Original Article

The Effect of Early Mobilization Programs on the Heart-focused Anxiety in Patients with Acute Myocardial Infarction: A Randomized Clinical Trial

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Abstract

Background: Early Mobilization (EM) after a myocardial infarction is an effective strategy to reduce complications associated with immobility. However, heart-focused anxiety (HFA) can hinder exercise capacity and negatively impact self-reported physical health. Consequently, we aimed to evaluate the effect of the current EM program on HFA in patients who have experienced an acute myocardial infarction (AMI). **Materials and Methods:** In this randomized controlled trial, patients with AMI were selected using a convenience sampling method and were randomly assigned to either the intervention group (n = 30) or the control group (n = 30). The measurement tools included a section on demographic information, a patient activity checklist, and the Cardiac Anxiety Questionnaire (CAQ). The intervention group underwent a six-stage EM program, while the control group received standard care. Data analysis was performed using SPSS Version 20, employing independent and paired t-tests. **Results:** The comparison of the average HFA score and its components before the intervention showed no significant differences ($p > 0.05$). After the trial, the HFA score showed a significant decrease (t = -3.065, $p = 0.003$) compared to the control group. Its components, including attention (t = -2.040, $p = 0.046$) and fear (t = -2.259, $p = 0.028$), also decreased significantly, while avoidance (t = -1.608, $p = 0.114$) did not show a significant change. **Conclusions:** This EM program, initiated about 6 hours after admission to the CCU, decreased the CAQ score. Thus, this program is an affordable and nondrug approach recommended to prevent complications from immobility.

Keywords: *Anxiety, attention, avoidance learning, early mobilization, fear, heart, myocardial infarction*

Introduction

Cardiovascular Diseases (CVDs) remain the leading cause of mortality worldwide and significantly contribute to morbidity and increased health system costs.[1] In Iran, CVDs are the primary cause of death, with ischemic heart disease accounting for an average of 829.1 new cases (ranging from 719.9 to 945.2) per 100,000 individuals, as noted in one of the most comprehensive review studies.[2] This makes ischemic heart disease the most significant cause of mortality and the primary contributor to Disability-Adjusted Life Years (DALYs) in the country.[3] Among CVDs, Acute Myocardial Infarction (AMI) has an age-specific prevalence rate of 73.3 per 100,000, making it the most common cause of death.[4] Furthermore, survivors of AMI often experience a lower quality of life due to persistent heart and lung problems.[5] In this category of patients, improving cardiac function, preventing reinfarction, and facilitating rehabilitation are crucial.[6] While immobilization with bed rest during the initial hours is one of the most effective methods for managing AMI,[7] it can lead to various complications affecting different body systems.[8] The severity of these complications often depends on the patient's age, overall health status, and duration of immobilization.[9] Therefore, EM following an MI is an effective strategy to minimize the complications associated with prolonged immobility. EM involves initiating a patient's physical activity as soon as possible to prevent the adverse effects of extended bed rest and to aid in the restoration of basic functional abilities.[10] A review study conducted in 2020 supported the effectiveness of EM. However, it also raised concerns regarding safety, feasibility, and outcomes following MI.[11] In light of these concerns, researchers have

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stated that EM after an AMI not only reduces morbidity but also alleviates the psychological burden associated with the condition.[12] Alao, a nurse-driven EM program conducted in a Cardiac Intensive Care Unit with 234 older adults demonstrated that half of the participants improved their functional status. Those who participated in the program were also more likely to be discharged and experienced a lower incidence of in-hospital death compared to the control group.[13] Additionally, Asgari *et al*.[14] found that EM could improve heart rates in patients with MI who were hospitalized in the Cardiac Care Unit (CCU). Nevertheless, there is still a need for further research to determine the optimal start time, duration, and intensity of movement activities.[12] In this field, Schmitz *et al*.[15] demonstrated that Heart-Focused Anxiety (HFA) is a significant factor that inhibits exercise capacity and negatively impacts self-reported physical health. HFA encompasses three dimensions such as fear of heart-related perceptions, avoidance of initiating activities, and heightened attention to heart-related symptoms. Despite its importance, HFA is rarely assessed in clinical settings. It reflects psychocardiological rehabilitation in hospitalized patients and is associated with a higher likelihood of adverse outcomes in patients who have experienced an MI. In light of the need to investigate the start time, duration, and intensity of physical activities, the current intervention was designed. The earliest time for initiating rehabilitation was established as 6 hours after admission to the CCU, although previous records indicated that rehabilitation had begun 12 hours postadmission. Additionally, we tested a combination of the most effective rehabilitation activities based on existing published research. Furthermore, we examined the impact of this intervention on HFA, which is a predictor of reduced exercise capacity and mobility both before rehabilitation and in the long term. Moreover, we have not come across any studies about this before.

