

Evaluation of Sixty Days of Patients' Safety Program under Self-Management Protocol among Patients with Acute Coronary Syndrome: A Clinical Trial Study

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ARTICLE INFO	ABSTRACT
<p>Article type: Original Article</p> <hr/> <p>Article History: Received: 08 Feb 2023 Accepted: 07 Mar 2023</p> <hr/> <p>Key words: Acute coronary syndrome, LIPAD questionnaire, Quality of life, Self-management</p>	<p>Introduction: The improvement of patient safety and the quality of life in acute coronary syndrome (ACS) patients are the main objectives of health care systems. Self-management education programs are thus considered one of the effective protocols to improve patients' quality of life. This study aimed to evaluate the effect of the self-management protocol 5A model on elderly ACS patients' quality of life.</p> <p>Materials and Methods: This clinical trial was conducted on 53 ACS patients of the Cardiology Department, Imam Reza Hospital, Bojnourd, Iran. Patients were selected according to the permutation blocks for two groups: intervention and control. The intervention group received a self-management program based on the 5A model: Assessment, Advisement, Agreement, Assistance, and Arrangement. The two groups answered demographic and LIPAD questionnaires during the admission and after two months of follow-up. Data were analyzed by the SPSS software (version 16).</p> <p>Results: The findings presented that most ACS patients were female, married, and uneducated. All dimensions of quality of life increased significantly after the study process ($P < 0.05$). However, these elevated levels were not statistically different between the two groups during the study ($P > 0.05$).</p> <p>Conclusion: We presented elevated levels of quality of life among ACS cases after the self-management program during the two-month interval. Considering any difference between the two study groups, further research is needed to improve ACS patients' health levels and quality of life.</p>
<p>► Please cite this paper as: Javanvash Z, *Nodehi S, Khani A. Evaluation of Sixty Days of Patients' Safety Program under Self-Management Protocol among Patients with Acute Coronary Syndrome: A Clinical Trial Study. <i>Journal of Patient Safety and Quality Improvement.</i> 2022; 11(1): 23-31. Doi: 10.22038/PSJ.2023.70615.1387</p>	

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Introduction

Today, cardiovascular diseases (CVDs) are dealt with as the most common global diseases. Despite rapid progresses in the diagnosis and treatment of CVDs during recent decades, death and not recovering due to heart attacks are still prevalent among CVDs patients (1). According to the World Health Organization, most deaths occur in developing countries due to the increasing rate of CVD (2). One of the most serious CVDs is the acute coronary syndrome (ACS) (3), which is one of the leading reasons of death globally (4). There are also reports of the increasing prevalence of CVDs in Iran (5). The ACS is one of the health-threatening conditions in old age, as well as one of the most common disorders and causes of death in people over 65 years (6). If patients do not have sufficient knowledge in the field of self-care, they cannot make decisions about their health and hygiene (7,8).

Recently, attention has been paid to supportive treatments and training to improve the quality of patients' life, mostly through accepting treatments based on self-management programs (9). Meanwhile, various educational and self-management methods have been used to improve the quality of life; however, contradictory results have been obtained (10). The self-management program based on the 5A model is an evidence-based approach used to change behavior and ensure health under five steps, including Assessment, Advisement, Agreement, Assistance, and Arrangement (11). This self-management program model is a short and simple method for improving patients' safety and quality of life. Self-management means that patients actively participate in the self-care and management of their disease. The main goal of self-management programs is for patients to achieve maximum independence and self-determination by relying on their abilities and, as a result, increasing their quality of life (12).

There are few studies in the category of self-management based on the 5A model among patients with cardiovascular problems. This study aimed to investigate the effect of the self-management program on the quality of life of the elderly with ACS.

We hope this solution helps nurses and patients to reduce the duration of hospitalization and increase the levels of patient safety, as well as the quality of life.

Materials and Methods

This clinical trial study was performed on patients with ACS who were referred to the Heart and Cardiac Care Unit (CCU) Department, Imam Reza Hospital, Bojnourd, Iran, in 2021. To carry out this study, permission was obtained from the Local Ethics Committee of the Bojnourd Medical University under the IR.MEDSAB.REC.1395.79 code.

Patients who had the following criteria were included in the study: 1) willingness to cooperate, 2) over 21 years of age, 3) confirmed diagnosis of ACS (unstable angina-MI with or without elevated ST), 4) the ability to speak or understand Persian (or having a companion who was fluent in Farsi), 5) the absence of Alzheimer's disease or a clear, severe depression, 6) the absence of any disability, 7) the ability to read or write (or having a literate companion), and 7) patients who lived with family and were resident in Bojnourd. On the other hand, patients with the following criteria were excluded: 1) a disease during the study (such as musculoskeletal and physically debilitating diseases) that led to the hospitalization of elderly cases, 2) non-participation in meeting sessions, 3) a desire to withdraw from the study, 4) death of the patient, and 4) any sudden stressful life events and conditions at each stage of the research, such as the death of family members or immigration.

