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Address: Mashhad Nursing and Midwifery School, Ebn-e-Sina St., Mashhad, Iran
P.O.Box: 9137913199
Tel.: (098 51) 38591511-294
Fax: (098 51) 38539775
Email: EBCJ@mums.ac.ir

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Self-administered Medications in Cardiovascular Ward: A study on Patients' Self-efficacy, knowledge and Satisfaction

Reza Haji Ali Beigloo [1],Samira Mohajer [2], Ali Eshraghi [3],Seyed Reza Mazlom [4]*

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Abstract

Background: Self-efficacy of medication use and pharmaceutical knowledge are important factors for medical treatment completion.
Aim: This study aimed to determine the effect of self-administration of medication program on pharmaceutical knowledge and satisfaction of patients with cardiovascular diseases.
Methods: This randomized clinical trial was conducted on 60 patients with cardiovascular diseases (CVD) in Imam Reza hospital in Mashhad during 2018. Self-efficacy was examined using the standard scale of self-efficacy for appropriate medication use. Moreover, pharmaceutical knowledge was examined using the standard scale for the measurement of patients' knowledge level before and after the intervention. Patients' satisfaction with the medication use manner was also evaluated at the time of discharge from the hospital. Data were analyzed in SPSS software (Version 20).
Results: According to the results, the mean ages of patients in the intervention and control groups were 40.9±8.6 and 44.4±8.5, respectively. In the pre-test, the self-efficacy and pharmaceutical knowledge scores obtained from independent t-tests and Mann-Whitney U test were homogeneous. However, self-efficacy scores in the post-test were 32.0±3.3 and 24.7±3.1 in the intervention and control groups, respectively. The mean satisfaction of patients with medication use manner was significantly higher in the intervention than that in the control group ($P<0.001$).
Implications for Practice: The self-administration of medication program in qualified patients with CVD can improve medication use and pharmaceutical knowledge. Therefore, the application of these programs is suggested improving medication compliance.

Keywords: Patients' pharmaceutical knowledge, Patients with cardiovascular diseases, Patients' satisfaction, Self-administration of medication program

1.Msc of Medical Surgical Nursing, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran.
2.PhD Candidate, Instructor in Gerontological Nursing, Nursing and Midwifery Care Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
3.Heart Disease fellowship, Faculty Member of Mashhad University of Medical Sciences, Mashhad, Iran
4.Instructor, Nursing and Midwifery Care Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

* Corresponding author, Email: mazlomr@mums.ac.ir

Introduction

Cardiovascular diseases (CVD) are considered as the first mortality factor in the world that accounts for more than 50% of all deaths in developed countries (1). In spite of the gradual reduction in the mortality rates of these patients in recent decades, it is still the cause of death in more than one-third of people over 35 years of age (2). Based on the newly published statistics by the American Heart Association, 15.5 million people over the age of 20 suffer from coronary artery disease in the United States (3). Cardiovascular diseases are the first cause of mortality in Iran in all ages and genders (1). Moreover, they are among the main reasons for disability and the fourth common factor to apply for disability insurance (4).

Disability-adjusted life years (DALYs) estimate the disease load or collection of the lost years by premature death or disability caused by cardiovascular disease (CVD). In 2005, there were 847309 DALYs in Iranian adults who were 30 years and older. By 2025, this figure is expected to reach 1728836 DALYs. In other words, DALYs caused by CVD will increase because of aging. Therefore, more actions are required to cope with the effects of CVD in the next decades (5).

The CVD imposes a heavy economic burden on an individual and society because of long term health defects (6). These direct costs reduce the resources that can be used for the family and society's health benefits (7). The afflicted patients to CVD are exposed to the risk of recurrence of this disease and should undergo long-term treatment (8). One of the most important treatments is medical treatment. The execution of the medical instruction is the inseparable part of clinical care with high quality that aims at improving and evaluating the treatment procedure (9). The accomplishment of this matter is relevant to the pharmaceutical knowledge of patients about their treatment (10). Their knowledge of the prescribed medicines may show the relationship between the doctor and treatment team with the patient (9). The unanswered questions in the patients' mind about the prescribed medications may provide a sense of non-motivation and change or avoid medication use manner based on his/her own criterion.

