was performed on 259 patients with IHD that were randomly allocated to the HBCR and UC groups for stress management. Data were collected using the "Beck Depression Inventory" (BDI) at baseline and 6 and 12 months. Generalized estimating equation (GEE) models were applied to examine the associations between times of the groups and changes in outcomes over the study times. Data analysis was done in SPSS software at the significance level of 0.05.

RESULTS: A total of 247 participants with a mean age of 55.22 ± 7.40 years participated in this study, and 209 (84.6%) of the study participants were men. Among patients, 128 patients in the UC program and 119 patients in the HBCR program attended at least one of the pre-determined visits (months 6 and 12). The patterns of change of the depression parameter were similar through the course of the study between the two groups ($P = 0.04$). In the HBCR group, the depression reduced continuously from baseline to 6 months, baseline to 12 months, and 6 to 12 months ($P < 0.05$). In the UC group, depression was significantly reduced from baseline to 6 months and from baseline to 12 months.

CONCLUSION: HBCR was effective in continuous reducing of depression scores in long-term follow-up of patients with IHD. These findings suggest that HBCR can alleviate depression in patients who do not participate in hospital-based cardiac rehabilitation (CR).

Keywords: Cardiovascular Rehabilitation; Depression; Myocardial Ischemia; Exercise Therapy

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Introduction

Cardiovascular disease (CVD) is the leading cause of disease burden globally and in 2019, it caused 6.2 million deaths of people aged 30-70 years.¹ Depression is a common problem in patients with CVD, leading to increased mortality and decreased quality of life (QOL).

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Notably, depression challenges the management of CVD by affecting risk factors of CVD and reducing adherence to a healthy lifestyle and medical therapies.² Evidence shows that depressive symptoms are associated with higher rates of cardiovascular events in patients with ischemic heart disease (IHD).³ In addition, symptoms of depression are associated with increased hospitalization, especially cardiac admission, and decreased secondary prevention measures, and can affect disease prognosis and enhance health care costs.⁴

Notably, depression is associated with the number and duration of cardiac hospitalizations and mortality from all causes in patients with IHD.⁵ Evidence shows that depressive symptoms are related to many lifestyle risk factors in patients with IHD and further reduce physical activity, medication adherence, and sleep quality.⁶ A systematic review and meta-analysis conducted in Iran showed that the prevalence of depression in cardiovascular patients was 47%, which is higher than that in developed countries.⁷

Cardiac rehabilitation (CR) in patients with IHD is associated with reducing depressive symptoms and related mortality. Only a slight improvement in fitness level is required to provide these benefits for the symptoms of depression and the resulting mortality.⁸ Moderate depression symptoms are prevalent in 18% of adults entering CR programs.⁹ However, depression is associated with decreased outpatient CR completion and adherence rate and worsens clinical outcomes.^{10,11} Clinical, logistic, and health system factors are the main factors of non-participation in CR.¹²

Home-based CR (HBCR) is a valuable and safe alternative strategy for low to moderate-risk patients who are eligible for CR but cannot attend a hospital-based CR.^{13,14} Besides, HBCR is associated with more patient satisfaction and is more cost-effective than hospital-based CR.¹⁵ Previous studies show that hospital-based and home-based exercise training effectively reduces depressive symptoms.¹⁶⁻¹⁸ Evidence showed that reducing depression was associated with improved exercise capacity and QOL during CR.¹⁹ Even after CR, depression is associated with other types of psychological stress that lead to higher mortality.²⁰

Despite the usefulness of HBCR, the evidence for its effectiveness in reducing depression in heart patients is limited. In this study, we sought to compare the effects of HBCR on depression in patients with IHD.

Materials and Methods

The present study is a multicenter randomized

clinical trial that compared the effectiveness of an HBCR program versus usual care (UC) in the depression of patients with IHD. In this study, 259 patients were recruited from Al-Zahra, Chamran, and Noor Hospitals in Isfahan, Iran. All patients with IHD who were reluctant to participate in a hospital-based CR program were eligible for inclusion in the study and were selected during hospital discharge. Patients with dementia, unstable angina, cardiac arrhythmia, and inability to exercise were excluded.

