## **Original Article**

Investigating the Effect of Family-Centered Self-Care Program based on Home Visits Regarding Dietary and Medication Regimen Adherence of Discharged Patients with Acute Coronary Syndrome

### Abstract

Background: Dietary and medication regimen adherence in patients with history of Acute Coronary Syndrome (ACS) is very important in preventing readmission and reducing the complications of the disease. The objective of the present study was to investigate the effect of the family-centered self-care program based on home visits dietary and medication regimen adherence in patients with ACS discharged from Shahid Chamran Hospital during 2017-2018. Materials and Methods: This clinical trial was conducted on 80 ACS patients. The samples by using the random numbers table, were randomly divided into control and experimental groups. The routine interventions were administered for the control group, and family-centered self-care was conducted on patients of the experiment group. In order to obtain the quantitative data of this study, three questionnaires were used including demographic characteristics, Morisky questionnaire, and dietary adherence. Results: The difference between the mean score of medication and diet regimen adherence in both groups before the intervention was not significant (p > 0.05), data was demonstrated that scores of medication and diet regimen adherence were significantly higher immediately and 6 weeks after the intervention; (f = 64.06, p < 0.001). Conclusions: Family-centered self-care program based on home visits can be used as an effective method to increase the dietary and medication regimen adherence in ACS patients.

Keywords: Acute coronary syndrome, family nursing, house calls, medication adherence, self care

## Introduction

Cardiovascular Diseases (CVDs) are among the most common diseases which are globally been dealt with. Despite the rapid progresses in diagnosing and treatment of these diseases in recent decades, one-third of patients with heart attacks die, and two-thirds of the survivors never recover.<sup>[1,2]</sup> According to World Health Organization (WHO), about 30% of deaths in developed countries and 35%-82% of deaths in developing countries are due to Cardiovascular Diseases.<sup>[3]</sup> It is estimated that Cardiovascular Diseases would be responsible for more than 75% of the world's total deaths in 2020. Moreover, this trend would continue to the point that deaths from CVDs would increase from about 17 million to 23.4 million per year.<sup>[4]</sup> Acute Coronary Syndromes (ACS) including unstable angina and myocardial infarction, are among the most common Cardiovascular Diseases in most countries of the world.<sup>[5-7]</sup> The manifestations of the disease include a wide range of physical psychological symptoms, and which may include pain, sweating, vomiting, stress, and anxiety. The disease is mostly seen in industrialized societies and developed countries.<sup>[7]</sup> The prevalence of Cardiovascular Diseases' risk factors is increasing in Isfahan. More than 75% of Isfahan population have at least one main risk factor of Cardiovascular Diseases, and more than 33% of the population have two major risk factors.<sup>[8]</sup> Therefore, taking appropriate measures to reduce the burden of the ACS and secondary prevention of the disease is a major concern.<sup>[9]</sup>

Considering the widespread prevalence of Cardiovascular Diseases, changing lifestyle and long-term medication regimen adherence are very important.<sup>[10]</sup> According to the WHO, only 50% of patients with

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chronic diseases keep their diet. In addition, there is a low rate of medication adherence in cardiovascular medicines, including anti-diabetic, anti-hypertensive, and lipidregulating drugs in patients.<sup>[11,12]</sup> Non-adherence of cardiac patients to medical recommendations is the main barrier in achieving therapeutic objectives, which leads to the failure of preventive and therapeutic measures for cardiovascular patients, as well as increasing the costs of treatment.<sup>[13]</sup> Medical non-adherence and lack of self-care behaviors is a multifactorial process including a wide range of factors such as social, economic, and clinical factors, as well as patient-caregiver interactions.<sup>[9,14]</sup>

The primary principle of self-care is the participation of the patient. The cardiac patients would have better chance of controlling many complications of heart disease by accepting more responsibility toward an appropriate self-care.<sup>[15]</sup> Therefore, the engagement of patient and family members in patient's care is an effective way to reduce the physical and psychological complications of the disease.<sup>[16,17]</sup> There has been an increase in the number of families caring for patients with chronic conditions over the last two decades.[18] Family-centered care is an aspect of growth in the general health of the community.<sup>[16,19]</sup> Family-centered care is a major concept in nursing which focuses on maintaining family integrity and providing high-quality care for each patient. In addition, family-centered care is known as a concept that recognizes the importance of the family unit as the central point in all health care manners.<sup>[20,21]</sup> The family-centered self-care model consists of constant and interconnected steps which form a process improving the health of individuals within the family contexts.<sup>[22]</sup> Therefore, this study was conducted to determine the effect of a family-centered self-care program on medication and dietary regimen adherence in patients of ACS according to the family-centered pattern and through home visits. The research was conducted in order to improve the health of the patients and prevent the re-occurrence of heart attacks and consequent complications.