In addition to proper diagnosis and administration of the appropriate medication, the patient must have the necessary information to use the medication according to the goals of the treatment team (9). Since medication use begins the day the patient is admitted to the hospital and continues long after hospital discharge, it is important that the patients have the ability to take medications as prescribed by their physicians. Therefore, the patient is required to learn this behavior. Many behavioral theories have been used for regular medication use. It seems that Bandura's Social Cognitive Theory (1986) is a very useful framework in this field (11). Self-confidence is the key structure in this theory. A person can successfully obtain the desired result when he/she knows how to do the behavior. Bandura believes that self-efficacy is the most important prerequisite for this behavior change and considers it as an important aspect of disease administration (12). Furthermore, self-efficacy is one of the important predictors of medication compliance (13).

Self-efficacy is defined as an individual's belief to do a specific behavior to reach a specific goal. This belief increases and controls self-confidence and provides a condition of changing behavior (14). Based on Bandura theory, a person perception about his/her ability make him/her uses self-care behaviors to reach the desired results. Accordingly, patients with a greater sense of self-care ability are more wishful to undertake these responsibilities (15). Bandura believes that skill and knowledge are not enough for a successful action (15). Knowledge, skills, health beliefs, personal characteristics, and social support are the important indices for behavior change; however, self-efficacy is an important and vital factor for behavior change process (16).

Pharmaceutical self-efficacy means an individual belief in the ability to use and administer prescribed medications in different conditions (17). Various educational interventions have been examined so far to treat several patients with the aim of promoting regular medication intake.

Nevertheless, most of these programs only increased the patients' awareness of the importance of medications. Therefore, their success has not been conspicuous as expected (18). Therefore, self-administration of medication program (SAM) has been suggested in the literature to prevent these failures (19). This program lets patients take the prescribed medications after the essential training while hospitalization under the observation of nurse, doctor, or pharmacist (20). The SAM let patients participate in pharmaceutical program administration longer (21). The self-administration of medications by patients in the hospital can promote their knowledge level about the taken medications and improve their independence and self-sufficiency (22).

In the clinical observation of the first author, it was noticed that medication prescription and distribution were conducted by doctor and nurse, respectively, without any patients' participation. Nonetheless, the responsibility of medication intake administration is assigned to the patient or his/her family immediately after discharge from the hospital, while the patient is not ready in terms of knowledge and self-efficacy to do this.

This process may lead to confusion, error, and ultimately the lack of regular use of medications. In spite of the application of SAM in other countries, no studies and operational program have been conducted using the SAM program in Iran. On the other hand, the results of studies on SAM program conducted in other countries can't be generalized to the Iranian settings according to the differences in terms of culture, environment, pharmaceutical knowledge, and treatment team beliefs between Iran and other countries. Therefore, this study aimed at determining the effect of SAM program on pharmaceutical knowledge, self-efficacy, and satisfaction with medication intake in cardiovascular inpatients.

Methods

Totally, 60 patients referred to the cardiovascular section of Imam Reza hospital in Mashhad participated in this two-group clinical trial during 2018. The inclusion criteria were: 1) full consciousness, 2) the diagnosis of cardiovascular disease symptoms by the specialized factor, 3) age range of 18-60, 4) education status (at least under diploma), 5) lack of cognitive or psychological disorders based on the medical profile, and 6) lack of audible and visual impairment. On the other hand, the patients who 1) had exacerbation of disease, 2) needed special care, 3) diagnosed with the inability to administer medications using the appropriate checklist at each stage, 4) discharged early, 5) had loss of short-term memory, and 6) were reluctant to continue the trial were excluded from the study.

Based on a pilot study on 20 patients (n=10), the sample size was determined 22 people in each group with regard to the confidence coefficient of 95%, test power of 80%, and comparison of the means of two distinct populations. For more confidence, 30 patients were entered and studied in each group to the end of the study.

