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Original Article

Effect of Education Based on the Health Belief Model on Treatment Adherence in Patients With Heart Valve Replacement Surgery

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Abstract

Background: Adherence to the treatment regimen reduces complications of surgery after heart valve replacement. Educating the patient can improve treatment adherence. This study thus aimed to evaluate the effect of education based on the health belief model (HBM) on treatment adherence in patients with heart valve replacement surgery.

Methods: In this quasi-experimental research, a total of 90 patients undergoing valve replacement surgery were studied. The subjects were selected randomly and then divided into an intervention and a control group using the permutation blocks method. The data were collected using a demographic questionnaire, an HBM- based questionnaire, and a treatment adherence questionnaire during two stages before and one month after the education. Three 60-minute sessions on HBM- based education were held based on a need assessment for the intervention group. The collected data were analyzed using the chi-square test, paired *t* test, independent *t* test, and linear regression in SPSS software version 16.0.

Results: Most of the patients in the two groups were male, married, and employed, had reading and writing literacy and lived in an urban area. Both groups were similar in terms of demographic data except for marital status, disease history, and familial disease history. The mean scores of knowledge, HBM constructs (e.g., perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy, and cues to action), and treatment adherence were greater in the control group than in the intervention group pre-intervention. However, the mean scores of all variables improved in the intervention group, and there were significant differences in the knowledge, all HBM constructs (except for perceived susceptibility and perceived self-efficacy), and medical adherence between the two groups post-intervention ($P<0.05$).

Conclusion: Considering the positive effect of HBM-based educational intervention on the patients' treatment adherence, HBM-based education could be suggested for patients with heart valve replacement surgery.

Keywords: Cardiac valve annuloplasty, Educational models, Health education, Patient compliance

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Introduction

Heart diseases are among the most common reasons for death worldwide, including in Iran (1,2). The deaths from cardiovascular disease (CVD) are estimated to increase to 23.6 million per year by 2030 (3). Heart valve diseases are a significant group of heart diseases due to their complications, such as heart failure. About 10 to 30% of all heart surgeries are related to heart valve surgery (4).

Heart valve diseases are significant because of their chronic, complex, and progressive nature. More than 79 000 patients have heart valve surgeries in the United States, and their statistics are increasing yearly (5). Unfortunately, the mortality rate from these surgeries is reported to be about 4%-9% (6). Heart valve diseases are treated with medication, including inotropic and diuretic drugs, surgical procedures, such as valve repair or replacement, or both (7). Valve replacement affects the patient's behavior, lifestyle, and adherence to treatment (6). The significant problem is that, unlike other chronic diseases, these patients do not have a specific association, so their education, disease monitoring, and following a treatment regimen are neglected in many cases (8).

Failure to follow the recommended treatment is one of the reasons for treatment failure. Complications and recurrence of the disease, prolonged treatment, reduced quality of life, and increased costs are among most patients' problems in the field of healthcare (9). Many factors cause the patients not to follow their treatment, so it is necessary to know and plan to eliminate these factors by the treatment group (10). Evidence shows that the best treatment regimens become worthless if the patient does not follow the recommendations of the medical staff (11).

In patients with heart valve problems, adherence to treatment is an essential element of postoperative care after heart valve replacement surgery, which includes adherence to medication, diet, weight control, exercise, physical activity, tracking the time of referral for treatment, and changing the style (12). However, patients' treatment adherence after heart surgery is not desirable, and there is a need for educational intervention (13). Evidence shows that education has a significant role in improving adherence to treatment (14). Furthermore, one of the most educational measures is to choose an educational model or theory (15).

Health education theories have a special place in health promotion, information about risk factors for health, and behavior change. These theories can thus be used to improve treatment adherence (16). One of the most widely used health education models is the health belief model (HBM) (17). As a behavioral theory, HBM was founded in the late 1950s (18). According to the HBM, people adopt behaviors when they feel threatened (perceived susceptibility) with unpleasant effects (perceived severity). So, they would believe that healthy behaviors lead to some benefits (perceived benefit) and feel few barriers alongside that healthy behavior (perceived barrier) (19). Furthermore, stimuli to a safety behavior (cues to action) and belief in oneself (self-efficacy) cause an individual to perform a healthy behavior (17).