Materials and Methods

This randomized controlled trial (IRCT20220116053740N1) was conducted on patients with AMI who were hospitalized at Shahid Chamran Hospital in Isfahan from December 2022 to July 2023. Participants were initially selected using a convenience sampling method and were then assigned to either the intervention group (n = 30) or the control group (n = 30) through random assignment [Figure 1]. This was done using a table of random numbers, available in statistics textbooks and online. We determined that patients assigned an even number would be placed in the intervention group, while those assigned an odd number would be placed in the control group, in such a way that the responsible person closed her eyes and placed her finger on one of the digits of the random table. She then recorded the row and column numbers as the starting point. The direction of her finger movement was determined to be horizontally to the right, then up, and finally to the left. This process continued until the required sample size was achieved. It is important to note that a drop in the sample was also taken into account. For each participant who was removed based on the exclusion criteria, another subject was chosen as a replacement. The sample size was calculated to be 25 people in each group. After accounting for a 10% dropout rate, the final sample size was adjusted to 30 per group [Figure 1]. This calculation was done using the following formula: $(Z1 + Z2)\ 2 \times (S2)/d2 = (1.96 + 0.84)\ 2 \times (0.8)\ 2(0.8S)\ 2 = 25$, in which Z1 = 1.96, Z2 = 0.84, S represents the estimated standard deviation of the HFA score, and d is the minimum difference in heart-focused anxiety between the two groups, epitomized as 0.8S. Inclusion criteria included obtaining written consent, demonstrating hemodynamic stability during the intervention without continuous infusion of inotropic drugs, and having an uncomplicated MI. An uncomplicated MI is defined as the absence of death, MI, recurrent ischemia, shock, heart failure, or stroke at the start of the target hospital day.[16] Additionally, participants must have undergone Percutaneous Coronary Intervention (PCI). Participants were excluded if they had a history of MI, second- or third-degree atrioventricular block, complete heart block, life-threatening dysrhythmias, or inferior MI. Other exclusion criteria included the patient's unwillingness or inability to adhere to the study protocol as determined by the physician, as well as the occurrence of any threatening conditions. Moreover, the two groups were found to be statistically similar in various health factors. These included the prevalence of type 1 or type 2 diabetes, hypertension (defined as a blood pressure of 140/90 or higher), hyperlipidemia, previous exercise history, family history of cardiovascular disease, smoking habits, and being overweight or obese, as well as the presence of respiratory diseases.[17] Also, patients were routinely taken off nitroglycerin 24 hours after admission, ensuring no interference with the current intervention.

For all patients in both groups, systolic and diastolic blood pressure, heart rate, and arterial blood oxygen saturation were measured within the first 6 hours after admission to ensure patient stability. Subsequently, the measurement tool was administered by the researcher (the corresponding author) for both groups before and after the intervention (this was done only once). The tool included a demographic information questionnaire, a patient activity checklist,[18] and a cardiac anxiety questionnaire.[19] Physiological indicators were recorded at least 2 hours before the patient took beta-blockers and calcium channel blockers. A patient activity checklist was utilized to ensure the accuracy of educated activities at each stage according to the current protocol. This checklist also assessed the characteristics of tolerance or intolerance related to each activity based on the Borg scale,[18] which has been validated and proven reliable in Iran.[20] Additionally, Eifert's heart-focused anxiety measurement scale,[19] also known as the Cardiac Anxiety Questionnaire (CAQ), is a standardized tool consisting of 18 questions that evaluate