The research sample was selected by convenience sampling method based on input and output criterion among the hospitalized patients in the cardiovascular section of Imam Reza hospital in Mashhad. This unit included 32 beds in which a nurse is responsible for taking care of 8 patients when the unit is full. Participants were selected using convenience sampling method and subsequently assigned into control and intervention groups.

The SPSS software was used to extract the random sequence to assign predications to each week of the period to one of two groups. This sequence was kept in the closed envelope. It was indicated at the beginning of each sampling week by opening an envelope to place research units into the intervention or control group. In this regard, all the entered patients to the research that week was placed in one of two groups. This procedure was done to prevent the dissemination of information between patients in two groups.

Data were collected using unit selection form, personal information scale, checklists of controlling the patients' ability to continue SAM steps (including 3 standard checklists based on protocol), self-efficiency scale for appropriate medication use, standard scale of patients' knowledge level measurement about the prescribed medicines, and scale of measuring patients' satisfaction with medication intake.

Self-efficiency scale for appropriate medication use was designed by an expertise team containing several sub-groups of experts of medication compliance and specialists. Its validity was examined by Risser et al. (2007) using 436 patients with cardiovascular or other relevant diseases. Its reliability was evaluated through internal consistency, pre-test, and post-test.

In this study, the internal consistency of this 13-item scale was reported to be 0.89 (α=0.89). The scores ranged from 13 to 39 and higher scores indicated higher self-efficacy of patients for the appropriate prescribed medication use. After taking the permission, this instrument was translated into Persian by the research team in January 2018. The translation was given to English language expertise. Two main translated versions were compared after re-translation to English. The translation validity was confirmed with a content validity index of 0.86 based on equality of two translations. Its validity was confirmed using the content validity index by receiving 10 authors' opinion.

The reliability of the translated instrument was evaluated by the test-retest method on 10 persons and was confirmed by the correlation coefficient of 0.84. The standard scale for the measurement of patient's knowledge level about the prescribed medication was designed by Frohlich et al. (2006). Content validity index was used to determine the translated tool validity in this study. The validity of the final version of the instrument was confirmed after including the essential considerations with a coefficient of 0.95. Moreover, internal consistency method with Cronbach's alpha coefficient was used on 10 persons to determine the reliability of the scale for the measurement of patient's knowledge level. Its Cronbach's alpha coefficient was obtained at 0.81 (α=0.81). In addition, its internal consistency was efficient in this study.

Patients' satisfaction scale with the medication use was prepared by one of the authors through reusing texts and new references about the satisfaction index with the medication use under the supervision of the research team. Content validity index method was used to determine the designed tool validity. Subsequently, the validity of the final version of the instrument was confirmed by the coefficient of 0.93 after including the essential modifications and suggestions. The test-retest method with 2-3 days interval was used on 10 persons to determine the reliability which was confirmed with a correlation coefficient of 0.89.

This study was conducted after coordination with managers and supervisors and taking permission letter from the authorities in the cardiovascular section of Imam Reza hospital in Mashhad. The nurses in different shifts were subjected to face-to-face and group training by the author and research team members over two days. The sampling lasted 3 months. After taking written informed consent, the competent patients entered the study. All participants were informed about the research process using a verbal face-to-face explanation. One of the authors from the cardiovascular care unit filled the patients' demographic forms through interviews. As pre-test, self-efficacy of medication use was measured using self-efficacy scale of appropriate medication use and patients' pharmaceutical knowledge by one of the authors 25 h after hospitalization.

Medications were given by the unit nurses under the supervision of the author to the intervention group in the first 24 h. Moreover, the patients were taught about the name of medications, dose, method, intake time, intake reason, and probable side effects verbally and by face-to-face about 10-20 minutes depending on the number of medications. The medication guide and brochures were prepared, formulated, and approved by the training committee of the treatment department of Mashhad University of Medical Sciences, Mashhad, Iran, with the cooperation of nursery and midwifery faculty members.