The data collection tool for the present study was the Beck Depression Inventory (BDI). BDI has been validated in a previous study in Iran.²¹ In the present study, internal consistency was measured by Cronbach's coefficient alpha ($\alpha = 0.87$). After baseline measurements, eligible patients were randomized in a 1:1 ratio to either HBCR and UC groups based on randomized blocks. The flow diagram for randomization is given in figure 1. The intervention group received a comprehensive HBCR program, which included four supervised CR sessions and eight weeks of home rehabilitation. The control group received the UC program, which included general recommendations for a healthy lifestyle, aerobic exercise, and nutritional guidelines. Project statisticians and outcome assessors were blinded to the study groups.

Statistical analyses: The SPSS statistical software (version 20.0, IBM Corporation, Armonk, NY, USA) was used for all data analyses. Categorical data were reported as numbers (percentage) and continuous variables were presented as mean \pm standard deviation (SD). The Kolmogorov-Smirnov test was applied to examine the normality assumption of quantitative variables. The chi-square test (or Fisher's exact test) was used to test the differences of frequency distributions in contingency tables. Generalized estimating equation (GEE) models were applied to examine the associations between times of the groups and changes in outcomes over the time of the study. Time points in the analyses were included at baseline and 6 and 12 months. P-values less than 0.05 were considered statistically significant.

Ethical approval: Ethics Committee on Research of National Institute of Medical Research Development of Iran approved the informed consent (approval number: IR.NIMAD.REC.1394.019). The study was conducted in accordance with the Declaration of Helsinki. Iranian Registry of Clinical Trials (IRCT) approved the study protocol (approval number: IRCT2016022926820N1) according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

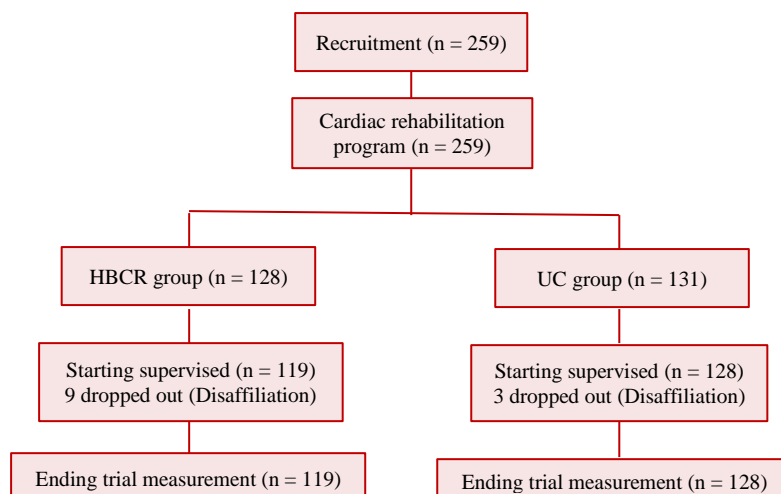


Figure 1. The flow diagram for the randomization process of the study
HBCR: Home-based cardiac rehabilitation; UC: Usual care

Results

A total of 247 patients with a mean age of 55.22 ± 7.40 years (range: 29-69 years) participated in this study. 38 (15.4%) of patients were women and 209 (84.6%) patients were men. Among patients, 128 patients in the UC program and

119 patients in the HBCR program attended at least one of the pre-determined visits (months 6 and 12) and were included in the analyses (Figure 1). Demographic characteristics and baseline anthropometric measurements of the participants are presented in table 1.

Table 1. Demographic characteristics and baseline anthropometric measurements of the study participants

