

Original article

Exploring the Effect of Self-Efficacy Enhancement Program on Medication Adherence and Self-Efficacy among Patients with Acute Coronary Syndrome

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SUMMARY

Introduction/Aim. This study aimed to determine the effect of the self-efficacy enhancement program on medication adherence and self-efficacy in patients with the acute coronary syndrome.

Methods. The parallel randomized clinical trial study was conducted on 86 patients with the acute coronary syndrome in Shahroud, Iran, by using a convenience sampling method. Data collection tools included a demographic questionnaire and a self-efficacy scale for appropriate medication. The self-efficacy enhancement program group received the self-efficacy program in five sessions of 30 to 45 minutes for 40 days, and the control group received routine support. The data were analyzed using descriptive and inferential statistics. The level of significance was considered at 0.05.

Results. After the intervention, a greater improvement in self-efficacy score ($p < 0.001$) and higher medication adherence score ($p < 0.001$) were observed in the self-efficacy enhancement program group than the control group.

Conclusion. Considering the results of the present study, the self-efficacy enhancement program improves self-efficacy and medication adherence in acute coronary syndrome patients. Therefore, it is recommended to apply this intervention as an effective method.

Keywords: acute coronary syndrome, coronary care unit, medication adherence, self-efficacy

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INTRODUCTION

Cardiovascular diseases are the most important cause of mortality in the world today (1). It accounts for 46% of all deaths in Iran (2). Ischemic heart disease includes a range of diseases, including stable angina and ACS (such as unstable angina and myocardial infarction with or without ST-segment elevation) and imposes a high financial burden on individuals and communities due to its severe long-term complications (3). The ideal treatment for this disease involves the use of several measures including drugs, interventions, surgery, risk factor control, and lifestyle modification (4). One of the barriers to appropriate prevention and treatment of cardiovascular disease and prevention of increased treatment costs is the non-adherence to medication regimens and lack of lifestyle modification (5).

Adherence to therapeutic regimens in patients with heart disease involves adherence to the drug and non-drug methods that should be implemented by the patient (6). The adherence concept is one of the fundamental variables of health behavior. In other words, adherence to therapeutic regimens refers to adherence to the recommendations and instructions of medical care professionals (7).

Medication adherence is an effective factor in reducing heart attacks and complications, mortality, hospital readmission, and healthcare costs. However, previous studies have reported a poor medication in cardiovascular patients (8). One of the factors related to medication adherence is self-efficacy. The results of the study of Shen et al. showed that medication adherence can be improved and driven by increasing self-efficacy (9). One of the important theories in the field of self-efficacy is Bandura's theory of self-efficacy. This theory is based on the assumption that people's beliefs about their abilities and talents have optimal effects on their actions and is the most important determinant of behavior. High self-efficacy when approaching difficult tasks and actions helps to create a sense of ease and success, and these successes result in strong beliefs about efficacy, whereas failures weaken these beliefs (10). Self-efficacy judgments include what one thinks they can do, not what one has. These judgments are the product of a complex process of self-evaluation and self-efficacy that relies on the cognitive processing of various sources of efficient information (10, 11).

Cardiac self-efficacy is in fact a specific cardiac measure of one's belief in one's ability to perform activities related to symptoms and challenges posed by coronary artery disease (CAD) (12). Self-efficacy also predicts health-related behaviors in patients with acute myocardial infarction. Self-efficacy had a significant mediating effect on the relationship between medication literacy and medication adherence. Also, the results of the previous study showed that self-efficacy has a positive significant relationship with medication adherence (6). Therefore, it was suggested that cardiovascular patients' medication adherence might be improved and driven by increasing self-efficacy (13). Targeted interventions to improve patients' self-efficacy should be developed and implemented such as a self-efficacy enhancement program (9). There is insufficient literature review documentation on medication adherence in the first three months after discharge in these patients. However, the results of the study by Polsook et al. also indicated that the self-efficacy enhancement program has a significant effect on increasing medication adherence among post-acute myocardial infarction patients (6). In addition, the results of Vibulchai's study showed that the implementation of a self-efficacy enhancement program is effective in improving self-efficacy in Thai patients with myocardial infarction one month after discharge (14).