The brochures were further distributed to each patient for more study. Subsequently, the patients' ability to initiate the second step of the study was measured by the nurse and one of the authors using the checklist of the first step. If the patients were recognized qualified, they would be eligible to enter the second step of the research process.

In the second step, medications of the next 24 h were prepared by the nurse who was responsible to take care of the patient. The medications were placed in the specific pillboxes without locks and kept in lockers in nursery station. The nurses were given the numbered keys of the lockers. The Persian name of the medication, dose, and consumption time was labeled on each medicine. Subsequently, according to training, the patient asked his/her medication in the due time verbally or by alarm ring when the nurse was present or not, respectively. When the nurse arrived, the patient took out his medication from the box and took it under the direct supervision of the nurse. The nurse then confirmed the accuracy of the taken medication by the patient. The nurse was required to check the pulse and other vital signs before taking control of the medication intake. The patient was also given the necessary training in this regard.

In this step, the patients were asked to fill the medication checklists after taking the medication to ensure that the patient received the right medicine at the right time. Moreover, these checklists prevented the medication from being missed or re-used due to concerns about the use of the drug. In addition, the nurses in each shift were able to observe the medications taken by the patients.

If a patient delays medication intake for 1 hour, s/he is reminded by the nurse and this delay is considered as the first sign of unreadiness. If this delay repeats in the next step, s/he turns to the previous step to take the medication by the nurse once more. This process repeats two times. If the patient is not able to take medication, s/he will be excluded from the study.

In the case of two delays as mentioned above, the routine manner was used to administer medication by nurses. At the end of the second 24 h (second step), the ability, competence, and efficacy of patients regarding the medication intake were measured by a checklist of the third step. If these medications are taken correctly and timely at the end of the second 24 h (according to the checklist of patient control and standard medication use program protocol), medications of the next 48 h were put in the specific pill box for the patient.

One key was given to the patient and s/he was responsible for taking medications and keeping the key. The nurse was responsible for indirect control using the method of counting the pills. This counting was done at certain hours (i.e., 6:30 am, 12:30, and 6:30 pm). At this stage, the patient was required to complete the checklist of taken medications to prevent any potential problems and the checklist was controlled by the nurse.

This trend continued to discharge day from the hospital (4-6 days). Possible errors were also examined in this step. The examined checklists showed that no errors happened in any steps by the patient. It is to be noticed that the nurse controlled all medication orders daily after the doctor prescription. In addition, any changes in medication order about the intake dose, adding, or cutting any medication during hospitalization was announced by the nurse. Moreover, the medications in the pillbox were reviewed and modified by the nurse if needed.

Medications were given to the patient by a nurse in a routine manner in the control group and patients received face-to-face medication training and medication guide brochures while hospitalization. Self-efficacy of medication use in both groups was measured by self-efficacy scale of appropriate 96 h medication use (4 days) after pre-test by a similar method with the previous step of intervention (24 h, Figure 1).