# **Materials and Methods**

This clinical trial (IRCT20180306038970N1) was conducted on two groups and three stages including two pre-test stages and one post-test in wards and critical care units of Shahid Chamran Hospital in Isfahan, as well as house environment of patients with ACS during 2017-2018. According to the formula of determining the sample size for comparing variables' average between the two groups (Pukak formula, d<sup>2</sup>: with 95% confidence coefficient: 1.96, z2: with the test power coefficient of 80% is 0.84, s: An estimate of the standard deviation of medication and diet regimen adherence in both groups and d: Minimum difference in mean medication and diet regimen adherence between both groups that is significant and considered to be 0.7s), the sample size of the current

study was calculated to be at least 32 individuals for each group.<sup>[22-24]</sup> It was considered to have 40 participants ultimately regarding the 20% downfall. Inclusion criteria included hospitalization with the diagnosis and treatment of ACS in Shahid Chamran Hospital in Isfahan, being over 18 years of age, patients' having the minimum literacy for reading and writing, having active member of the family for taking care of the patient, acquaintance to Persian language, as well as not having psychological illnesses, retardation, blindness, deafness, and severe malignancy in patients or the caregiver based on medical records and history, residence in Isfahan, and the possibility for making phone calls and visiting the patients and their family during the study. Exclusion criteria were inability to adhere to the anticipated treatment regimen due to readmission and new therapeutic interventions during the study, progression of disease during study or patient's death, unwillingness to continue participating in the study or any problems so that the caregiver and patient are unable to continue the study. Sampling was done by available sampling method according to inclusion and exclusion criteria, explanation of project plan for patients and their families, obtaining the informed consent, and studying the medical records of patients. For randomization 80 patients by using the random numbers table, were divided into two groups of intervention and control.

The data collection instrument was the Morisky questionnaire of medication regimen adherence and a questionnaire of dietary adherence which included demographic information (age, sex, occupational status, marital status, education level, suffering from other diseases) and the information of caregiver (age, sex, employment status, marital status, educational level, and relationship to the patient). The Morisky questionnaire for medication regimen adherence includes 8 items. The first seven items are as follows (Yes: one point, and No: zero points), and the 8<sup>th</sup> item is based on Likert 4-point scale (Always: 0 points, Usually: 0 points, Sometimes: 1 point, and Never/Rarely: 1 point). In order to calculate the total score of the questionnaire, the score of all items of the questionnaire was summed. The overall scores ranged from 0 to 8, which 0 showed high adherence, 1 and 2 showed moderate adherence, and more than 2 indicated poor medication adherence. The Morisky questionnaire of medication adherence was reported by Kooshyar H, Shoorvazi M, Dalir Z, et al. (2014). They confirmed the face and content validity by expert professors and calculated the Cronbach's alpha to be 0.68.[25,26] The questionnaire of diet regimen adherence included a number of questions about the patient's food basket, the amount of consumed fat and salt, and the frequency and the method of consumption for 30 main foods. In order to score this table according to food items, a score of 0 to 100 was assigned to each food item, and then the overall scores of this section were calculated. The classification showed

that 100% of the total score was 3000, and the unfavorable adherence was less than 50% of the total score (<1500), a relatively desirable adherence was 50% to 75% of the total score (2250-1500), and a desirable adherence was a score greater than 75% of the total score (more than 2250). The questionnaire of diet regimen adherence was a part of the medication adherence questionnaire designed and used by Sanaie et al. (2014). In order to determine the scientific validity of the instrument, face validity and content validity were used, so that the questionnaire was completed by 10 patients with the criteria of the research in the hospital and was repeated after one week and the Cronbach's alpha coefficient for the patient's ability questionnaire was calculated to be 0.79. These patients were excluded from the study, then, the correlation coefficient was calculated to be 0.79 in the dietary adherence questionnaire using statistical analysis and SPSS software. As a result, the reliability of the instrument was confirmed. Sanaie et al., calculated Cronbach's alpha in their questionnaire of diet regimen adherence to be 0.79 as well.<sup>[23]</sup>