Considering the widespread prevalence of cardiovascular diseases and subsequent complications, their chronicity, long treatment process, high costs during frequent hospitalizations, it seems necessary to design appropriate educational strategies and follow-up after discharge to promote long-term medication adherence.

AIM

The present study aimed to determine the effect of self-efficacy enhancement program on medication adherence and self-efficacy in ACS patients.

PATIENTS AND METHODS

Study design

The present study was conducted based on a parallel randomized clinical trial design (Code: IRCT20180623040204N1).

Participants

This study was conducted on 86 ACS patients admitted to the CCU ward of Imam Hossein Hospital in Shahroud, northeast of Iran. The participants were randomly allocated in two groups of self-

efficacy enhancement program and control by quadruple blocking. The allocation sequence was performed by a methodology consultant. Block randomization (using a block size of 4) was used. Allocations were placed in white envelopes to conceal

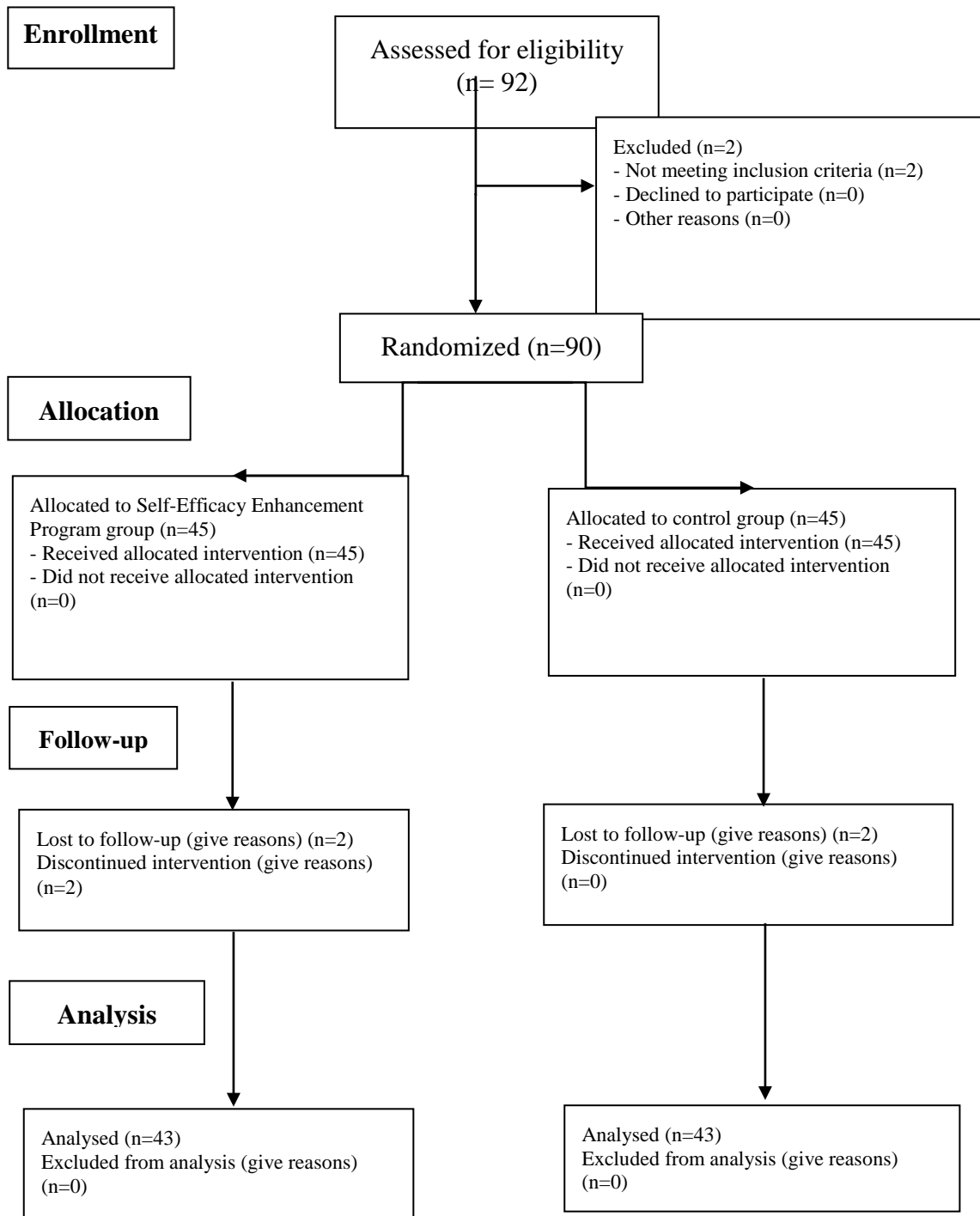


Figure 1. The flow diagram of the study

the allocation sequence. A trained colleague enrolled those participants who met study inclusion and exclusion criteria in hospital and the questionnaires were filled by them before being assigned to two groups. Then an envelope was opened based on the order of entry and the individual was assigned to the target group. Considering the nature of the intervention in this study, it was not possible to blind the participants, but the data collectors and data analysts were not aware of individuals' grouping

Inclusion criteria included individuals aged 20 years or older, the ability to speak and understand the Persian language, and those suffering from acute coronary syndrome. Exclusion criteria also included treatment-resistant ventricular arrhythmias, cardiogenic shock, a history of mental disorders based on patient history and physician's approval.

Ninety patients who met the inclusion criteria were divided into two groups after completing the questionnaires. Four patients were excluded during the study and after discharge from the hospital due to lack of answering telephone calls and inaccessibility. Finally, the data of 86 participants entered the data analysis phase (Figure 1).

Measurements

Data collection tools included a demographic questionnaire, the Self-efficacy for Appropriate Medication Use Scale (SEAMS), and a pill count form for measuring medication adherence. Demographic questionnaire and SEAMS were completed in both experimental and control groups at the first opportunity after the patient's condition was stabilized (based on the cardiologist's opinion).

Demographic characteristics of the participants included age, gender, educational status, occupational status, marital status, insurance coverage, cohabitation status, and caregiver relationship.