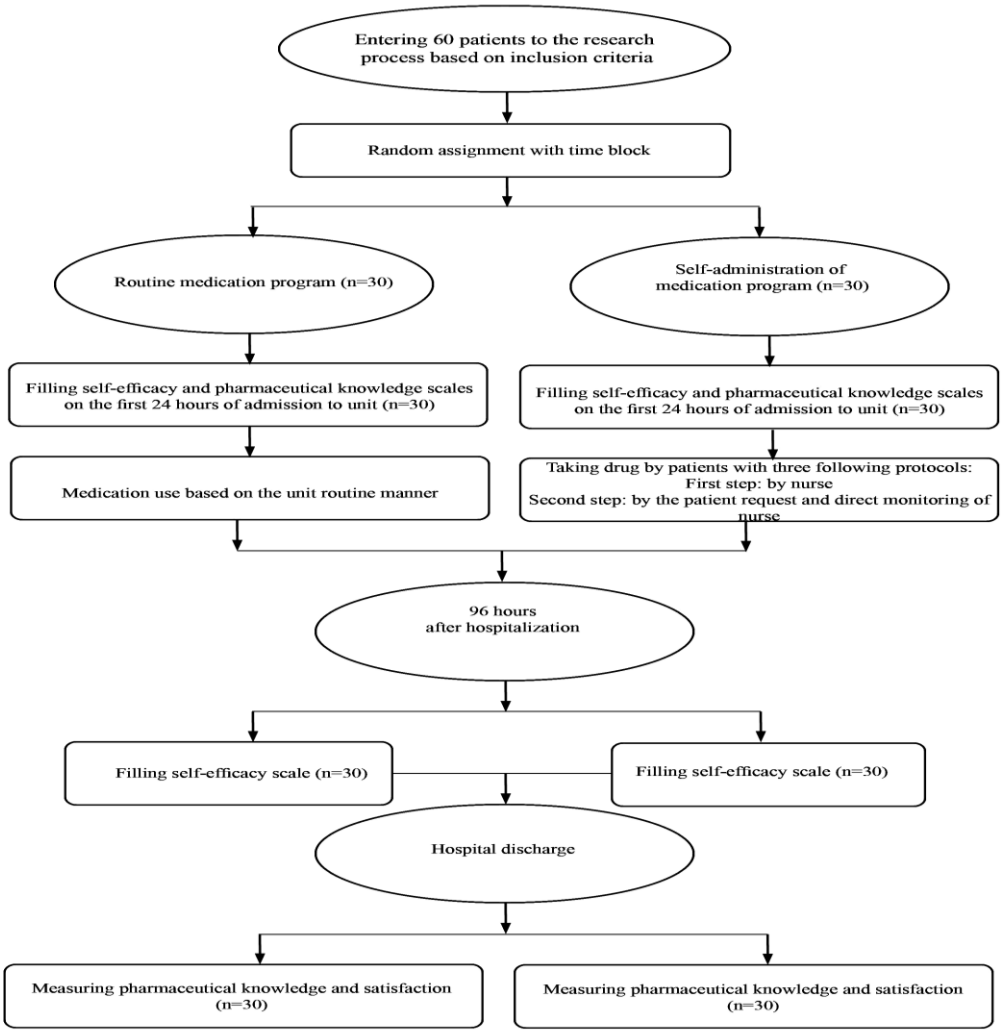

Figure 1: Research process steps

Furthermore, pharmaceutical knowledge and satisfaction were evaluated at the time of hospital discharge.

The research protocol was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.REC.1396.381). In addition, written informed consent was taken from participants and they were informed of the confidentiality of their information. The normal distribution of quantified variables of the study was determined through the Kolmogorov-Smirnov and Shapiro-Wilk test. To assess the intergroup and intragroup comparisons to reach the aims of the study, independent t-test or Mann-Whitney U tests, and Wilcoxon test was utilized, respectively. The consistency of variables in the two groups was examined using Fisher's exact test, the chi-square test, and the Mann-Whitney U test. In all tests, the confidence coefficient was estimated at 95% and p-value less than 0.05 was considered statistically significant. Data were analyzed in SPSS software (version 20).

Results

In this research, 60 hospitalized patients in the cardiovascular section were examined from which 21 (70%) and 18 (60%) cases were assigned into intervention and control groups, respectively. The mean ages of patients in the control and intervention groups were 44.4±8.5 and 40.9±8.6, respectively. According to the results, there was no significant difference between the two groups in terms of age, occupational status, hospitalization background caused by cardiovascular diseases, housing, and other chronic diseases. However, a significant difference was observed between the two groups regarding gender (Table 1).