Characteristics	HBCR group (n = 128)	UC group (n = 119)	P
Age (year) (mean \pm SD)	55.04 \pm 6.79	55.42 \pm 8.03	0.32
BMI (kg/m ²) (mean \pm SD)	27.62 \pm 4.37	28.41 \pm 4.00	0.15
Sex [n (%)]			0.48
Men	106 (82.81)	103 (86.55)	
Women	22 (17.19)	16 (13.45)	
Marital status [n (%)]			0.74
Married	124 (96.87)	112 (95.70)	
Single	4 (3.13)	5 (4.30)	
Education [n (%)]			0.24
Illiterate	14 (10.90)	9 (7.60)	
Primary school	42 (32.80)	56 (47.10)	
Middle school	24 (18.80)	20 (16.80)	
Diploma	32 (25.00)	23 (19.30)	
Academic	16 (12.50)	11 (9.20)	
Job status [n (%)]			0.56
Employee	80 (63.50)	71 (60.20)	
Unemployed	27 (21.40)	32 (27.10)	
Housewife	19 (15.10)	15 (12.70)	
Smoker [n (%)]			0.50
Yes	52 (43.70)	48 (48.50)	
No	67 (56.30)	51 (51.50)	
Risk factors [n (%)]			
HTN	40 (31.20)	45 (37.80)	0.43
Hyperlipidemia	42 (32.80)	60 (50.40)	0.02
Diabetes	23 (18.00)	17 (14.30)	0.31
Diagnosis [n (%)]			
MI	61 (47.66)	63 (50.80)	
CABG surgery	9 (6.90)	14 (10.90)	0.25
Stable angina	23 (17.60)	21 (16.40)	0.81
Unstable angina	33 (25.20)	44 (34.40)	0.11

HBCR: Home-based cardiac rehabilitation; UC: Usual care; BMI: Body mass index; HTN: Hypertension; MI: Myocardial infarction; CABG: Coronary artery bypass graft; SD: Standard deviation

The two groups were similar in the parameters evaluated at baseline except in the hyperlipidemia variable ($P = 0.02$). This variable was investigated as a confounding variable in the model and had no significant effect.

The prevalence of depression in the UC and HBCR groups at baseline was 44 (36.98%) and 51 (39.84%), respectively. In the last follow-up (12 months), the prevalence of depression in the UC and HBCR groups decreased to 19 (15.97%) and 21 (16.41%), respectively.

In the HBCR group, the means of depression score decreased continuously with a slower slope than the UC program group (Figure 2). In the UC group, the depression reduced from baseline to month 6 and from baseline to month 12. This difference between times was statistically significant, while the change from 6 months to 12 months was not significant ($P = 0.61$). In the UC group, reduction in the depression from baseline to 6 months was greater than HBCR group. Between baseline to 6 months, the reduction in depression scores in the HBCR and UC groups was 2.23 and 4.14, respectively (Tables 2 and 3).

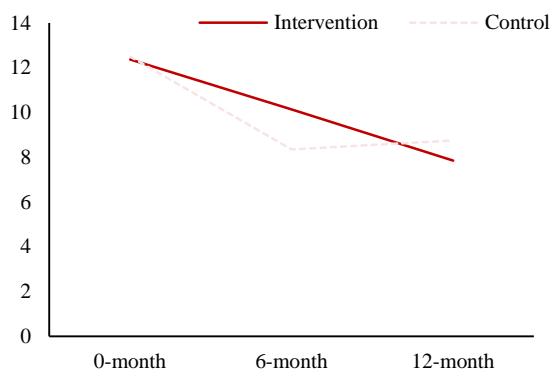


Figure 2. Change in depression over time in usual care (UC) and home-based cardiac rehabilitation (HBCR) groups

In the HBCR group, the depression reduced continuously from baseline to 6 months, 6 months to 12 months, and baseline to 12 months. This difference between times was statistically significant.

Table 3. Generalized estimating equation (GEE) results of the intervention group in comparison with the control group on depression

Variables	Group	Month	Estimate (mean ± SE)	95% CI		P
				Lower bound	Upper bound	
Depression						
Group × month	HBCR group	6	2.23 ± 0.66	0.93	3.53	0.010
Group × month	HBCR group	12	4.49 ± 0.76	3.01	5.98	< 0.001

*The baseline (month 0) and UC group are considered as the reference levels for the time and group, respectively. HBCR: Home-based cardiac rehabilitation; CI: Confidence interval; SE: Standard error

Compared to the UC group, the HBCR group had a fewer reduction in depression from baseline to 6 months. But in 12 months, there was a more significant decrease in the HBCR group than the UC group (Tables 2 and 3).