The SEAMS scale was designed by Risser et al. to evaluate self-efficacy for appropriate medication use in chronic diseases for illiterate patients and its validity and reliability were confirmed (15). This scale consists of 13 questions. Patients were asked to indicate their level of confidence about medication use using three scores of 1 = I'm not confident; 2 = somewhat confident, and 3 = confident. Scores ranged from 13 to 39, with higher scores indicating higher levels of self-efficacy for medication adherence. Internal reliability was obtained by Cronbach's alpha = 0.89 and external reliability was obtained by

test-retest method and Spearman's correlation coefficient ($r = 0.62$, $p < 0.001$) (15). The Persian version of SEAMS was validated by Sanchooli et al. in Iran (16). The face validity and content validity were assessed qualitatively and were confirmed. Reliability of the instrument was reported at 0.81, 0.77, and $r = 0.97$ using Cronbach's alpha, split-half method, and Spearman's test-retest, respectively ($p < 0.001$) (16).

The pill counting form used to measure medication adherence included a diary which consisted of a chart that was presented as a table listing the patient's name and medication schedule for 40 days and the patient was marked on the chart at each time of medication use. To further control the accuracy of chart completion by the patient, the patient and his/her companion, if any, were trained on the day of discharge. The medication adherence of each patient was obtained by dividing the total number of pills a person took in 40 days by the total number of pills to be taken in 40 days multiplied by 100.

Intervention

After obtaining the required permissions, intervention was conducted according to Self-Efficacy Enhancement Program at CCU ward of Imam Hossein Hospital, Shahroud, Iran. The main goal of this kind of intervention was the promotion of self-efficacy in ACS patients (including three areas of motivation, skill training, and supervision) after discharge period. The first phase of the self-efficacy training program began three days after the first admission. The intervention steps were performed by the first author who was an expert and trained nurse in CCU setting. Therefore, she provided the necessary face-to-face training to the patient on the definition of the acute coronary syndrome, risk factors and symptoms of heart disease, medication regimen, and home care in the room located in CCU or in the day room of the above unit if the patient was transferred to the cardiology ward. Each participant received a drug brochure including the type of drug, mechanism of action, dose, side effects, and drug interactions. It should be noted that significant and more frequent complications were presented and we avoided talking about complications leading to medication non-adherence. Valid pharmacology books and cardiovascular specialists' opinions were used to provide the above training to patients. The context of the intervention and the provided education was personalized-tailored and carried out