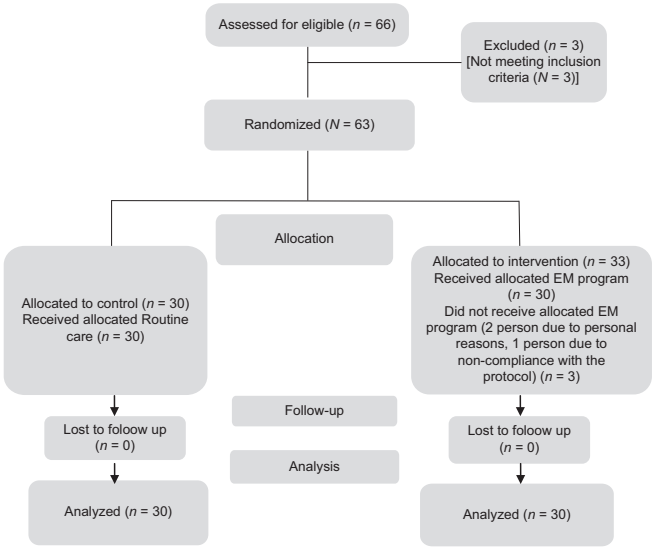

Figure 1: CONSORT trial flow diagram for patients with MI who recruited

and score the impact of anxiety on cardiac symptoms in three areas including fear (8 questions), avoidance (5 questions), and attention (5 questions). Responses are scored using a Likert scale ranging from "never" (0) to "always" (4), with higher scores indicating greater levels of anxiety. The validity and reliability of the cardiac anxiety questionnaire have also been confirmed within the Iranian population.[21] To ensure the face validity of all three parts of the tool, the authors reviewed relevant texts, books, and scientific articles in the field to create the initial version of the questionnaire. This version was then evaluated by specialists in nursing, cardiology, physiotherapy, and rehabilitation, who provided their feedback. Based on their recommendations, the researchers made the necessary revisions and prepared the final version for approval. To assess reliability, the questionnaire (which included all three parts) was completed by 10 eligible patients. The internal consistency was assessed using Cronbach's alpha coefficient, which exceeded 0.70, thereby confirming the reliability of the tool. For the control group, the authors focused solely on routine hospital care. In contrast, a specific program was administered to the intervention group by the corresponding author in the CCU. She had extensive expertise in teaching movement exercises and monitoring patients' physiological indicators and was also responsible for completing the checklist and questionnaire [Figure 1]. The statistical significance was based on a p value below 0.05, and the analysis was performed using IBM SPSS Statistics version 22.0.

Interventional program: According to hospital officials, the average stay for patients in the CCU after an AMI is 96 hours. Therefore, we aimed to implement the current exercise regimen for patients within a 72-hour timeframe in the experimental group. The intervention began as soon as the patients were admitted to the CCU.[22] During each phase of the physical activity training, the researcher was present at each patient's bedside to teach the exercises, monitor their performance, and observe their physiological indicators. It should be noted that the maximum amount of energy expenditure for the patients' activities was considered 1 Metabolic Equivalent (MET) on the first day, 2 METs on the second day, and 3 METs on the third day[23], which was placed in the category of low-intensity physical activities based on the relevant guidelines.[24] MET, or Metabolic Equivalent of Task, is a measure of energy expenditure. One MET corresponds to the rate of oxygen uptake while at rest, which is approximately 3.5 milliliters of oxygen per kilogram of body weight per minute.[25] The Early Mobilization Program for the intervention group consisted of six stages: In zero Stage, the patient was on complete bed rest for 6 hours following admission. In Stage 1 (Activity in Bed), this stage began 6 hours after patients were admitted to the CCU and performed a series of exercises while lying on their backs. These included diaphragmatic breathing, opening and bending fingers and toes, and performing inversion and eversion of the wrists, as well as pronation and supination of the forearms. Each exercise was done 6–10 times. Additionally, they practiced elbow extension and flexion, shoulder abduction and adduction, and leg extension and flexion at the knee joints, each also performed 6–10 times. After completing these exercises, patients were assisted in turning in bed. Defecation at this stage was managed using a bedpan. From this point forward, every patient was educated that each succeeding stage would involve an active level of training activities, tailored to their capacity and willingness. Throughout each stage, the researcher monitored vital physiological indicators, including systolic and diastolic blood pressure, pulse rate, cardiac rhythm, and arterial blood oxygen percentage. In stage 2 (Ability to Sit), this stage began 12 hours after the patient was admitted. The researcher supervised the change in the patient's condition from lying down to sitting on a bed (only for one). Following this, the patient's blood pressure, heart rate, and cardiac rhythm were monitored using the Saadat hemodynamic monitoring system of the Alborz model. In the absence of any hemodynamic disturbances or arrhythmias, the patient was assisted in sitting on the side of the bed with their legs hanging down for 5 minutes. After this, the patient moved to a chair next to the bed and sat for 5 minutes; again, this was done only once. Subsequently, based on the patient's tolerance and personal preference, they either were returned to a lying position or remained sitting. During this stage, the patient was encouraged to perform some self-care activities from the bed and utilize the bedside services. In stage 3 (Ability to Stand), 24 hours after the patient's admission, the researcher monitored the patient's blood pressure, heart rate, and cardiac rhythm. If the clinical conditions were stable, the patient was instructed to sit in a chair next to the bed for 10 minutes. After that, the patient stood beside the bed for another 10 minutes before returning to the bed. In stage 4 (Walking Less than 20 Meters), this phase was conducted