The data were obtained using a questionnaire of demographic information in both control and experimental groups. Hence, selection of samples was done based on the inclusion criteria during the first session in the hospital, and informed consent was obtained from the participants. The data were collected based on the information obtained from the patient and the caregivers, as well as the medical records. In the next stage, after the initiation of experiment in the intervention group, questionnaires of dietary and medication regimen adherence were completed by the patients themselves and in their home before the intervention (the first visit at home), immediately after the intervention (the last visit at home), and 6 weeks after the end of the intervention (a short visit to the house of patients and completing the questionnaires by them). Patients were asked to freely and honestly answer the questions. For each questionnaire of medication and dietary adherence completed in the intervention group, a participant in the control group was contacted and a questionnaire was completed during a brief visit to the Patient at home. During this research, the processes of home visits (including the starting session, pre-visit, visit, the ending session, and post visit) were performed according to the standard protocol. The researcher conducted the intervention program in 5 to 7 sessions with a duration of 45 to 60 minutes for each patient of the intervention group for about 7 weeks (one session per week).<sup>[27,28]</sup> The first session of the meetings began at least two weeks after the patients' discharge.<sup>[29]</sup> The objective of the first session was to gain more acquaintance and trust of family members and the patient, and in case of acceptance by the patients and their families, the family-centered self-care programs would begin if the appropriate conditions were met.

This program includes four steps. The first step, which includes perceived susceptibility and severity, discuss about

the nature and physiology of the disease, the prognosis, the symptoms, the likelihood of its complications, the therapeutic prevention strategies, medication regimen, the correct nutrition pattern. This topic explained to the patient and family members in a simple and understandable way. This was according to home care guidelines for patients with ACS and scientific resources<sup>[16,30]</sup> as well as for continuing learning, pamphlets and educational cards related to the topic of discussion, with full content yet simple language and images. Patients and their Caregiver seemed to be at their disposal. Also, for the purpose of continuing learning, pamphlets, and educational cards related to the topic of discussion, with simple language provided for patients and their Caregiver. The second step was self-efficacy through problem solving and its purpose was to identify the problem by the patient and to provide a solution by themselves. At this stage, patient noted his/ her successes and failures and was encouraged to express his/her problems and experiences and then attempted to select the appropriate solutions to the problems, by consulting with family members and the primary caregiver. The third step includes self-esteem through the client's educational participation. In this step, the patient took on the role of educating family members as a Health interface. In this way, learning has become more in him/her by observing one's ability. Also, the sense of self-efficacy led to increased self-esteem. In the fourth step, the process evaluation, during the intervention process in each session with verbal questions from learning the contents of the before sessions were done. Then the final evaluation was done immediately and 1.5 months after the intervention by completing the questionnaires of dietary and medication regimen adherence. During the study, 4 participants from the intervention, and 4 participants from the control group were excluded due to death or their refusal to continue the project.

SPSS version 20 (SPSS Inc., Chicago, IL, USA, SPSS) software was used to analyze the data. Descriptive statistics were used to determine the abundance, average, and standard deviation of variables. In order to compare the score of medication and dietary regimen adherence before, immediately after, and 6 weeks after the intervention, the test of variance analysis with repeated observations was used. In addition, independent t-test and one-way ANOVA tests were used to compare the scores of medication and dietary regimen adherence between the intervention and control groups. The significance level was considered as p < 0.05.

### **Ethical considerations**

This study was conducted after receiving the Code of Ethics: IR.MUI.REC1396.3.869 from the Office of Vice President for Research at Isfahan University of Medical Sciences. Prior to enrollment in the study, enough explanations about the purpose and method of the study, were provided to the research units and written informed consent were taken from them.