Numerous studies, such as the studies by Darya Beigi Salimi et al in Kerman (20), Vazini and Barati in Hamedan (21), and Yue et al in China (22), have shown that HBM-based education has caused an increase in the adherence to treatment in many diseases, including CVD. The studies' results also show that HBM-based education improves the patients' health behaviors and medication adherence more than six months after discharge (23); Although HBM is an effective and comprehensive model, studies on applying this model for treatment adherence after heart surgery are limited. To our knowledge, this is the first study focusing on the application of health models, namely HBM, to promote patients' medical adherence after heart surgery. So, the aim of this study is to evaluate the effect of the HBM- based education on treatment adherence in patients with heart valve replacement surgery.

Materials and Methods

This quasi-experimental study with pretest-posttest design was conducted on 90 patients who were candidates for heart valve replacement surgery in a hospital in Hamadan, Iran, in 2021. Inclusion criteria were: having the doctor's permission to participate in the study and having elementary reading and writing literacy. Exclusion criteria were the need for readmission and special clinical procedures, the patient's death, and the patient's unwillingness to continue to participate in the study.

A total of 90 patients participated in this study (90% power with a 2-sided significance level α set at 0.05). The sample size was determined based on an effect size of 2 (Glass's delta effect size). The participants were selected randomly and assigned either to an intervention group or a control group (45 patients per group) using the permutation blocks method. By supposing "A" as the intervention group and "B" as the control group, six blocks, including: "ABBA"; "ABAB"; "BAAB"; "BABA"; "BBAA"; and "ABAB" were generated and enveloped into packets. By entering the individuals over time, one of the packets was selected randomly and the first patient was allocated to the "A" or "B" group based on the selected sequence on the envelope. This was done until all 90 patients were enrolled and allocated to the groups of the study.

Instruments

Regarding the lack of a questionnaire, a researcher-made questionnaire was used, including demographic data (e.g., age, gender, education level, occupation, family income, and family residency), the patient's knowledge, HBM constructs, and the patient's medical adherence.

As the perceived sensitivity is a significant cognitive construct of HBM and is significantly related to individual knowledge (17), the patient's knowledge was also evaluated via seven items scored based on multiple-choice questions, in which a score of one is given for every correct answer.

HBM constructs consisted of perceived susceptibility (6 items), for example: If I unfollow the medication or diet regimen, I will be more affected by post-surgery complications; perceived severity (6 items), for example: If I do not measure the international normalized ratio (INR), severe complications, such as bleeding will occur; perceived benefit (6 items), for example: Medication adherence can make me recover faster; perceived barrier (8 items), for example: Due to the high cost of PT/INR testing, I cannot perform this test regularly; perceived self-efficacy (7 items), for example: I can follow the prescribed physical activity guidelines, scored on the basis of a five-point Likert scale ranging between 1 (strongly disagree) and 5 (strongly agree). Another construct of HBM is the cues to action (9 items), for example: In order to recover as quickly as possible, I use the nurses' recommendations, which is scored on the basis of a five-point Likert scale ranging between 1 (never) and 5 (very much).

The patient's medical adherence was evaluated through seven items scored on the basis of a scale ranging between 1 (no) and 2 (yes).

The qualitative content validity was used to assess

the validity of the research-made questionnaire. First, questionnaire items were generated from the related literature (7,10,17); Then, it was sent to 10 expert faculty members, including three cardiologists, three health education specialists, two clinical expertise nurses, and two community health nurses. They were requested to evaluate items, and their suggestions were applied to the questionnaire. Moreover, the quantitative content validity was examined using content validity ratio (CVR) and content validity index (CVI). The CVR was greater than 0.62 (the Lawshe threshold for the number of 10 experts), indicating that all the questions were essential. Also, the CVI of all questions was greater than 0.9. A pilot study was conducted on ten patients to examine the reliability of the study's questionnaires. Both internal consistency (Cronbach's alpha) and external consistency (intra-class correlation (ICC) as an index of Repeatability) were considered. The ICCs were calculated based on scores obtained from test and retest, which were greater than 0.90, indicating an acceptable repeatability of the questionnaire. Also, the Cronbach's alpha of the questionnaire ranged between 0.95 and 0.98, indicating an acceptable reliability.

