



The Effect of Continuous Nursing Care Program on Anxiety Level, Episodes of Chest Pain, and Readmission Rate after Myocardial Infarction: A Randomized Controlled Trial

Rahim Baghaei¹, PhD; Naser Parizad^{1*}, PhD; Abolhassan Sharifi², MSN; Vahid Alinejad³, PhD

¹ Patient Safety Research Center, Clinical Research Institute, Nursing & Midwifery School, Urmia University of Medical Sciences, Urmia, IR Iran

² Department of Medical Surgical Nursing, Urmia University of Medical Sciences, Urmia, IR Iran

³ Department of Biostatistics, Urmia University of Medical Sciences, Urmia, IR Iran

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ABSTRACT

Background: Chest pain, anxiety, and readmission are patients' adverse outcomes after Myocardial Infarction (MI). Therefore, post-MI patients require a proper care program to overcome these outcomes.

Objectives: This study aimed to determine the effect of a continuous nursing care program on patients' anxiety level, episodes of chest pain, and readmission rate after MI.

Methods: In this randomized, controlled trial, 120 patients who met the inclusion criteria were selected using convenience sampling. The patients were allocated into the control (n = 60) and intervention (n = 60) groups using numbered opaque sealed envelopes. A demographic information form and the State-Trait Anxiety Inventory (STAI) were used to collect the data (primary outcome). The patients in the intervention group received education and practical rehabilitation exercises from the beginning of hospitalization until 12 weeks after discharge. However, the control group only received the routine care. Checklists were used to record the episodes of chest pain and readmission rate (secondary outcomes). The data were analyzed using the SPSS software, version 16.0. The data were distributed normally based on the results of Shapiro-Wilk test. Hence, they were analyzed using descriptive (mean, standard deviation, number, and percentage) and inferential (independent t-test, paired t-test, chi-square, Mann-Whitney U test, and Fisher's exact test) statistics.

Results: The results revealed a significant reduction in the readmission rate (P = 0.014) and episodes of chest pain (P = 0.025) in the intervention group after the implementation of the continuous nursing care program. The results also showed a significant difference between the two groups regarding the mean scores of trait and state anxiety 12 weeks after discharge (P = 0.001). Accordingly, anxiety levels reduced significantly in the intervention group after the intervention (P = 0.001).

Conclusions: This continuous nursing care program, as a low-cost and non-pharmacological approach, played a vital role in caring for the patients after MI and positively affected the patients' recovery. Hence, this program could be used to improve post-MI outcomes in patients and accelerate their recovery.

1. Background

Cardiovascular Diseases (CVDs) are the leading cause of death in the world. World Health Organization (WHO) reported an estimated 17.9 million deaths from CVDs in 2016, which accounted for 31% of all deaths worldwide. It should be noted that 85% of these deaths were caused

by Myocardial Infarction (MI) and stroke (1). Post-MI patients face several problems, such as chest pain, activity intolerance, abnormal variations in tissue blood flow, ineffective coping, and anxiety (2). Chest pain, anxiety, and hospital readmission are the particular concerns when rehabilitating patients who have experienced MI (3).

The incidence of chest pain leads to anxiety and worsens ischemic myocardium. Given the importance of chest pain as a warning factor for ischemia and re-infarction, it is critical to reduce chest pain episodes and prevent their

*Corresponding author: Naser Parizad, Nursing and Midwifery Faculty, Campus Nazlu, 11 KM Road Seru, Urmia, West Azerbaijan, Iran. Postal Code: 575611-5111. Tel: +98-4412752303, Fax: +98-4412752378, Email: nparizad@gmail.com.

occurrence (3). Anxiety is also one of the most common and critical psychological reactions in post-MI patients, which negatively affects patients' recovery processes (4). The prevalence of anxiety after MI has been reported to be 20-30%, resulting in impaired quality of life and loss of interest in participating in rehabilitation programs (5). In fact, patients are at the highest risk for readmission after MI, leading to higher morbidity and mortality rates (6). Stress caused by readmission is intolerable for some patients and their relatives because of its uncertain consequences and the possibility of death (7).