Table 2. Depression over time in the control and intervention groups

Variables	Groups		P
	HBCR ^{†‡§} (mean ± SE)	UC ^{†§} (mean ± SE)	
Depression			0.004*
Baseline	12.37 ± 0.83	12.49 ± 0.65	
6 months later	10.14 ± 0.63	8.35 ± 0.50	
12 months later	7.88 ± 0.46	8.74 ± 0.62	

*The P-value for Group × Time interaction (based on the results of GEE analysis); † $P < 0.05$ for the statistical difference from baseline to 6 months within the group; ‡ $P < 0.05$ for the statistical difference from 6 months to 12 months within the group; § $P < 0.05$ for the statistical difference from baseline to 12 months within the group HBCR: Home-based cardiac rehabilitation; UC: Usual care; SE: Standard error

Discussion

To the best of our knowledge, this study is the first study that considered comprehensive HBCR to depression reduction in patients with IHD in Iran. The results show a significant decrease in depression scores in both groups. The decline continued overtime in the HBCR group, but there was no significant difference between months 6 and 12 in the UC group.

This study is part of a randomized controlled trial (RCT) that compared the effect of a comprehensive HBCR program with UC in patients with IHD. A detailed description of the study protocol has already been published elsewhere.²² A meta-analysis to evaluate the effect of CR on depression showed that most HBCR programs could significantly reduce depressive symptoms. The meta-analysis also showed that appropriate interventions with more specific content, including nutritional, exercise, and psychosocial interventions, were likely to be more effective in reducing depression in people with heart disease than UC.²³

In this study, depression in both HBCR and UC groups was significantly reduced at 6-month follow-up. The difference between the baseline and 6-month follow-up in the UC group is greater and shows a lower depression score. There is evidence that discharge education intervention alone reduces depression in patients with CVD.^{24,25} Moreover, we might speculate that this is due to differences between the two groups in other causes of depression after rehabilitation. Evidence shows that in patients attending CR, the number of comorbidities, weight gain, inactivity, smoking, heart failure (HF), and being single are factors that increase depression.²⁶

A previous study examining the effect of a home-based intervention on depression in patients with coronary artery bypass grafting (CABG) showed that at 6-week and 6-month follow-up, a significant improvement in depression symptoms was observed in both intervention and control groups. This difference between the groups was not significant. However, in a subgroup of patients with depressive symptoms initially, improvement in depression score at the 6-month follow-up was greater in the intervention group than in the control group.²⁷

In this study, depression was significantly reduced over time in the HBCR group, and patients had lower depression scores between 6 and 12 months of follow-up. There was no significant reduction in depression score in the UC group between 6 and 12 months of follow-up. CR has positive effects on psychological aspects such as depression, even without specific psychological interventions,²⁸ and this positive effect can be maintained for a long time.²⁹ Comparison of mental health treatments and CR to reduce depression and prevent vascular accidents showed that although both reduced depression, CR further reduced total mortality risk.³⁰

A telephone-based intervention which was focused on the effects of a home-based exercise maintenance intervention on psychosocial outcomes after phase II CR showed no significant difference between the two groups in the depression scale at 6 months of follow-up. However, the change in depression was significantly different between the intervention and control groups at only 12 months of follow-up.³¹

Conclusion

The results of this study provide evidence in continuous reducing of depression in patients with IHD. These findings suggest that for patients who

do not participate in hospital-based CR, HBCR can be an effective prevention measure and can alleviate depression.

Limitations: Our study has several strengths. This study is the first to investigate the effect of a comprehensive HBCR program on depression in patients with IHD in Iran. Most previous studies have examined the effect of rehabilitation in the short term, but the main strength of the present study is the long-term follow-up. This study is a randomized trial with relatively large sample size. Although our study included different ethnicities in Iran, the limitation of our study was the predominantly male subject pool (84.61%), so the generalizability of the findings is limited.

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Conflict of Interests

Authors have no conflict of interests.

Authors' Contribution

MS, AAM, HR, MHA, and GM were involved in the conception and design of the study. MHA, HH, MM, SY, and LV were involved in the data collection. MJ and MM were involved in the analysis and interpretation of the collected data. MJ and HOA were involved in the drafting of the paper and critical revision. All the authors have read and approved the manuscript.

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