Intervention

After approving the study project by the Ethics Committee of Hamadan University of Medical Sciences, the researcher selected patients who were eligible to take part in this study given the inclusion criteria. All the admitted patients were provided with explanations about the study's method and objectives. Moreover, the informed written consent forms were obtained from all patients. At the baseline, the self-reported questionnaires, i.e., demographic data, knowledge, and the HBM constructs questionnaires were completed by both groups.

The experimental group, participated in a diagnostic evaluation performed by the researchers after running the pre-test. Then, according to the mean scores of the knowledge and constructs of HBM, the patients' educational needs were diagnosed. Besides the routine education, the researchers implemented three 60-minute education sessions of the HBM-based education (24), in the lectures, questions and answers, and group discussion form in groups consisting of 3–5 patients. Two training sessions were held for patients in the ward on days 3 and 7 after the heart valve replacement surgery. Another session was held in the clinic by one of the researchers from day 10 to 12 following the patient's discharge.

In the first session, the researchers lectured regarding heart valve disease, heart valve replacement surgery, and complications of post-heart valve surgery. The related information and statistics were presented to indicate heart valve replacement surgery complications (perceived severity), the risks of non-adherence to regimen treatment, and the vulnerability of the patients to possible complications (perceived susceptibility).

In the second session, the researchers lectured on a medication regimen, i.e., diet and medication, checking the INR, wound infection control and dressing, activity, exercise, and physician visits. Furthermore, the researchers focused on the significance of treatment adherence and wrote down the benefit of treatment regimen compliance by question and answer (perceived benefits). Then, the participants were asked to list their treatment adherence barriers, such as cost and time for anticoagulant treatment, nutrition, and wound care (perceived barriers), and discuss ways to overcome these barriers. In this regard, patients are recommended to deliver cues to action to improve treatment regimen compliance from family, friends, and physicians; and use their booklet (cues to action).

In the third session, the researchers introduced strategies for adherence to treatment, i.e., diet and medication, checking INR, wound infection control and dressing, and activity and exercise. The participants were then asked to discuss their self-care strategies to improve treatment regimen adherence. For example, they discussed the ways of having a healthy food diet, maintaining a balanced weight, preventing infection, checking INR, etc, (self-efficacy). Moreover, the participants were provided with a visual reminder, i.e., a booklet about treatment adherence (cues to action).

The control group received a simple pamphlet as routine education. The data were finally collected again from the two groups one month later. The gathered data were analyzed using the Kolmogorov-Smirnov test, chi-square, paired *t* test, independent *t* test, and linear regression (to adjust for the initial group differences, as well as variables in which the groups were not homogeneous) with SPSS software 16.0.

Results

As presented in Table 1, most of the patients in the intervention group (37.8%) were 45 years old and younger, but the majority of the patients in the control group (53.3%) were 46-55 years old. Most of the subjects in the two groups (53.3%) were male, and a majority of them in the intervention group (91.1%%) and control (68.9%) group were married. Furthermore, about half of the subjects in the intervention (48.8%) and control (55.5%) groups were employed. Considering the education level, the participants in the intervention group (36.2%) and control (46.7%) group had reading and writing literacy. A majority of the patients in the intervention group (91.1%) and control (93.3%) group lived in an urban area and had a moderate income. No significant difference was observed between both groups regarding demographic characteristics ($P > 0.05$) except for marital status.

As shown in Table 2, most patients in the intervention (53.3%) and control (46.7%) groups had undergone a mitral valve replacement. Most of the subjects in the intervention group had no family health history of cardiac disease (62.2%) and no history of disease (77.8); however, most of the subjects in the control group (64.4%) had a family history of cardiac disease and had a disease history (66.7). Most subjects in the intervention group

(57.8%) and control (66.7%) group had no substance abuse history. Furthermore, most of the patients in the intervention group (55.5%) and control (53.3%) group received disease information from at least one information source. No significant difference was observed between the two groups with regard to receiving information and its source data ($P > 0.05$); however, the two groups showed significant differences in terms of disease history and familial disease history ($P < 0.05$).