Sample Size

The sample size of the study was determined by the G*Power software (version 3.01, Franz Faul, Christian-Albrechts- Universität Kiel, Kiel, Germany). We used Shahbazi et al.'s investigation (13) of the effect of a self-management program based on the 5A model on the severity of fatigue and shortness of breath in patients with chronic obstructive pulmonary disease. Forty-five cases were determined considering a 2.99 cure rate, 80% study power, and 95% confidence interval. Moreover, considering a loss to follow-up of

20%, participants elevated to 27 patients for each group. Finally, one person was excluded from the study due to death during the study, and the study was performed on 53 cases.

Study Protocol under the 5A Model

For sampling, the researcher referred to the Medical Records Department and through the ICD-10 software, accessed the desired samples (all elderly patients with ACS who had a history of hospitalization from March 2019 to November 2019 in the heart and CCU departments). Afterward, the researcher accessed the contact of patients who met the inclusion criteria and performed sampling. Participants were divided into two groups, according to the block randomized method of sampling. Groups were defined as the intervention group (group A=27 members) and the control group (group B=26 members). During a face-to-face meeting before the intervention, all participants were asked to fill out an informed consent form, a related demographic questionnaire, and the LIPAD quality of life questionnaire.

We performed the self-care management interventions based on the 5A model under five processes, including Assessment, Advisement, Agreement, Assistance, and Arrangement. In the assessment stage, the patient's risk factors, disease history, joint problems, medication use, sleep status, nutrition, activity, and information in the file were checked through a face-to-face interview. In the advisement stage, according to the results of the previous stage, the patient was informed of the diagnosed health risks and the benefits of behavior change. Afterward, there was an Agreement stage between each patient and the researcher regarding the patient's performance. Due to the diagnosed problems, the appropriate behavioral goals agreed with the patient were determined. The follow-up phase (Arrangement) was performed according to the agreement with the participants (initially daily, after two weeks, twice a week, and after a month, once a week until the end of the intervention period). After one month, an individual face-to-face meeting was held, and the patient's progress in implementing practical plans

and behavioral goals was monitored. The contact number of the researcher was provided to the participants for any related problems at any time of the day or night. After two months, the participants came to complete the quality of life questionnaire.

Questionnaire

In the present study, we applied the LIPAD questionnaire designed previously by De Leo et al.(14). It consists of 31 questions measuring seven dimensions of the quality of life, including physical dimensions (5 questions), self-care (6 questions), depression and anxiety (4 questions), cognitive (5 questions), social (3 questions), life satisfaction (6 questions), and sexual issues (2 questions). All items are scored on a four-point Likert scale ranging from 0 to 3, representing the worst case to the best. Furthermore, the scoring of the LIPAD questionnaire ranges from 0 to 93, with a higher score representing a better quality of life. In Iran, Hesamzadeh et al. calculated the validity and reliability of this questionnaire, and Cronbach's alpha reliability coefficient was reported 0.831 (15). We also reported previously Cronbach's alpha at 0.953 (95% CI: 0.946-0.958) among the older adult population. A demographic questionnaire was also completed by all patients. This questionnaire was evaluated by 10 people included in the study (faculty members, nursing and midwifery staff, cardiologists, and the nursing personnel with experience in the CCU department) and after making corrections, it was compiled for use in research. Previously, Cronbach's alpha reliability coefficient for this demographic questionnaire was reported as 0.831 (16). In this study, we measured the Cronbach's alpha reliability coefficient under evaluation by 10 people. Each person evaluated this tool once, and then Cronbach's alpha regarding the single questions and their dimensions was calculated at 0.95.

Data analysis

Data were analyzed by the SPSS software (version 16.0, SPSS Inc., Chicago, Illinois, USA). Quantitative variables were described using mean and standard deviation (SD), and qualitative variables by frequency and percentage.

The Mann-Whitney U test and the Chi-square test were performed to determine differences between the two groups of the study in demographic variables. Moreover, the estimation of the effect of demographic variables and the overall score of quality of life was performed under the repeated measures analysis of variance (Repeated measures ANOVA) test. Furthermore, the Wilcoxon test and the Paired T-Test were performed for comparing the results of the LIPAD questionnaire between the two groups and in each group before and after the study, respectively.