Table 1: Comparison of the demographic characteristics of patients in two groups

Variables		Group		Results of the intergroup test
		Control (n=30)	Intervention (n=30)	
Gender (number %)	Male	18 (0.06%)	9 (0.30%)	*P =0.02
	Female	12 (0.04%)	21 (0.70%)	
Hospitalization background (Number %)	Yes	6 (0.02%)	12 (0.30%)	*P =0.09
	No	24 (0.08%)	18 (0.60%)	
Other chronic diseases (Number %)	Yes	15 (0.05%)	9 (0.30%)	*P =0.11
	No	15 (0.05%)	21 (0.70%)	
Occupational status (number %)	Self-employed	18 (0.06%)	9 (0.30%)	**P = 0.053
	House wife	11 (% 7.3)	19 (63.3%)	
	Clerk	1 (3.3%)	2 (7.6%)	
	Elementary school and under diploma	9 (0.30%)	13 (3.43%)	**P =0.6
	High school and diploma	18 (0.60%)	14 (7.46%)	
	Higher than diploma	3 (0.10%)	3 (0.10%)	
Age (year) Standard deviation ± Mean		44.4±8.5	40.9±8.6	***P=0.08

* The Chi-square test
** The Fisher's exact test
*** The Mann-Whitney U test

According to the independent t-test results, the mean self-efficacy score of appropriate medication use in pre-test for the patients with CVD didn't have a significant difference in control and intervention groups (P=0.069). However, the mean self-efficacy score of appropriate medication use in the intervention group (32.3±0.3) was significantly higher than that in the control group (24.3±7.1) based on the results of Mann-Whitney U test (P<0.001). Moreover, the Mann-Whitney U test showed a significant difference (P<0.001) between the mean scores of self-efficacy for appropriate medication use in patients with CVD in post-test than pre-test in two groups. Wilcoxon test results in intragroup

comparison showed that the post-test mean score of self-efficacy was significantly higher than that in pre-test (P<0.001); however, there was no significant difference between the two steps (P=0.220) (Table 2).

Table 2: Mean and standard deviation of self-efficacy of medication use, pharmaceutical knowledge, and satisfaction with medication use program in intervention and control groups

Variable	Group	Intervention group (n=30)	Control group (n=30)	Test Result
		Mean±SD	Mean±SD	
Self-efficacy of appropriate medication use	Pre-test (on the first 24 h)	7.9±22.2	2.1±24.3	*P=0.07
	Post-test (96 h after hospitalization)	0.3±32.3	7.1±24.3	**P<0.001
	Intragroup comparison	P<0.001***	***P=0.220	
Pharmaceutical knowledge	Pre-test (on the first 24 h)	0.6±6.2	6.5±5.1	**P=0.68
	Post-test (at the time of hospital discharge)	1.9±0.12	0.27±7.1	*P<0.001
	Intragroup comparison	***P<0.001	***P<0.001	
Satisfaction with medication use manner	Post-test (at the time of hospital discharge)	29.2±1.2	11.1±1.8	0.001 **P<

***** The independent t-test
** The Mann-Whitney U test
*** The Wilcoxon test

According to the results of the Mann-Whitney U test in the pre-test, there was no significant difference between control and intervention groups (P=0.69) regarding the mean pharmaceutical knowledge of patients with CVD. However, the results of independent t-test in post-test showed a significant difference between the intervention and control groups (P<0.001) in terms of the mean scores of pharmaceutical knowledge of patients with CVD. Furthermore, the results obtained from the Mann-Whitney U test showed a significant difference (P<0.001) between control and intervention groups regarding the mean scores of pharmaceutical knowledge in post-test rather than those in pre-test (Table 2). In addition, the Mann-Whitney U test showed higher levels of patients' satisfaction with medication in the intervention group, compared to the control group (P<0.001, Table 2).
The results of two-way ANOVA showed the effect of gender (that was not homogenous in both groups on the score of self-efficacy, pharmaceutical knowledge, and patients' satisfaction based on group showed that group has a significant effect on these variables (P=0.035, P=0.015, and P=0.024, respectively); however, the effect of gender and reciprocal effect of gender and group was not significant on them (P>0.05). In addition, no significant effect on other background variables, including self-efficacy, pharmaceutical knowledge, and patients' satisfaction was observed based on the results of two-way ANOVA (P>0.05).

Discussion

According to the results, the self-administration of medication program on hospitalized patients with CVD in the cardiovascular section can increase self-efficacy of appropriate medication use at the time of discharge from hospital (41%). However, the medication undertaken by a nurse in a routine manner leads to 21% of an increase in self-efficacy levels ($P<0.001$).