A recent study showed that educational programs could improve patients' outcomes after MI (8). Education increased patients' knowledge, reduced their anxiety, increased their adherence to treatment, and improved their quality of life (9, 10). Thus, education should be started immediately after the patient is diagnosed. Nurses can play an essential role in educating patients through the recovery period (11, 12). Nurses usually use care models to take care of their patients. In Iran, Ahmadi et al. designed and evaluated the continuous care model to manage patients with chronic coronary artery disease in 2001 (13). The ultimate goal of the continuous care model was to produce a care plan for promoting acceptance, proper performance, and management of the disease and its potential complications (14). Following up clients' behaviors could help manage heart diseases more efficiently. This reduced the frequency of their readmission, cost of hospitalization, and mortality rate (15). Despite numerous recommendations by several studies (15, 16), continuous care programs have been underused for patients (16). In fact, post-MI patients do not receive any regular education and have to participate in a rehabilitation program or continuous care program during hospitalization or after discharge in less developed and low-income countries (16, 17). Thus, nurses are required to develop and implement an educational and exercise program for post-MI patients to improve their outcomes (18). In the present study, a continuous nursing care program was designed to provide education and practical exercises for post-MI patients.

2. Objectives

This study aimed to investigate the effect of education and practical exercises on anxiety level, readmission rate, and chest pain episodes among these patients.

3. Patients and Methods

3.1. Study Design and Setting

This randomized, parallel-group, controlled trial was conducted in Urmia between February and July 2018. CONSORT 2010 was used to ensure the quality of reporting in this study (19).

3.2. Participants and Eligibility Criteria

The participants included 120 eligible patients with acute MI who met the inclusion criteria. After consulting a statistician and considering the study method, the sample size was calculated based on the results of t-test for two independent samples using the STATA software. According

to a previous similar study (20), a 104-subject sample size was calculated for the study. Considering a 10% attrition rate, 120 patients were enrolled into the study.

$$P_1=11.2\% \quad P_0=33.4\% \quad \alpha = 0.01 \quad \alpha = 0.01 \\ 1 - \beta = 1 - \beta = 80$$

$$N = \frac{4S^2 \left(\frac{Z_{\alpha}}{2} + Z_{\beta} \right)^2}{(P_1 - P_0)^2} = \frac{4(0.867)(3.575 + 1.27)^2}{(0.222)^2} = 104$$

$$n = \frac{N}{2} = \frac{104}{2} = 52$$

The participants were selected using convenience sampling and were randomly allocated into an intervention ($n = 60$) and a control ($n = 60$) group. The inclusion criteria of the study were definite diagnosis of MI by a cardiologist, not having any recognized psychiatric disorders, not having any cognitive, speech, or hearing disorders, not having untreated heart failure, not having uncontrolled arrhythmia, having a cell phone, and being willing to participate in the study. Patients who needed open-heart surgery, had chest pain during the continuous nursing care program, or were not willing to cooperate were excluded.

3.3. Intervention

First, an approval letter was obtained from the Research Deputy and the Ethics Committee of Urmia University of Medical Sciences. Then, the first researcher referred to the hospital, gained permission from the relevant authorities, and discussed the research process with nursing managers. In this stage, the patients who had referred to the hospital and met the inclusion criteria were listed as eligible participants. The first researcher was in charge of following up the patients and notifying the team whenever the patients' conditions were stable. It usually took 24 - 48 hours for the patients to undergo heart catheterization or to receive thrombolytic therapy. After that, they were invited to participate in the study. If the patients agreed to participate in the study, the researcher informed them about the purpose, stages, and duration of the study, answered their possible questions, and addressed their concerns. The researcher also assured them about their privacy and confidentiality of their information. After the participants signed the consent forms, they were randomly assigned to either the control or the intervention group using Sequentially Numbered Opaque Sealed Envelopes (SNOSE). In doing so, the researchers first created a random sequence using the table of random numbers. Then, they prepared some envelopes with aluminum wrappers based on the sample size. They recorded each of the random sequences on a card and placed the cards in the envelopes. The outer surface of the envelopes was numbered in the same way to maintain a random sequence. Finally, the envelopes were sealed and placed in a box. At the beginning of the participants' enrollment, one of the envelopes was opened according to the order of entry of the eligible participants into the study, and the assigned group was revealed. When the patients' conditions were stable,

they completed a demographic information questionnaire and the State-Trait Anxiety Inventory (STAI) (primary outcome). The researcher continued randomization until reaching the target sample size. Among the 150 consecutive eligible patients, 25 refused to participate in the study and five underwent coronary artery bypass graft surgery.