A P-value of less than 0.05 was considered significant for all statistical analyses.

Results

This study was conducted on 53 elderly cases with ACS. Table 1 presents demographic variables among the studied participants.

As can be seen, most participants were illiterate females (61.35%). In addition, most of them were healthy retired persons without any consumption history of smoking or drug abuse.

Table 1: Demographic variables among the studied participants

Variable		Mean±SD Number (%)
Age, years		66.18±4.68
Duration of heart disease, years		1.90±0.97
Number of hospitalization		2.90±2
Duration of hospitalization, days		2.74±4.66
Gender	Male	22 (41.50)
	Female	36 (58.50)
Marital status	Married	44 (83)
	Widow	9 (17)
Education	Illiterate	34 (64.20)
	Undergraduate	11 (20.80)
	Under diploma	1 (1.90)
	Diploma	2 (3.80)
	Higher than diploma	5 (9.40)
Job	Unemployed	7 (13.20)
	Retired	11 (20.80)
	Self-employed	7 (13.20)
	Housewife	28 (52.80)
Drug abuse	Yes	15 (28.30)
	No	38 (71.70)
Smoking	Yes	3(5.70)
	No	50 (94.30)
Nationality	Turkish	18 (34)
	Turkoman	9 (17)
	Kurdish	24 (45.30)
	Persian	2 (3.80)
Underlying disease	Healthy	35 (66)
	Diabetes	5 (9.40)
	Skeletal-articular	9 (17)
	Digestive disease	1 (1.90)
	Depression	1 (1.90)
	Lung disease	1 (1.90)
	Renal failure	1 (1.90)
Disability	Yes	1 (1.90)
	No	52 (98.00)
Income status	Below 5 million	23 (62.30)
	Between 5 to 10 million	11 (20.80)
	Higher than 10 million	9 (17)

Data are presented by mean±SD or frequency and related percentages Table 2 shows the evaluation of these demographic variables between the two groups of participants. As illustrated in the table, most of the studied demographic variables were

the same between the two studied groups (P>0.05). Therefore, the studied members were distributed similarly between the intervention and the control groups, and there was no confounding factor affecting the study results.

Table 2: Evaluation of the demographic variables between the two studied groups

Variable		Studied groups		P-value
		Case Mean±SD, N (%)	Control Mean±SD, N (%)	
Age, years		68.08±6.29	64.29±3.07	0.10
Duration of heart disease, years		1.85±0.96	1.96±0.98	0.62
Number of hospitalization		2.81±2.15	3±1.86	0.38
Duration of hospitalization, days		2.53±3.96	2.96±4.96	0.44
Gender	Male	11 (42.30)	11 (40.70)	0.65
	Female	15 (57.30)	16 (59.30)	
Married status	Married	21 (80.8)	23 (85.20)	0.47
	Widow	5 (19.20)	4 (14.80)	
Education	Illiterate	21 (80.80)	13 (48.10)	0.08
	Undergraduate	2 (7.70)	9 (33.30)	
	Under diploma	0	1 (3.70)	
	Diploma	1 (3.80)	1 (3.70)	
	Higher than diploma	2 (7.70)	3 (11.10)	
Job	Unemployed	4 (15.40)	3 (11.10)	0.67
	Retired	6 (23.10)	5 (18.50)	
	Self-employed	2 (7.70)	5 (18.50)	
	Housewife	14 (53.80)	14 (51.90)	
Drug abuse	Yes	7 (26.90)	8 (29.60)	0.82
	No	19 (73.10)	19(70.40)	
Smoking	Yes	2 (7.70)	1 (7.30)	0.53
	No	24 (92.30)	26 (96.30)	
Nationality	Turkish	9 (34.60)	9 (33.30)	0.91
	Turkoman	4 (15.40)	5 (18.50)	
	Kurdish	12 (46.20)	12 (45.30)	
	Persian	1(3.80)	1 (3.70)	
Underlying disease	Healthy	21 (80.80)	14 (51.90)	0.12
	Diabetes	1 (3.80)	4 (14.80)	
	Skeletal-articular	2 (7.70)	7 (25.90)	
	Digestive disease	0	1 (3.70)	
	Depression	1 (3.80)	0	
	Lung disease	0	1 (3.70)	
Renal failure	1 (3.80)	0		
Disability	Yes	0	1(3.70)	0.32
	No	26 (100)	26 (96.30)	
Income status	Below 5 million	18 (69.20)	15 (55.60)	0.51
	Between 5 to 10 million	5 (19.20)	6 (22.20)	
	Higher than 10 million	3 (11.50)	6 (22.20)	

Data are presented by mean±SD or frequency and related percentages. Data were also analyzed by the Mann-Whitney U test and the Chi-square test for qualitative and quantitative variables, respectively. A P-value of less than 0.05 was considered significant. We evaluated the overall score of

the LIPAD questionnaire on different demographic variables (Table 3). The analysis showed that, in every studied group, the effect of demographic variables on the quality of life wasn't statistically significant (P>0.05). However, based on the comparison of the two groups, age and drug

abuse could be considered two effective confounding variables on the quality of life of the studied participants ($P < 0.05$). The

grouping also had a considerable effect on the overall score of the quality of life, related to the LIPAD questionnaire.