Table 1. Socio-demographic Characteristics of the Patients

Demographic Data		Intervention Group	Control Group	*P* Value[a]
		No. (%)	No. (%)	
Age (y)	45 and less	17 (37.8)	8 (17.8)	0.052
	46-55	14 (31.1)	24 (53.3)	
	56 and more	14 (31.1)	13 (28.9)	
Gender	Male	24 (53.3)	24 (53.3)	0.58
	Female	21 (46.7)	21 (46.7)	
Marital status	Married	41 (91.1)	31 (68.9)	0.033
	Single	0 (0)	3 (6.7)	
	Other	4 (8.9)	11 (24.4)	
Occupation	Employed	22 (48.8)	25 (55.5)	0.912
	Unemployed	1 (2.4)	2 (4.5)	
	Housewife	22 (48.8)	18 (40)	
Education level	Reading & writing literacy	16 (36.2)	21 (46.7)	0.550
	High school	12 (26.4)	9 (20)	
	diploma	7 (15.3)	4 (8.9)	
	College education	10 (22.1)	11 (24.4)	
Residency	Urban	41 (91.1)	42 (93.3)	0.501
	rural	4 (0.9)	3 (0.7)	
Income	Low (<US$ 100)	10 (22.2)	13 (28.9)	0.315
	Moderate (>US$ 100)	35 (77.8)	32 (71.1)	

[a] Chi-square.

According to Table 3, the mean scores of HBM constructs and treatment adherence were greater in the control group as compared with the intervention group prior to the implementation of the HBM-based education ($P < 0.05$). However, a significant increase was observed in the mean scores of knowledge, the HBM constructs, and treatment adherence in the intervention group following the HBM-based education, and a significant difference was observed in these variables ($P < 0.05$) (except for perceived susceptibility and perceived self-efficacy) between the two groups. Notably, the patients' knowledge, perceived susceptibility, perceived severity, perceived benefits, perceived self-efficacy, and treatment adherence were also promoted in the intervention group following the implementation of the HBM-based education intervention ($P < 0.05$). Additionally, the mean score of perceived barriers was less in the control group in comparison to the intervention group prior to the implementation of the HBM-based education ($P < 0.001$); however, it was surprisingly decreased in the intervention group as compared with the control after the HBM-based education ($P = 0.024$).

Discussion

The purpose of this study was to evaluate the effect of HBM-based education on treatment adherence in patients with heart valve replacement surgery. In this study, 90 patients were either assigned to an intervention group or a control group. The two groups were similar in terms of demographic characteristics except for marital status, disease history, and familial disease history. According to the obtained results, the mean scores of HBM constructs and treatment adherence were higher in the control group than in the intervention group before the HBM-based education. However, after the HBM-based education, the

Table 2. Distribution Data of Current Disease, Receiving Information and its Sources

Patients' Status		Intervention Group No. (%)	Control Group No. (%)	*P* Value[a]
Present illness	Mitral valve replacement	24 (53.3)	21 (46.7)	0.660
	Aortic valve replacement	8 (17.8)	9 (20)	
	Tricuspid valve replacement	1 (2.2)	0 (0)	
	Together	12 (26.4)	15 (33.3)	
Disease history	Yes (diabetes, hypertension)	10 (22.2)	30 (66.7)	<0.001
	No	35 (77.8)	15 (33.3)	
Familial disease history	Yes	17 (37.8)	29 (64.4)	0.010
	No	28 (62.2)	16 (35.6)	
Substance abuse	Yes	19 (42.2)	15 (33.3)	0.250
	No	26 (57.8)	30 (66.7)	
Receive information	Yes	29 (64.4)	26 (57.8)	0.33
	No	16 (35.6)	19 (42.2)	
Information source	One source	25 (55.5)	24 (53.3)	0.71
	More than one source	20 (44.5)	21 (46.7)	

[a] Chi-square.