at least 3 hours after the previous stage. During this phase, if the clinical conditions were stable, the patient walked around their bed for 10 minutes before returning to the bed (only once), with continuous monitoring. Additionally, independent self-care activities were carried out during this stage, and the patient used the restroom facilities in the ward. In stage 5 (Walking More than 20 Meters), this phase was initiated 48 hours after admission. After the completion of phases 3 and 4, if the patient's clinical conditions were stable, they were allowed to walk for 15 minutes inside the CCU as tolerated and perform light exercises with an energy consumption of 2 METs. These light exercises included opening and bending the elbows, abducting and adducting the shoulders, bending and opening and turning the neck, turning the thighs to the left and right while the hands were placed on the waist, and rising on the toes (each of those 6–10 times, according to the patient's tolerance). After that, the patient returned to their bed and slept in a state of relative rest. In stage 6 (Climbing 3 Steps), this phase was conducted 72 hours after the patient's admission, on the third day. Under the direct supervision of the researcher, and after completing phase 5, the patient was assessed for clinical stability. If the patient's condition was stable, they were guided to climb three stairs that were set up in the intensive care unit before returning to bed.[10,26,27] It is important to note that the stair climbing could not be repeated due to the limitations of the CCU.

It is important to note that throughout all stages of the EM program, the activities were monitored by the researcher using a pre-prepared checklist. The activities were rated on the Borg scale, with scores ranging from 6 to 13.[18] Additionally, the readiness of each patient was assessed at every stage by measuring physiological indicators. Specifically, the heart rate was maintained below 120 beats per minute, and any changes in blood pressure and heart rate were kept within 20% of baseline values.[28,29] Oxygen saturation in the arterial blood was required to be greater than or equal to 95%, and it was crucial that the heart rhythm remained free of arrhythmias. Furthermore, all patients in both groups received standard medical treatment. Activities were scheduled for the afternoon, specifically between 15:00 and 18:00, to avoid conflicting with personal care and scheduling. In the routine mode designated for the control group, patients were placed on complete bed rest for 24 hours. Following this period, they were instructed to follow partial rest as ordered by their physician until discharge, which occurred 96 hours after admission. During this time, activities were carried out based on the patients' personal preferences and abilities.

Ethical considerations

This project received approval from the Ethical Committee of the Isfahan University of Medical Sciences Deputy of Research and Technology (IR.MUI.NUREMA.REC.1400.150). To prevent complications such as tachycardia, bradycardia, abnormal blood pressure, arrhythmia, signs and symptoms of recurrent myocardial infarction, and fluctuations in arterial blood oxygen saturation during each stage of the intervention, the researcher monitored the patients closely. In the event that any of these side effects occurred, the intervention would be halted, the patient would be allowed to rest, and a cardiologist would be informed. Based on the physician's recommendation, the patient would be either excluded from the study or allowed to resume training at a lower intensity if they recovered. Fortunately, none of these side effects were observed during the study.

Results

The baseline participants' characteristics and physiological indicators were compared using an independent *t*-test [Table 1]. Also, the average scores of HFA in each group before and after the intervention were compared using paired t-tests [Table 2]. Moreover, an independent *t*-test was used to compare the means of the main outcome (HFA score) before and after the trial between two groups [Table 2].

The two groups did not show significant differences regarding age, gender, education, occupation, marital status, and type of AMI ($p > 0.05$). Additionally, the mean values of physiological indicators, including systolic and diastolic blood pressures, pulse rate, and arterial blood oxygen saturation, were statistically similar between the two groups ($p > 0.05$) [see Table 1]. Furthermore, the comparison of the average HFA score and its components prior to the intervention indicated no significant differences.

After the intervention, the scores for HFA (t = -3.065, $p = 0.003$), attention (t = -2.040, $p = 0.046$), and fear (t = -2.259, $p = 0.028$) showed significant reductions compared to the control group. However, the avoidance score did not show a significant change (t = -1.608, $p = 0.114$) [Table 2]. Additionally, the paired *t*-test indicated that the average scores for HFA, attention, fear, and avoidance dimensions in the intervention group significantly decreased compared to their scores before the intervention. In contrast, in the control group, only the HFA and fear scores decreased significantly.