Table 3: Estimation of the effect of different demographic variables and the overall quality of life score

Variable	Studied effects, P-value	
	In-groups	Inter-groups
Age	0.59	0.05
Nationality	0.71	0.84
Education	0.23	0.10
Duration of heart disease	0.91	0.82
Numbers of hospitalization	0.65	0.37
Smoking	0.10	0.62
Drug abuse	0.57	0.05
Group	0.001	0.50

The P-value calculated by the Repeated measures ANOVA and less than 0.05 was considered significant.

In the next step, we investigated different dimensions of the LIPAD questionnaire before the study and after two months of follow-up between the intervention and control groups (Figure 1). The findings showed that the two studied groups had no significant difference in different dimensions of the LIPAD questionnaire ($P > 0.05$). Moreover, these differences were not significant for members of the control group after two months of follow-up sessions ($P > 0.05$). However, members of the intervention group experienced considerable

differences in most dimensions of the related questionnaire ($P < 0.05$). Regarding the depression and anxiety scores, members of the intervention group had significantly higher scores after the study protocol ($P = 0.001$). Furthermore, study participants in the other items, including cognitive, social, life satisfaction, and self-care dimensions experienced statistically significant higher scores after follow-up, compared to before the study ($P = 0.001$). However, members of the intervention group had a higher score after the study than before the study in the physical dimension of the LIPAD questionnaire but this difference was not statistically significant ($P = 0.78$).

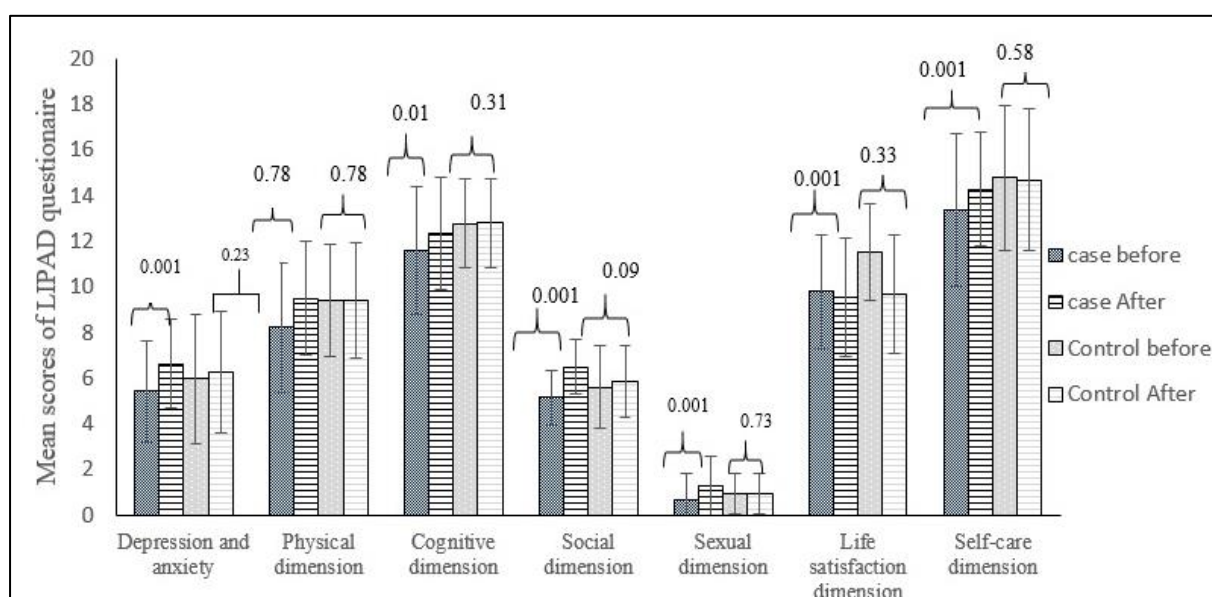


Figure 1: Comparison of the LIPAD questionnaire dimensions between the two study groups. Data in each column was calculated by the Paired T-Test and compared before and after the LIPAD scores in each group.