with the ACS setting, its outcomes, and the needs of patients with ACS. The training session lasted between 30 to 45 minutes and included the time for asking questions and answers. This time depended on patient's condition. Participants were also asked to explain their medication, drug interventions, dose, and side effects to evaluate their knowledge. Medication adherence was monitored by asking participants to complete a diary to record their medication use. The participants recorded their medications in their diary and these data were used to report medication adherence. Therefore, at first, the number and frequency of drugs that each patient should take during the 40 days of the study (the drugs prescribed by the cardiologist) were determined. Since the researcher wanted to find scores for how the patient took the medication, she reviewed the completed chart for each patient. For this purpose, the number of drugs that the person had to take in total in 40 days and also the frequency of the drugs that the person had taken were investigated. When participants were discharged from hospital, the researcher continued their medication adherence through three telephone follow-ups in the next phases. In the second phase, 10 days after discharge, the first follow-up was conducted for 10 minutes, and the patient was provided with the necessary training on follow-up on treatment and medication, and self-care as well as in the case of any problem. Telephone follow-up was carried out three other times in ten-day intervals in the same way (17). All of intervention setting and information were provided according to the TIDieR checklist that was utilized for reporting and reproducibility (18).

The control group received routine ward training and supports, including training by physicians, nurses, or ward posters in the hospital and at discharge time. All participants of the two groups completed the SEAMS scale again and received a pill count chart to measure their adherence rate 40 days after discharge.

Sample size

According to the study by Polsook et al. (6) and taking into account $\alpha = 0.05$, study power = 90%, the sample size was estimated with 40 samples in each group. A total of 90 patients (N = 45 per group) were considered regarding the probable drop-out.

Blinding

Considering the nature of the intervention in this study, it was not possible to blind the participants, however, the data collectors and data analyzers were not aware of individuals' grouping.

Data analysis

Data were analyzed using descriptive (absolute and relative frequency, mean and standard deviation) and inferential statistics (Chi-square, independent sample t-test and Pearson correlation coefficient). Mean and standard deviation indices were used to describe the quantitative data and absolute and relative frequency indices were used to describe the qualitative data. A Chi-square test was used to determine the relationship between qualitative variables and to determine the mean difference between two independent groups; an independent t-test was used. Also, to reveal the changes in self-efficacy scores in each group, the paired-test was used. Analysis of covariance (ANCOVA) was performed to eliminate the effect of pretest scores of self-efficacy and group variables on post-test mean scores of self-efficacy. Pearson correlation coefficient was also used to determine the correlation between the two quantitative variables.

Ethical considerations

After obtaining the necessary permission from the Research Vice Chancellor for Research and Research Ethics Council of Shahroud University of Medical Sciences, all patients read and signed written consent forms regarding the aim of the research. This study was approved by the Ethics Council for Medical Research of Shahroud University of Medical Sciences with code IR.SHMU.REC.1397.066. All patients read and signed written consent forms about the purpose of the study and patients.

RESULTS

The mean age of the patients in the experimental and control groups was 63.7 and 61.8 years, respectively. The results of data analysis of demographic characteristic showed no significant difference between groups in terms of age, gender,

level of education, marital status, insurance coverage, supplementary insurance after discharge, and first manifestation of coronary disease. Two groups were homogeneous in this regard. Ten pa-

tients (23.3%) in the control group and 16 patients (37.2%) in the experimental groups had not experienced coronary artery disease symptoms and taking related medication (Table 1).