Table 3. Comparison of Knowledge, Constructs of HBM, and Treatment Adherence in Two Groups Before and After Educational Intervention

HBM Constructs	Range	Group	Before Intervention Mean ± (SD)	After Intervention Mean ± (SD)	*P* Value
Knowledge	0–7	Intervention	1.64 ± 1.19	5.86 ± 0.86	< 0.001[a]
		Control	2.24 ± 1.56	3.73 ± 1.1	< 0.001[a]
		P value	0.11[b]	< 0.001[c]	
Perceived susceptibility	6–30	Intervention	9.2 ± 3.2	17.06 ± 2.19	< 0.001[a]
		Control	15.9 ± 4.04	15.86 ± 3.17	0.431[a]
		P value	< 0.001[b]	0.059[c]	
Perceived severity	6–30	Intervention	9.73 ± 4.66	17.42 ± 2.35	< 0.001[a]
		Control	15.91 ± 3.95	15.8 ± 3.09	0.870[a]
		P value	< 0.001[b]	0.003[c]	
Perceived benefits	6–30	Intervention	8.84 ± 3.50	17.24 ± 2.73	< 0.001[a]
		Control	15.33 ± 3.52	15.95 ± 3.33	0.372[a]
		P value	< 0.001[b]	0.011[c]	
Perceived barriers	8–40	Intervention	31.55 ± 4.95	20.95 ± 4.84	< 0.001[a]
		Control	19.28 ± 5.97	17.28 ± 6.67	0.128[a]
		P value	< 0.001[b]	0.042[c]	
Perceived self-efficacy	7–35	Intervention	11.37 ± 4.0	18.73 ± 3.50	< 0.001[a]
		Control	17.09 ± 4.65	19.04 ± 4.12	0.136[a]
		P value	< 0.001[b]	0.126[c]	
Cues to action	9–45	Intervention	13.62 ± 4.15	23.53 ± 4.08	< 0.001[a]
		Control	17.93 ± 5.57	19.11 ± 5.97	0.187[a]
		P value	0.003[b]	0.0429[c]	
Treatment adherence	1–14	Intervention	7.35 ± 1.09	11.20 ± 2.64	< 0.001[a]
		Control	9.84 ± 2.59	10.28 ± 2.7	0.348[a]
		P value	< 0.001[b]	0.039[c]	

[a] Paired *t* test, [b] Independent *t* test, [c] linear regression: Adjusted for confounding factors (marital status, disease history, and familial disease history).

mean scores of knowledge, HBM constructs (except for perceived susceptibility and perceived self-efficacy), and treatment adherence increased in the intervention group. Furthermore, the construct of perceived barriers was decreased in the intervention group following the HBM-based education.

The results of this study also revealed that the patients' knowledge increased following the implementation of the HBM-based education. In a similar study, most patients with smear-positive pulmonary tuberculosis (TB) acquired an average knowledge following the-HBM based education intervention (25). A similar study in Iran also indicated that the use of HBM-based education raised the awareness level for kidney care in patients with diabetes (26). Furthermore, the findings of an interventional study showed that by implementing an HBM-based training program, the awareness of patients with heart disease could be increased (27). It can be concluded that a patient's knowledge is one of the main factors affecting treatment adherence. In the same vein, a study in Iraq also indicated that better patient medication adherence is needed to increase the level of awareness of patients (28).

In this research, the mean score of perceived sensitivity for treatment adherence increased after the HBM-based education in the intervention group as compared with the control, although it was not significant. Furthermore, the perceived severity in treatment adherence of the patients with heart valve replacement surgery was changed after the HBM-based education. For example, after HBM-based education, they saw themselves as more vulnerable to being affected by unfollowing the medication or diet regimen. They also realized that without medical adherence, irreversible effects of the heart valve replacement surgery would increase that might delay their recovery. Furthermore, they would see themselves as more vulnerable to severe complications, such as bleeding, due to the increased level of the INR if they did not follow the guidelines. A study result showed that HBM-based education causes patients to be more sensitive to TB and consider themselves more susceptible to this disease (29). These findings indicate that one of the essential measures to create a positive attitude in patients and improve their health beliefs is to strengthen their sense of vulnerability to the disease or the consequences of a threatening situation to change their behavior. In this regard, a similar study in Nigerian patients showed that patients with higher perceived sensitivity had better treatment compliance (30).