3.4. Hospital Routine Care

The patients who were in the control group only received the hospital’s routine care during hospitalization and at discharge. These patients received no exercise programs when they were in the hospital or after discharge at home.

3.5. Continuous Nursing Care Program

In addition to the hospital’s routine care, the patients in the intervention group received the comprehensive continuous nursing care program during hospitalization and three months after discharge (Figure 1). The program was developed based on the education and rehabilitation guidelines of the American Heart Association (AHA) for patients with MI (21). It consisted of education and exercise sections. In the education section, face-to-face education was given individually in two 60-minute sessions during hospitalization and three 30-minute sessions a week during the follow-up period by a trained cardiac care nurse. The first session took place when the patient’s condition was stable. The second session was held when the patient was ready to be discharged and every time the patient referred to the

hospital for exercise. The first researcher gave an educational handbook and a DVD to the patients in the intervention group after their conditions were stable. A qualified cardiac care nurse prepared the educational content under the supervision of a cardiologist. It contained information about MI, including risk factors, clinical symptoms, treatment, complications, and warning signs of recurrent MI. It also included recommendations for lifestyle changes, such as physical activity, diet, weight loss, smoking cessation, meditation methods, and checking vital signs regularly. The educational package was provided to the patients in the control group after the intervention was finished.

The second section of the continuous care program involved the moderate-intensity aerobic exercise program. The exercise program consisted of 50-minute sessions three times a week, including 10 minutes of warm-up, 15 minutes of brisk walking (at least four kilometers per hour), 15 minutes of biking (slower than 16 kilometers per hour), and 10 minutes of cool-down (21) (Figure 2). This section of the intervention was begun when the patients’ cardiologist allowed them to exercise, and the patients were stable enough to perform exercises. This exercise program was performed in the physiotherapy department three times a week during hospitalization and three months after discharge by the first researcher who had passed training classes before the study.

The first researcher showed training videos regarding exercises to the patients and their companions and answered