## Results

In this research, the age range of participants was 37-90 years. Demographic characteristics of the samples are presented in [Table 1]. This table indicated that the studied variables had no statistically significant difference between the control and intervention groups. The results of independent t-test indicated that the mean score of medication and dietary regimen adherence before the intervention was not significantly different between the two groups (p > 0.05) [Tables 2 and 3]. However, immediately after and 6 weeks after the intervention, the results were significantly higher in the intervention group compared to the control (p < 0.05). ANOVA test with repeated observations indicated that the mean score of medication and dietary regimen adherence

was not significantly different in the control group in all three periods (p > 0.05). However, a significant difference was seen between the three periods in the intervention group (p < 0.05). In addition, the LSD post hoc test indicated that the mean score of medication and dietary regimen adherence in the intervention group immediately and 6 weeks after the intervention was significantly higher compared to before the intervention (f = 64.06, p < 0.001). However, no significant difference was seen between the results immediately and 6 weeks after the intervention (p = 0.13).

The results of Mann-Whitney test [Tables 4 and 5] indicated that there was no significant difference seen between the two groups in medication and dietary regimen adherence before the intervention (p > 0.05). However, immediately after and 6 weeks after the intervention, the results were significantly higher in the intervention group compared to the control (p < 0.05).

Table 1: The comparison of demographic variables in patients and caregivers in intervention and control groups					
Variable	Groups	Intervention group <i>n</i> (%)	Control group n (%)	Test	
				$\chi^2$	р
Gender	Female	7 (19.40)	8 (22.20)		
	Male	29 (80.60)	28 (77.80)	0.08	0.77
Employment	Employed	14 (38.90)	15 (41.70)		
status	Unemployed	9 (25.00)	11 (30.60)	0.63	0.73
	Retired	13 (36.10)	10 (27.70)		
Marital	Single	0 (0)	1 (2.80)		
status	Married	34 (94.40)	31 (86.10)	2.20	0.33
	Widow	2 (5.60)	4 (11.10)		
Level of	Below high school	25 (69.40)	24 (66.70)		0.77
education	High school graduate	7 (19.40)	7 (19.40)	0.29	
	Academic	4 (11.20)	5 (13.90)		
Other illness	No	10 (27.80)	13 (36.10)		
	Yes	26 (72.20)	23 (63.90)	0.57	0.45

Table 2: Comparing the mean score of medication adherence in each group between three periods				
Group	Mean (SD)		Independent <i>t</i> -test	
Time	Intervention Group	<b>Control Group</b>	t	р
Before the intervention	5.42 (2.09)	5.39 (1.55)	0.06	0.95
Immediately after the intervention	7.08 (1.08)	5.50 (0.97)	6.54	< 0.001
6 Weeks after the intervention	7.56 (1.44)	5.22 (0.90)	8.24	< 0.001
Analysis of variance with repeated observation				
F	13.57	1.91		
<i>p</i>	< 0.001	0.16		

Table 3: Comparing the mean score of dietary regimen adherence in each group between three periods				
Group	Mean (SD)		Independent <i>t</i> -test	
Time	Intervention group	Control group	t	р
Before the intervention	71.44 (6.96)	70.39 (6.67)	0.65	0.52
Immediately after the intervention	78.11 (5.54)	70.22 (4.83)	6.44	< 0.001
6 Weeks after the intervention	83.72 (4.32)	70.30 (3.74)	14.09	< 0.001
Analysis of variance with repeated observation				
F	64.06	0.01		
<i>p</i>	< 0.001	0.99		

Montazami, et al.: A family centered care plan for patients with acute coronary syndrome

Table 4: Frequency distribution of medication adherence in three periods in both groups					
Period	Medical	Intervention	Control	Mann-Whitney test	
	adherence	group <i>n</i> (%)	group <i>n</i> (%)	Ζ	р
Before the	Poor	17 (47.20)	18 (50)	0.66	0.51
intervention	Moderate	13 (36.10)	16 (44.40)		
	High	6 (16.70)	2 (5.60)		
Immediately after	Poor	2 (5.60)	15 (41.70)	4.91	0.001
the intervention	Moderate	19 (52.70)	21 (58.30)		
	High	15 (41.70)	0 (0)		
6 Weeks after the	Poor	1 (2.80)	19 (52.80)	7.08	< 0.001
intervention	Moderate	4 (11.10)	17 (47.20)		
	High	31 (86.10)	0 (0)		