Data are presented by mean±SD. Data were calculated by the Wilcoxon test for comparing the results of the LIPAD questionnaire between groups. In addition, the Paired T-Test was performed to compare the results of the questionnaire in each group before and after the study. A P-value of less than 0.05 was considered significant.

Discussion

In the present study, the results showed that the overall average quality of life at the end of the study increased, compared to the beginning of the study.

Moreover, the average of all dimensions of the quality of life increased at the end of the study, based on the LIPAD questionnaire assay. However, the Repeated measures ANOVA showed that changes in the quality of life between the two groups during the study processes were not statistically significant.

There are limited studies on the implementation of the previously-mentioned self-management program, especially in patients with ACS. A previous study evaluated the effect of self-care training on the quality of life of 126 heart failure patients (17).

The results showed a significant difference in the average quality of life between the control and intervention groups after the investigation. In their study, four to six sessions of 30 to 45 min were arranged for 50 participants in the intervention group. The training package was also given to the patients at the end of the study. In another study, the questionnaire was completed before the study and one month after the intervention. Most patients were male with an average age of 57 years, married, and graduated.

The differences between our study and this might be due to the larger sample size of this study, compared to ours. Furthermore, the number of face-to-face meetings was more and the education of the participants was higher, compared to our study. These reasons might be considered the related difference. Another investigation on the effect of self-care education on patients with unstable angina showed different results (18). Their evaluation included 80 patients divided into two groups (intervention and control). Two educational sessions were

held for the intervention group during the admission and hospital discharge. The quality of life was measured before training and one month after training. The results showed a significant difference between the two groups in the physical health dimension of the LIPAD questionnaire. The difference between this study and the current study may be because most of the participants were men with an average age of 40 years. The training was also conducted by the researcher from the time of hospitalization until discharge on consecutive patients. However, in the present study, several months had passed since patients were hospitalized, and both groups benefited from hospital training, which may have impacted the results.

In the present study, we evaluated the relationship between demographic status and the quality of life of ACS patients during the self-management program. Previous studies showed that family members and high marital quality could have an important role in providing both practical and emotional support to CVD patients (19, 20). Family members could provide psychosocial assistance through more hours of strong emotional interactions with the patient (21,22). These supports could increase patients' self-care and health-related quality of life (HRQOL) and decrease depression (23,24). Moreover, improving adherence to treatment courses and professional educational programs for patients is possible with sufficient support from these family members (25).

We could not find any significant effect of demographic variables on the quality of life dimensions. It might be due to the non-significant differences in the demographic variables between the two groups of participants at the beginning of the study. Similar to our results, previous studies found that there were no group differences in HRQOL, depressive symptoms, patients' self-care behaviors, and partners' experiences of caregiver burden (26).

Similar to the present results, they found that there was no direct effect of demographic variables on the quality of patients' life during self-care programs for patients with heart failure (26). Another study among patients with myocardial

infarction and coronary artery bypass graft surgery found that the quality of life increased at the end of the study (27).

However, this was not significant, and these patients had a lack of sexual knowledge. Moreover, there was no significant relationship between the quality of life and the patient's age and level of education. The difference between the present study and the previously-mentioned one might be due to factors including the difference in economic status, old age, anxiety due to heart disease, the illiteracy of most participants, the presence of elderly women, as well as cultural and religious differences.

Due to the old age of the samples, there is a possibility of forgetting their behavioral goals or their premature fatigue. However, we tried to avoid this by guidance during the follow-up sessions.

Quality of life is a subjective concept that can be evaluated. Furthermore, trusting the accuracy of the researchers' answers might be mentioned as one of the study's limitations. There were also uncontrollable underlying factors, including the cultural background, beliefs and opinions, individual differences, interests, as well as the attitudes of the subjects learning and applying training.

Conclusion

This study evaluated the effects of a self-management program based on the 5A model on the quality of life of the elderly with ACS at a two-month interval.

The results showed that the training in this program did not have a statistically significant effect on the quality of life of the participants.

According to the results of the study, it seems necessary to investigate the reasons for the unfavorable results of the quality of life of the research units to improve the health level of patients and consider ways to increase the quality of life.

Acknowledgment

This study, as a master thesis of Internal Medicine-Surgery Nursing, was supported financially by the Research Council of Sabzevar University of Medical Sciences, Sabzevar, Iran, under the following research

number (IR.MEDSAB.REC.1395.79). We sincerely thank and appreciate the respected officials of Imam Reza Hospital, Bojnourd, Iran, the respected staff of the Medical Records Department, and the dear patients who helped us in conducting this study.

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