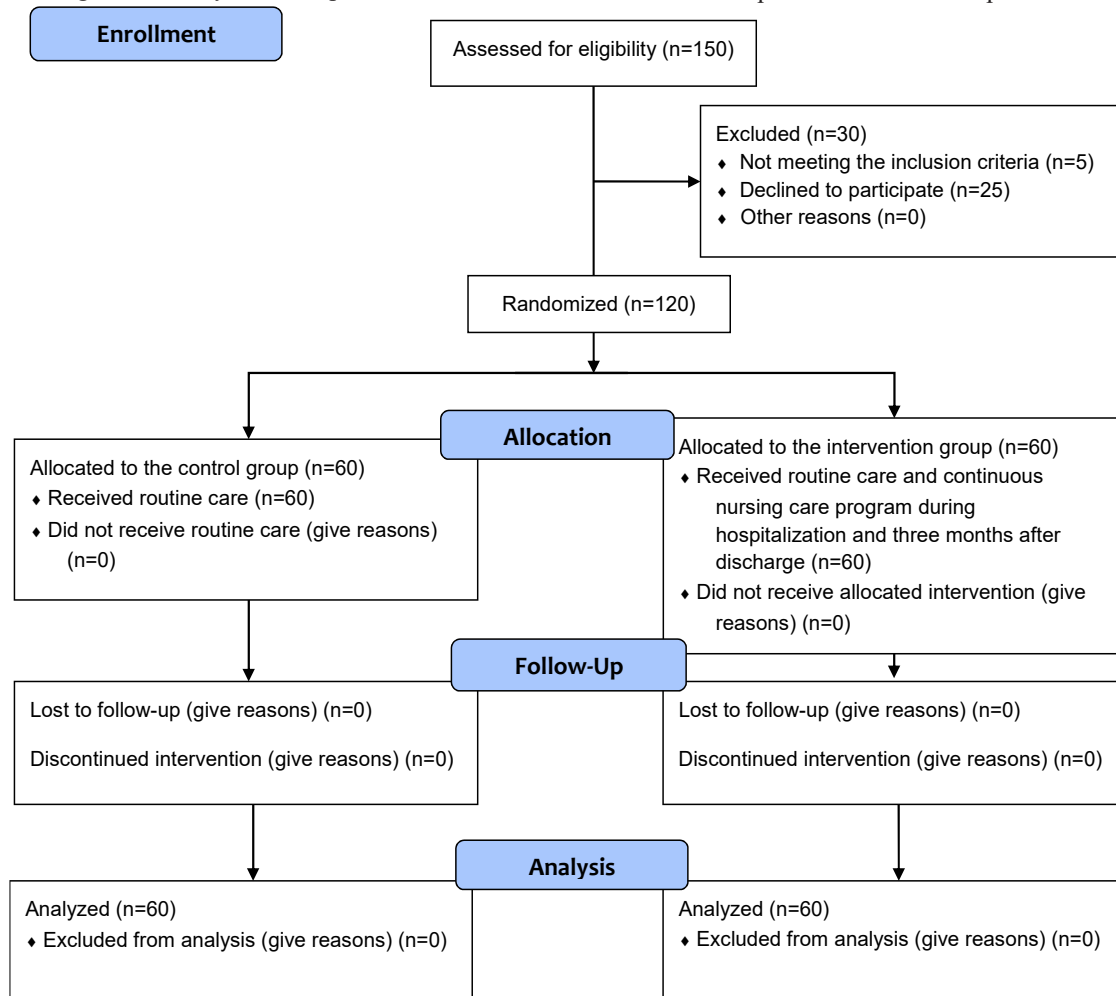


Figure 1. Consort 2010 Flow Diagram

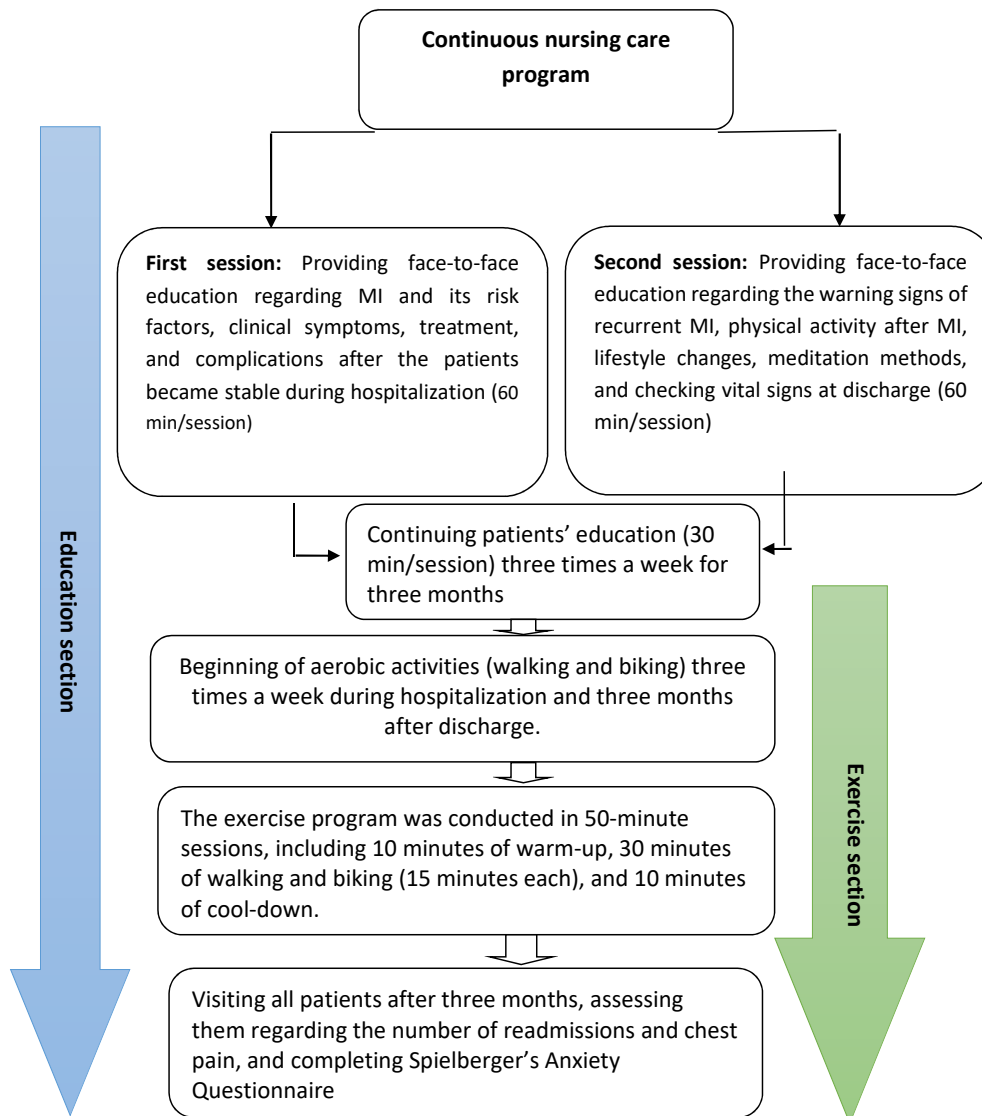


Figure 2. The Flow Chart of the Continuous Nursing Care Program

their questions. At the time of discharge, all patients were told that they would be asked to return to the hospital after three months to complete the questionnaires. The patients in the intervention group went through a prepared three-month schedule for follow-up sessions. The program was held on Monday, Wednesday, and Friday mornings. The research team used text messages to remind the patients regarding the program. The first researcher called the patients or their family members in case they did not attend the sessions. If the patient was unable to attend, a compensatory session was scheduled, and the patient was notified. The STAI was completed by the patients in both groups after three months. It should be noted that the researcher gave all patients a phone number and asked them to notify the research team whenever they were hospitalized or had chest pain. Checklists were used to record the readmission rate and the episodes of chest pain (secondary outcomes).

3.6. Data Collection

The study data were collected using a self-report demographic questionnaire (age, gender, marital status, education level, place of residence, educated family member, income level, accessibility to the hospital, and household

status) and the STAI (21). The STAI consisted of two parts; i.e., present or state anxiety and absent or trait anxiety. The state anxiety test involved the patients' current feelings, while trait anxiety referred to their typical feelings most of the time (22). Each part contained 20 questions scored using a four-point Likert scale. In the state anxiety scale, one and four scores were assigned to "not at all" and "very much so", respectively. In the trait anxiety scale, scores one and four were allocated to "almost never" and "almost always", respectively. Thus, the total scores ranged from 20 to 80, with higher scores indicating higher anxiety levels.

The face and content validity of the questionnaire were evaluated and confirmed by ten faculty members. In addition, the reliability of the questionnaire was assessed using the test-retest method. In doing so, 50 post-MI patients were asked to complete the questionnaire with a two-day interval. The reliability of the questionnaire was confirmed based on the scores obtained from the two tests ($r = 0.91$, alpha coefficient = 0.825). Besides, the content and construct validity of the questionnaire were confirmed by Khodayarifard et al. Its reliability and internal consistency were also approved by Cronbach's alpha coefficient ($\alpha = 0.87$), test-retest ($r = 0.87$), and split-half ($r = 0.88$) methods (23).