Table 1. Comparison of demographic characteristics of patients with acute coronary syndrome for both intervention and control group

Group		Intervention	Control	p
Variable		(Mean ± SD)	(Mean ± SD)	
Age (year)		63.7 ± 9.3	61.8 ± 13.4	0.45
The duration of the disease (year)		5.1 ± 4.7	3.1 ± 3.5	0.51
Successful education (year)		5.1 ± 5.3	3.8 ± 4.9	0.23
		N (%)	N (%)	
Gender	Male	20 (46.5)	18 (41.9)	0.19
	Female	23 (53.5)	25 (58.1)	
Marital status	Single	9 (20.9)	11 (25.6)	0.80
	Married	34 (79.1)	32 (74.4)	
Insurance	Yes	42 (97.7)	42 (97.7)	0.75
	No	1 (2.3)	1 (2.3)	
Supplementary insurance after discharge	Yes	26 (60.4)	16 (37.2)	0.31
	No	17 (39.6)	27 (62.8)	

p: P value; SD: Standard deviation; N: Number; %: Percent

Table 2. Mean self-efficacy score for appropriate medication use in the intervention and control group before and after the intervention

Group	Intervention	Control	Intergroup test results
Self-efficacy	(Mean ± SD)	(Mean ± SD)	
Before intervention	31.7 ± 3.7	29.6 ± 5.3	0.045*
After intervention	33.8 ± 3.6	29.7 ± 4.6	< 0.001*
Mean difference	2.1 ± 3.6	0.3 ± 3.1	< 0.001*
Intragroup test results	< 0.001**	0.769**	

SD: Standard deviation;

*: Independent sample t-test

**.: Paired t-test

There was a significant difference between the two groups in terms of pre-intervention self-efficacy scores so that the mean self-efficacy score in the control group was lower than the experimental group. The mean post-intervention self-efficacy score in the control group remained almost constant, but it increased in the experimental group, so that there was a significant difference between the two groups in terms of mean post-intervention self-efficacy score. Also, the mean difference in self-efficacy score

(before and after intervention) was significantly higher in the experimental group than the control group. In addition, the results of the present study showed that the mean scores of self-efficacy increased after intervention in the experimental group ($p < 0.001$) (Table 2).

In addition, Table 3 showed the factors affecting scores of self-efficacy after the intervention based on the analysis of covariance (ANCOVA). The results showed that the pre-intervention mean score

Table 3. The influence of independent variables on post-intervention self-efficacy score by analysis of covariance (ANCOVA)

Variables		β	SE	t	p
Constant value		10.952	3.352	3.268	0.002
Self-efficacy (before intervention)		0.634	0.103	6.135	< 0.001
Group	Control	ref			
	Intervention	2.727	0.607	4.496	< 0.001

p: P value; SE: Standard error

Table 4. Mean medication adherence score in the intervention and control group after the intervention

Group	Intervention	Control	p
Variable	(Mean \pm SD)	(Mean \pm SD)	
Medication adherence	94.8 \pm 2.2	91.5 \pm 2.8	< 0.001

p: P value; SD: Standard Deviation

of self-efficacy and group variables were effective on the post-intervention mean score of self-efficacy. Also, the patients in the intervention group reported a higher self-efficacy score of 2.727 units than the control group.

There was also a significant difference between the intervention and control groups in terms of the mean of the medication adherence after the intervention, so that the mean medication adherence score in the experimental group was higher than the control group (Table 4).

In addition, there was a positive and significant correlation between self-efficacy score of appropriate medication use with medication adherence in both experimental ($r = 0.645$, $p < 0.001$) and control ($r = 0.491$, $p = 0.001$) group, i.e. increased self-efficacy scores resulted in an increase in proper medication use and medication adherence.

DISCUSSION

The results showed that the mean increase in self-efficacy score (mean difference) was significantly higher in the experimental group than the control group. In other words, the self-efficacy enhancement program increased the self-efficacy of appropriate medication use in the experimental group. Previous studies showed that self-efficacy enhancement programs based on a text message and telephone follow-up increased self-efficacy in patients with CAD (19), acute myocardial infarction

(20) and hypertensive patients (21), which is consistent with the results of the present study.