Table 5: Frequency distribution of dietary regimen adherence in three periods in both groups					
Period	Dietary regimen	Intervention	Control group	Mann-Whitney test	
	adherence	group <i>n</i> (%)	n (%)	Ζ	р
Before the	Poor	0 (0)	0 (0)	1.08	028
intervention	Moderate	25 (69.40)	29 (80.60)		
	High	11 (30.60)	7 (19.40)		
Immediately after	Poor	0 (0)	0 (0)	4.91	< 0.001
the intervention	Moderate	7 (19.40)	29 (80.60)		
	High	29 (80.60)	7 (19.40)		
6 Weeks after the	Poor	0 (0)	0 (0)	7.08	< 0.001
intervention	Moderate	2 (5.60)	34 (94.40)		
	High	34 (94.40)	2 (5.60)		

## Discussion

This study was conducted to investigate the effect of family-centered self-care program based on home visits on medication and dietary regiment adherence in discharged patients having ACS. The results showed that immediately after, and 6 weeks after the intervention, the results were significantly higher in the intervention group compared to the control. These results were similar to Baljani *et al.*,<sup>[31]</sup> and the difference between the two studies was in the form of the questionnaire. According to other studies (considering the significant relationship between health-related quality of life and medication adherence in patients, it was suggested that educating patients and trying to increase their medication adherence would lead to an increase in the life quality.<sup>[32,33]</sup>

The program of this study was performed in four steps includes perceived threat (including perceived severity and perceived susceptibility), self-efficacy through problem solving, educational participation, and evaluation that emphasize the effectiveness of the role of the individual and other family members. The results showed that the mean score changes in medication adherence immediately and 6 weeks after the family-centered self-care program based on home visits was significantly higher in the intervention group compared to the control and before the intervention. The study of Chung *et al.* (2006) investigated the medication adherence in patients of heart failure. They showed that married patients had greater adherence

to the medication regimen. These findings indicated that the presence of family and their support had a significant effect on appropriate use of prescribed medicines.<sup>[34]</sup> The study of Aghamohammadi *et al.* (2017) suggested that selfmanagement program may be suitable to persuade patients to make behavioral changes and have long-term medication adherence. Therefore, these programs can be used as a strategy to improve the health of patients.<sup>[35]</sup>

Family-centered self-care in patients suffering from ACS can increase dietary and medication adherence. The results of other studies indicated that the success of patients in adherence to medical recommendations was a mutual responsibility between the caregiver and the patient. The involvement of physicians and patients can be the main factor in motivating and persuading the patients in controlling dietary intake.<sup>[36,37]</sup> The investigation conducted by Dunbar *et al.* aimed at comparing the simple training of the patients and their families using collaborative training on managing the consumption of sodium through the diet of patients having heart failure. Their results showed that family-centered intervention was able to significantly reduce the sodium intake of heart failure patients.<sup>[38]</sup>

Nurses should look for measures and interventions including counseling and education so that patients do not receive their diet as a threat and challenge it with awareness. Doing so, diet adherence would improve in them.<sup>[39]</sup> Khorami *et al.* (2016) evaluated the effectiveness of the family-centered care education program on caregivers

They concluded that family-centered care education (with any method) could be effective in improving the knowledge of caregivers and could be helpful in improving the quality of life in patients.<sup>[40]</sup> Training and consultations provided to outpatient cardiac patients must be accompanied by social support to improve self-efficacy and self-care,<sup>[41]</sup> it is recommended that nurses utilize family-centered self-care program based on home to improve dietary and medication regimen adherence in patients. The family of patients should notice that they can persuade their patients toward dietary and medication regimen adherence through participating in care and treatment. Thus, they can play an important role in the control and prevention of symptoms and treatment of patients with the ACS, as well as having positive effects on their life quality. Following up patients at home after being discharged from the hospital and observing dietary and medication adherence under family's support and contribution can be considered as a goal in improving the patients' quality of life by dietary and medication adherence. In fact, the participation of the family members makes it possible to take a step towards this goal, and focus more on promoting the health of individuals.<sup>[42]</sup> Limitations of this study included a diversity of cultural, social, and emotional participants and families. Therefore, there may have been a degree of inability in the patient and caregivers to be educated.

### Conclusion

Family-centered self-care in patients suffering from ACS can increase dietary and medication adherence. Nurses can help to achieve the dietary and medication adherence through family-centered self-care programs, which can help to achieve treatment goals, reduce cardiovascular risk factors, improve life quality, and prevent related events.

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#### **Conflicts of interest**

Nothing to declare.

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Montazami, et al.: A family centered care plan for patients with acute coronary syndrome

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