3.7. Data Analysis

The study data were analyzed using the SPSS 16.0 software (Chicago, IL: USA). The analysis was performed on the 120 patients who completed both baseline and three-month follow-up assessments. At first, Shapiro–Wilk test was used to check the normal distribution of the data, and the results showed that the data were normally distributed. Then, the data were analyzed using descriptive (mean, standard deviation, number, and percentage) and inferential (independent t-test, paired t-test, chi-square, Mann–Whitney U test, and Fisher’s exact test) statistics. $P < 0.05$ was considered statistically significant.

4. Results

Based on the results, 42 patients (70%) in the control group and 49 ones (81.7%) in the intervention group were male, and 18 patients (30%) in the control group and 11 ones (18.3%) in the intervention group were female. The mean age of the patients in the control and intervention groups was 54.4 and 57.27 years, respectively. The findings showed no significant difference between the control and

intervention groups regarding the patients’ demographic information. In other words, both groups were homogenous in terms of all demographic characteristics (Tables 1 and 2).

The results revealed no statistically significant difference between the two groups regarding the risk factors, such as underlying disease ($P = 0.3$), smoking ($P = 0.58$), and type of MI ($P = 0.25$). In addition, there was no significant difference between the two groups with respect to weight ($P = 0.11$), height ($P = 0.073$), and body mass index ($P = 0.74$) (Table 1). However, the results of chi-square test indicated a significant difference in the two groups’ episodes of chest pain ($P = 0.025$) and readmission rate ($P = 0.014$) after the intervention (Table 3).

The results of independent t-test showed no significant difference between the two groups concerning the mean score of state anxiety at the admission time ($P = 0.14$). However, a significant difference was observed between the two groups in this regard 12 weeks after discharge ($P = 0.001$) (Table 4). The results also showed no significant difference between the two groups regarding the mean score of trait anxiety at the admission time ($P = 0.13$). However, a

Table 1. Demographic Characteristics of the Participants in the Control and Intervention Groups

Variable	Group	Control Group		Intervention Group		df	P-value
		N	Percent	N	Percent		
Gender	Male	42	70%	49	81.7%	1	$P = 0.136^*$
	Female	18	30%	11	18.3%		$X^2 = 2.22$
Marital status	Married	57	95%	55	91.7%	1	$P = 0.464^*$
	Single	0	0%	0	0%		$X^2 = 0.536$
	Divorced	0	0%	0	0%		
	Widowed	3	5%	5	8.3%		
Education level	Illiterate	32	53.3%	31	51.7%	4	$P = 0.462^*$
	Primary school	14	23.3%	9	15%		$X^2 = 3.603$
	Middle school	7	11.7%	6	10%		
	High school	4	6.7%	9	15%		
	Academic	3	5%	5	8.3%		
Place of residence	Owned	49	81.7%	51	85%	1	$P = 0.624^*$
	Rental	11	18.3%	9	15%		$X^2 = 0.24$
Educated family member	Yes	29	48.3%	27	45%	1	$P = 0.714^*$
	No	31	51.7%	33	55%		$X^2 = 0.134$
Income level	Good	9	15%	10	16.7%	2	$P = 0.931^*$
	Average	32	53.3%	30	50%		$X^2 = 0.143$
	Poor	19	31.7%	20	33.3%		
Access to the hospital	Easy	31	51.7%	37	61.7%	2	$P = 0.543^*$
	A little hard	15	25%	12	20%		$X^2 = 1.223$
	Difficult	14	23%	11	18.3%		
Household status	Living with family	49	81.7%	57	95%	2	$P = 0.086^{**}$
	Living with children	5	8.3%	1	1.7%		$F = 4.985$
	Living alone	6	10%	2	3.3%		
Underlying disease	Diabetes	22	36.7%	16	26.7%	3	$P = 0.442^*$
	Hypertension	11	18.3%	15	25%		$X^2 = 1.634$
	No disease	27	43.3%	29	48.3%		
Smoking	Yes	31	51.7%	34	56.7%	1	$P = 0.583^*$
	No	29	48.3%	26	43.3%		$X^2 = 0.303$
Type of MI	Inferior	26	43.3%	23	28.3%	5	$P = 0.24^{**}$
	Anterior	14	23.3%	24	40%		$F = 6.539$
	Lateral	5	8.3%	1	1.7%		
	Extensive	12	20%	9	15%		
	Posterior	1	1.7%	2	3.3%		
	Right ventricular	2	3.3%	1	1.7%		