The results of the present study revealed a significant difference between the two groups in terms of post-intervention medication adherence score. In other words, the self-efficacy enhancement program increased medication adherence in the intervention group. Consistent with this finding, the results of Paryad et al.'s study showed the significant effect of educational interventions on medication adherence among patients after coronary artery bypass surgery and the study of Ampofo et al. showed the effect of such interventions on medication adherence in patients with hypertension (22, 23). Also, the results of the Saki et al.'s study showed that patient-centered education is effective in the improvement of treatment regimen adherence in CAD patients (24).

There was also a positive and significant correlation between self-efficacy with appropriate medication use and medication adherence in both groups, i.e. increasing self-efficacy resulted in an increase in the appropriate medication use and medication adherence. Polsook et al. Uta Maeda et al. and Hosseinzadeh et al. also showed that increasing self-efficacy resulted in an increase in medication adherence, which is consistent with the results of the present study (6, 25, 26). Patients adhere to their medication regimens when they have confidence and believe in the important effects of their cardiovascular drugs (27, 28). Self-efficacy enhancement programs affect health behaviors in many

chronic diseases by enhancing patients' self-confidence and many health behaviors interventions help improve patients' self-efficacy (29, 30). According to Bandura's theory, the self-efficacy enhancement program was implemented using motivation activities by increasing medication adherence methods, training medication adherence skills, and monitoring the repetition and practice of medication adherence practices (31).

Limitations

The follow-up after the intervention was done only 40 days after the end of the intervention, so it is recommended to evaluate the patients at longer intervals and examine the long-term effects of the intervention. In the present study, it was personalized and implemented according to the acute coronary syndrome disease, so the results may have low generalizability. Therefore, it is necessary to check its reproducibility in other environments. Due to the lack of evaluation of patients with psychiatric diagnoses, the clinical benefits of the present study may have been reduced. Therefore, it is recommended that this exclusion criterion be removed for future studies, which may reconcile the findings with clinical reality considering psychiatric comorbidity (32). Since medication adherence was measured using the self-report method, there is a

risk of distortion by error-prone participants, and attempts were made to reduce or eliminate this limitation by providing training to the patient or one of the family members as well as telephone follow-ups.

CONCLUSION

Considering that the self-efficacy enhancement program improves self-efficacy and medication adherence, nurses and physicians are recommended to implement the self-efficacy enhancement program for patient education.

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Conflict of interest statement

The authors declare that they have no conflict of interest.

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Ispitivanje efekta programa za unapređenje samoefikasnosti u pridržavanju propisane terapije i samoefikasnost kod bolesnika sa akutnim koronarnim sindromom

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SAŽETAK

Uvod/Cilj. Cilj ove studije bilo je utvrđivanje efekta programa za unapređenje samoefikasnosti u pridržavanju propisane terapije i samoefikasnosti kod bolesnika sa akutnim koronarnim sindromom.

Metode. Primenom metode prigodnog uzorka, sprovedena je paralelna randomizovana klinička studija koja je uključila 86 bolesnika sa akutnim koronarnim sindromom u Šahrudu, u Iranu. Alati za prikupljanje podataka obuhvatili su demografski upitnik i skalu procene samoefikasnosti u uzimanju propisane terapije. Grupa uključena u program unapređenja samoefikasnosti dobila je informacije o ovom programu za narednih 40 dana u pet sesija koje su trajale od 30 do 45 minuta, dok je kontrolna grupa dobila rutinsku podršku. Podaci su analizirani primenom deskriptivne i inferencijalne statistike. Nivo značajnosti određen je na 0,05.

Rezultati. Nakon intervencije, zabeleženo je veće poboljšanje skora samoefikasnosti ($p < 0,001$), kao i poboljšanje skora u pridržavanju uzimanja propisane terapije ($p < 0,001$), u grupi koja je bila uključena u program nego u kontrolnoj grupi.

Zaključak. Rezultati naše studije pokazali su da je program unapređenja samoefikasnosti poboljšao samoefikasnost i pridržavanje uzimanja propisane terapije kod bolesnika sa akutnim koronarnim sindromom. Stoga, primena ove intervencije preporučuje se kao efikasna metoda.

Ključne reči: akutni koronarni sindrom, jedinica koronarne nege, pridržavanje propisane terapije, samoefikasnost