Moreover, pharmaceutical knowledge of patients with CVD hospitalized in the cardiovascular section was increased using the SAM program and it was 75% higher than that in the control group ($P<0.001$). No similar studies were found in the literature review to investigate the effect of SAM program on patients' medication use; therefore, the authors tried to use the results of similar studies in this study.

In a study conducted by Lam et al. (2009), the SAM program increased the elderly patients' efficacy to 10.8% for medication use administration. Moreover, pharmaceutical non-compliance reduced to 12.3% significantly (23). Since the prerequisite of change in behavior results from an individual belief in change along with the ability to do the action (17), it can be concluded that people self-efficacy increased before changing the participants' behavior in the study. Accordingly, the patients' performance was changed leading to the increased pharmaceutical compliance. Therefore, the results obtained from this study were in line with the findings of the mentioned study. The consistency between the findings resulted from the similarity of intervention in these two studies.

Moreover, Jensen et al. (2003) evaluated self-administration of medication use, pharmaceutical knowledge of patients with CVD, following the medication regimen, and patients' satisfaction with SAM. According to the results, pharmaceutical knowledge scores in the SAM group in hospitalization time was more than that of the group under the supervision of nurses to take medication (24). In addition, 73.3% of patients preferred to undertake medication intake administration during their hospitalization. Moreover, the satisfaction of the SAM group with medication use program was higher than that in other groups. Based on the result of one conducted study, there is a significant relationship between knowledge and self-efficacy in which an increase in pharmaceutical knowledge improves self-efficacy level (25). Therefore, the simultaneous increase of pharmaceutical knowledge and self-efficacy in the present study is related to the effect of pharmaceutical knowledge on self-efficacy.

Tavakoli et al. (1998) evaluated the SAM program on hospitalized patients with gastrointestinal diseases to increase patients' participation in taking their medication. According to the results, the mean pharmaceutical knowledge of intervention group increased to 81% after intervention. Moreover, 90.7% of the intervention group had high satisfaction with the SAM program. The results showed an increase in satisfaction and pharmaceutical knowledge due to patients' participation; moreover, the patients got more sense of independence (26).

According to other similar studies, there was a significant relationship between knowledge and self-efficacy in which increasing knowledge improved self-efficacy level (25). The findings of the mentioned study were consistent with the results obtained from the present study showing the increase of self-efficacy level in this study.

Although this study paved the way on the effect of SAM program, it suffers from some limitations. There are differences among patients regarding personal, social, cultural, and economic issues as well as gender. Moreover, the patients might not be precise and honest in answering the questions which could influence the study results. It was tried to reduce the adverse effects of these limitations using random allocation of cardiovascular section.

The two groups under study were homogeneous regarding the examined background and interruptive variables according to the statistical tests results. Moreover, their effect on dependent variables was not significant based on the results of three-way statistical tests. However, they were different in terms of executing the self-administration medication use program.

Therefore, the observed difference in self-efficacy, pharmaceutical knowledge, and satisfaction values between the two groups can be attributed to the intervention effect. Accordingly, the research hypothesis on increasing self-efficacy of medication use was accepted by executing self-administration of medication use program in the hospital. Obviously, the results obtained from 96 h of SAM initiation can be generalized and qualified patients with the necessary abilities can execute the protocol.

Implications for Practice

The SAM program significantly increases self-efficacy of medication use, pharmaceutical knowledge, and patients' satisfaction. Moreover, the required time and cost is relatively equal to the educational program which reduces the nurse time to give medication to the patients. Therefore, according to the high importance of regular medication use in treatment procedure and secondary prevention, and the effect of self-efficacy and pharmaceutical knowledge, the execution of such programs can help patients take medications better as well as improve the patients' satisfaction with their treatment program. It is suggested that further studies evaluated the effect of SAM program on patients with other diseases as well as other consequences with longer follow-up periods (i.e., 3 months).

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Conflict of interests

There is no conflict of interest regarding the publication of the study.

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