* Chi-square test; ** Fisher’s exact test

Table 2. Demographic Characteristics and Clinical Information of the Intervention and Control Groups

Group Variable	Control Group		Intervention Group		df	P-value
	Mean	SD	Mean	SD		
Age (Year)	55.4	9.23	57.27	9.6	118	P = 0.50 * t = 1.042
Weight (kg)	77.4	10.51	80.83	12.4	118	P = 0.110 * t = 1.6
Height (m)	171.6	5.9	173	6.03	118	P = 0.073 * t = 1.808
BMI ¹ (kg/m ²)	26.09	3.07	26.38	3.86	118	P = 0.743 ** t = 0.455

* Independent t-test; ** Mann-Whitney U test

Table 3. Comparison of the Two Groups Regarding the Episodes of Chest Pain and Readmission Rate after the Implementation of the Continuous Nursing Care Program

Group Variable	Control Group		Intervention Group		df	P-value
	N	Percent	N	Percent		
Episodes of chest pain	22	36.7%	11	18.3%	1	P = 0.025 * X ² = 5.057
Readmission rate	19	31.7%	8	13.3%	1	P = 0.016 * X ² = 5.783

* Chi-square test

Table 4. Comparison of the Two Groups Regarding the Mean Score of State Anxiety at the Admission Time and 12 Weeks after Discharge

Groups Anxiety	Control Group		Intervention Group		df	P-value
	Mean	SD	Mean	SD		
State anxiety Admission time	36.01	4.84	34.93	2.98	119	P = 0.14* t = -1.475
12 weeks after discharge	35.65	4.29	33.05	4.10	119	P = 0.001* t = -3.39

* Independent t-test

Table 5. Comparison of the Two Groups Regarding the Mean Score of Trait Anxiety at the Admission Time and 12 Weeks after Discharge

Anxiety Groups	Control Group		Intervention Group		df	P-value
	Mean	SD	Mean	SD		
Trait anxiety Admission time	30.63	3.64	29.66	3.43	119	P = 0.13* t = -1.494
12 weeks after discharge	30.2	3.42	27.61	3.42	119	P = 0.001* t = -4.164

* Independent t-test

Table 6. Comparison of the Control Group's Mean Scores of State and Trait Anxiety at the Admission Time and 12 Weeks after Discharge

Variable	Control Group		df	P-value
	Admission time Mean ± SD	12 weeks after discharge Mean ± SD		
State anxiety	36.01 ± 4.84	35.65 ± 4.29	59	P = 0.12* t = 1.56
Trait anxiety	30.63 ± 3.64	30.2 ± 3.42	59	P = 0.097* t = 1.685

* Paired t-test

significant difference was observed between the two groups in this regard 12 weeks after discharge (P = 0.001) (Table 5). The results showed no significant improvement in the mean scores of state anxiety (P = 0.12) and trait anxiety (P = 0.097) in the control group after the implementation of

the continuous nursing care program (Table 6). However, anxiety levels reduced significantly in the intervention group after the implementation of the continuous nursing care program (P = 0.001) (Table 7). No harm or injury was reported during or after the intervention in this study.

Table 7. Comparison of the Intervention Group's Mean Scores of State and Trait Anxiety at the Admission Time and 12 Weeks after Discharge

Variable	Intervention group		df	P-value
	Admission time Mean ± SD	12 weeks after discharge Mean ± SD		
State anxiety	34.93 ± 2.98	33.05 ± 4.10	59	P = 0.001* t = 6.47
Trait anxiety	29.66 ± 3.43	27.61 ± 3.42	59	P = 0.001* t = 7.993

* Paired t-test

5. Discussion

In the present study, it was hypothesized that the continuous nursing care program might positively affect post-MI outcomes, such as anxiety level, readmission rate, and chest pain episodes. The findings indicated that the continuous nursing care program positively affected chest pain episodes, readmission rate, and anxiety level in the post-MI patients.