Discussion

The present early mobility program significantly decreased the mean scores of HFA in the intervention group, while all dimensions of the assessment scale, except for avoidance, showed improvement compared to the control group.

Similarly, the rehabilitation-focused nursing model effectively reduced negative emotion scores, as measured by the self-rating anxiety and depression scales.[30] When the negative scores and unpleasant feelings of patients decreased, the motivation to engage in rehabilitation exercises and the need for early rehabilitation intervention

increased in the intervention group. This led to improvements in heart performance indicators and a reduction in risk factors. As a result, tolerance to hypoxia increased, and both cardiac and exercise performance improved.[30] Moreover, one study demonstrated that exercise and early mobilization in patients after cardiac surgery reduced their anxiety, particularly after a decrease in pain intensity from the exercises.[29] The research indicated that combining early exercise and mobilization with psychotherapy could significantly reduce anxiety and stress. In contrast, a hospital setting that promotes inactivity and lacks a support system tends to have adverse effects on patients. Therefore, the ability to return to work and resume normal activities is linked to higher satisfaction in both physical and mental health, a finding that aligns with previous studies.[29] Furthermore, a meta-analysis has shown that cardiac rehabilitation incorporating exercise education can be an effective approach for addressing anxiety and depression in patients who have experienced an MI.[31]

Psychological risk factors have been identified as contributing agents for MI.[32] Additionally, psychological symptoms, such as anxiety, can negatively affect cardiac outcomes following an AMI.[33] In this field, large-scale studies have shown that symptoms of depression after an MI are linked to a higher risk of reinfection and mortality. Therefore, reducing psychological distress can positively influence the health status and outcomes of patients after an MI.[33] Furthermore, another study found that early exercise—initiated just 12 hours after an AMI—improved emotional scores in the intervention group.[34]

Table 1: Patients' characteristics according to study groups

Variable	Intervention (*n*=30) Mean (SD)	Control (*n*=30) Mean (SD)	*t*	*p*
Age (years)	57.73 (12.29)	61.50 (11.81)	1.21	0.231
Systolic blood pressure (mm Hg)	133.00 (13.99)	130.58 (14.65)	-0.65	0.511
Diastolic blood pressure (mm Hg)	87.07 (11.60)	85.51 (11.17)	-0.53	0.596
Pulse rate (bpm*)	81.62 (13.13)	83.18 (11.79)	0.49	0.629
Arterial blood oxygen saturation (percentage)	94.51 (2.05)	94.27 (2.72)	-0.37	0.709
Variable	**Intervention (*n*=30) Number (Percentage)**	**Control (*n*=30) Number (Percentage)**	***F***	***p***
Gender			0.09	0.759
Female	6 (20)	7 (23.30)		
Male	24 (80)	23 (76.70)		
Education			0.02	0.884
Uneducated	3 (10.0)	1 (3.30)		
University education	5 (16.70)	7 (23.30)		
< Dipolma	13 (43.30)	14 (46.70)		
Dipolma	9 (30.0)	8 (26.70)		
Job			0.55	0.460
Employed	11 (36.70)	15 (50.0)		
Unemployed	10 (33.30)	9 (30.0)		
Retired	9 (30.0)	6 (20.0)		
Marital status			0.56	0.456
Married	25 (83.30)	27 (90.0)		
Single	5 (16.70)	3 (10.0)		
Type of AMI**			0.70	0.405
Anterior	28 (93.30)	29 (96.70)		
Anteriolateral	1 (3.30)	0 (0)		
Septal	1 (3.30)	1 (3.30)		
Medications used				
Medication use according to self-report (%)				
Nitrates	30 (100)	30 (100)	0.54	0.672
Beta blockers	25 (83.33%)	23 (76.66%)		
Calcium blockers	17 (56.66%)	19 (63.33%)		
Angiotensin II enzyme inhibitors	20 (66.66%)	18 (60%)		
Angiotensin receptor blockers (ARBs II)	10 (33.33%)	9 (30%)		
Anticoagulant and antiplatelet aggregation	30 (100%)	30 (100%)		
Antiarrhythmics	9 (30%)	11 (36.66%)		

*Beats per minute. Single: Unmarried, Widow, Divorsed; **AMI: Acute Myocardial Infarction

Table 2: Comparison of the total score of the questionnaire and its components before and after intervention within and between study groups