The results demonstrated that the episodes of chest pain were reduced significantly in the intervention group. The study conducted by Chou et al. also showed that the exercise and educational program improved chest pain, exercise capability, and psychosocial health in patients with cardiac problems (24). Similarly, a recent study reported that cardiac rehabilitation programs improved myocardial perfusion, reduced the frequency and severity of chest pain, and improved blood pressure in patients with microvascular angina (25).

The present study results indicated that the readmission rate was significantly reduced in the intervention group after the performance of the continuous nursing care program for three months. In the same line, a review study showed that nursing education reduced the clinical symptoms, complications, anxiety, and readmission rates in post-MI patients (11). Another research also revealed a significant decrease in the readmission rate after the implementation of the continuous nursing care model (15). A similar study conducted in the U.S.A indicated that the cardiac rehabilitation program had a significant impact on post-MI outcomes, reducing the risk of readmission and death (26). In contrast, Meisinger et al. studied the effect of intervention-based nursing care in patients with MI. They continuously followed up patients through home visits or telephone communication for one year and discovered no significant differences between the two groups regarding the readmission rate (27). The discrepancy between the results might be due to the fact that the patients were followed up by phone or home visits, whereas face-to-face education with an exercise program was employed to improve the patients' outcomes in the current research.

The present study results indicated a significant improvement in the patients' anxiety levels after the implementation of the continuous nursing care program. Accordingly, the level of anxiety was lower in the intervention group compared to the control group. In the same vein, a recent study reported that health coaching via telephone had a positive effect on reduction of anxiety and effectively improved patients' anxiety after MI (28). A review study also demonstrated that cardiac rehabilitation based on exercise reduced depression and anxiety symptoms

among patients with MI (29). Korzeniowska-Kubacka et al., too, conducted an interventional study and disclosed that an exercise training program significantly decreased anxiety and depression levels among post-MI patients (30).

This study was conducted in a small region of Urmia with its unique culture. Since people's culture could affect their learning and obeying behaviors, the generalization of the results for further research or clinical use should be done cautiously. Collecting the data through self-report was another limitation of the study. Yet, it was attempted to provide a private environment to promote honest responses. Lack of blindness was another limitation, which could affect the results. Future studies are recommended to be conducted in different large regions with various cultures to deeply investigate the impact of the continuous nursing care program among post-MI patients.

5.1. Conclusion

The results indicated the positive effect of the continuous nursing care program on reduction of the episodes of chest pain, readmission rate, and anxiety level in the post-MI patients. This program, as a low-cost and non-pharmacological approach, could play a significant role in caring for patients after MI and could positively affect the patients' recovery. Given the consequences of MI, the implementation of this program could be beneficial for post-MI patients, particularly in developing countries where cardiac rehabilitation programs have not been well implemented. The authors recommend the results of this study to be implemented as a guide for healthcare providers and family caregivers to improve post-MI outcomes in patients and accelerate their recovery.

5.2. Ethical Approval

The investigation conformed to the principles highlighted in the Declaration of Helsinki (Br Med J 1964; ii: 177). The study was also approved by the Ethics Committee of Urmia University of Medical Sciences (IR.UMSU.IRC.1394/220) and was registered in the Iranian Registry of Clinical Trials (IRCT2016062625366N17). The participants were fully informed about the study objectives. They were also explained that taking part in the study was voluntary and that they could leave the study at any time. The participants were also assured about their privacy and confidentiality of their information. Written informed consent forms were obtained from all participants.

5.3. Informed Consent

The first researcher fully informed the participants about

the purpose of the study. He explained them the voluntary nature of participation, and they could leave the study at any time. Participants also assured the privacy and confidentiality of their information. Each participant signed written consent before participation.

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Authors' Contribution

Study concept and design: R.B. and A.S.; analysis and interpretation of data: N.P., A.S., and V.A.; drafting of the manuscript: R.B. and N.P.; critical revision of the manuscript for important intellectual content: R.B., A.S., N.P., and S.B.; statistical analysis: V.A.

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The authors have no financial interests related to the material in the manuscript.

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