Variable	Intervention (*n*=30)		*t*	*p**	Control (*n*=30)		*t*	*p**	*t*	*p*¹**	*t*	*p*²**
	Baseline Mean (SD)	Follow-up Mean (SD)			Baseline Mean (SD)	Follow-up Mean (SD)				Before intervention		After intervention
CAQ[$]	26.40 (6.09)	19.57 (4.73)	10.50	<0.001	25.87 (4.74)	23.43 (5.03)	11.16	<0.001	-3.06	0.706	-3.06	0.003
Attention	4.33 (2.40)	2.00 (1.93)	5.93	<0.001	3.53 (2.27)	3.60 (3.84)	-0.01	0.922	-2.04	0.190	-2.04	0.046
Fear	13.77 (3.35)	11.13 (2.83)	6.95	<0.001	14.17 (2.49)	12.90 (3.22)	3.14	0.004	-2.26	0.602	-2.26	0.028
Avoidance	8.30 (2.59)	6.77 (2.71)	2.93	0.006	8.13 (2.06)	8.17 (3.92)	-0.04	0.965	-1.61	0.745	-1.61	0.114

t: *t*-statistic. *p**: *p* value of paired *t*-test) The results of intragroup comparison of scores). p^{1}**: *p* value of independent *t*-test (The results of comparing the scores before the intervention between two groups). p^{2}**: *p* value of independent *t*-test (The results of comparing the scores after the intervention between between two groups). [$]CAQ: Cardiac Anxiety Questionnaire

The researchers demonstrated that a training program for patients post-MI positively impacted anxiety levels and significantly improved physical capacity in both men and women. This improvement in physical capacity, in turn, helps to reduce anxiety.[35] Additionally, exercise has been associated with a shift in the sympatho-vagal balance toward parasympathetic dominance. This shift is beneficial for prognosis in coronary artery disease in both genders and can be assessed by monitoring parameters such as heart rate, heart rate recovery, and heart rate variability.[36] Conversely, increased sympathetic activity is linked to a higher risk of disease and mortality.[37]

Exercise has anti-inflammatory effects that can help decrease symptoms of depression and anxiety. First, it reduces inflammatory cytokines such as C-reactive protein (CRP) and interleukin-6 (IL-6), which are associated with disease progression in individuals with heart disease and heart failure. Notably, anxiety and depression tend to elevate the levels of these inflammatory cytokines. Additionally, physical activity lowers proinflammatory markers and increases anti-inflammatory factors, such as interleukin 1-beta, in both the hippocampus and serum, leading to improved symptoms. Furthermore, exercise encourages neurogenesis, and problems in the autonomic nervous system play a significant role in the association between depression, anxiety, and their potential impact on heart failure. Physical activity boosts levels of brain-derived neurotrophic factors in the hippocampus, which promotes neuroplasticity. Additionally, it can elevate the levels of certain monoamine neurotransmitters, such as dopamine, noradrenaline, and beta-endorphin. This activity also influences the neuroendocrine function of the hypothalamus-pituitary-adrenal axis, resulting in increased insulin sensitivity. Furthermore, physical activity enhances antioxidant markers while reducing pro-oxidative markers, and it positively impacts the structure and function of the cerebral cortex.[38]

Last, exercise has been found to be effective in reducing anxiety in individuals with heart disease, as evidenced by studies.[39,40] In some studies, the researchers concluded that the evidence is still insufficient for a definitive conclusion.[41,42] However, there are conflicting results from some experiments. For instance, a study in Ukraine demonstrated that the dynamics of anxiety and depression were not affected by adding deep breathing exercises to the postoperative physical therapy program.[43] Also, Blumenthal *et al*.[44] observed that those who were assigned to an exercise-based program experienced no decline in anxiety or depression compared to those in the placebo group.

A key feature of the present study was the timing of initiation of the rehabilitation program. The exercise medicine (EM) program stages were initiated within 6 hours of being admitted to the coronary care unit (CCU) and appear to be the earliest reported start of EM in the literature. Additionally, this program was able to create a therapeutic relationship between the patient and the nurse as well as reduce the physical and mental complications related to immobility after a heart attack. By promoting earlier mobility, it also offered an effective strategy to reduce bed occupancy and hospital costs. However, the study had limitations, including a small sample size and the lengthy recruitment process, as participants entered the study one at a time.

Conclusion

The current exercise method, initiated about 6 hours after admission to the coronary care unit, effectively reduced the CAQ score. Therefore, this program is suggested as an effective, low-cost, nondrug strategy to prevent complications from immobility and decrease bed occupancy rates.

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Conflicts of interest

Nothing to declare.

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