According to the results of this study, HBM-based education improved the mean score of perceived benefits of the intervention group. A cohort study revealed that

HBM-based education increases the perceived benefits of AIDS prevention in Iranian students (31). Another similar study showed that if individuals understand the cancer prevention benefits, they will be led to follow the training and become more engaged in screening for colorectal cancer. Therefore, the authors suggest that healthcare workers should explain the benefits of disease-preventing behaviors to improve individuals' adherence to prevention guidelines (32). Researchers of a qualitative study also suggested that the perceived benefits of dialysis patients cause them to refer to dialysis regularly and monitor their health status (33). In fact, it can be concluded that through education, individuals could understand the benefits of following treatment, recognize the consequences of appropriate action, and therefore be more likely to follow treatments, such as medication, diet, and physical activity.

The other result of this study showed that the mean score of perceived barriers in the intervention group decreased after HBM-based education. For example, after the education, more patients believed that barriers such as distance, cost of follow-up tests, and family involvement could not be considered an obstacle to their treatment compliance. In other studies, the main perceived barriers were related to cost and time consumption, prolonged drug use, and medication side effects (24,34,35). So, researchers suggest that it is necessary to focus on perceived barriers as one of the factors influencing medication non-compliance, especially for patients with chronic diseases (34).

In this research, the mean scores of cues to action for treatment adherence increased after the HBM-based intervention in the intervention group as compared with the control. For example, more patients in the intervention group utilized the guidelines and instructions prepared by researchers, doctors, and nurses and tried to pay close attention to their recommendations. Indeed, the cues to action construct is considered a facilitator helping individuals do appropriate behaviors (17). In this study, the patients considered researchers, doctors, and nurses as the most significant cues to action. However, in other studies, TV, parents, teachers, and health coaching were the most important cues to action (24,36,37).

Moreover, in this research, the mean score of perceived self-efficacy in medication adherence increased following the HBM- based education in the intervention group compared to the control group, although it was not significant. For example, patients reported that their ability to follow warfarin and diet instructions was increased and that they try to plan to increase their physical activity, which can be considered one of the significant outcomes of the intervention. This finding of the study is also in agreement with a study in which patients with high self-efficacy were more likely to adhere to antiretroviral therapy (34). The results of a study conducted in Iran also indicated that the HBM-based education could increase self-efficacy, as one of the significant predictive constructs, in medication adherence among type II diabetic patients (38). The authors of a similar study also pointed out the necessity of self-efficacy in the self-management of diabetic patients (39).

Finally, this research revealed that treatment adherence increased in patients following HBM-based education. For example, more of them adhered to diet recommendations, engaged in physical activity and rehabilitation programs, monitored coagulation tests as prescribed by their physician, and performed wound dressing. Therefore, it can be concluded that HBM-based education affected the patients' medication adherence. In a similar study in China, the application of HBM-based education improved the process of patients' use of alternative therapy, namely methadone, by improving all constructs of HBM (40). Our study result is consistent with another similar study in which HBM-based education improved treatment adherence in patients with pulmonary TB in Indonesia (41). In a similar study, HBM-based education could improve diet and medication compliance in gestational diabetic pregnant women by increasing perceived sensitivity, perceived benefit, and decreasing perceived barriers (42). According to the results of the mentioned studies, it can be concluded that this model has the efficiency to improve treatment adherence.

One of the limitations of this study was that the patients' treatment adherence could not be observed directly; hence, the researchers asked the patients to answer the questions honestly. Another significant limitation of the research was the higher prevalence of family diseases in the control group than in the intervention group. Moreover, more patients in the control group had a disease history of hypertension and diabetes. These differences, such as familial disease history, might affect their experiences and therefore cause a significant difference in their knowledge, HBM constructs, and treatment adherence between the two groups pre-intervention. Furthermore, significant differences were observed between the two groups in terms of the mean scores of knowledge, HBM constructs, namely perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy, and cues to action constructs, pre-intervention. So, the researchers applied statistical tests, such as linear regression analysis to control the covariate variables.

This study is novel due to the implementation of the HBM-based education for patients with heart valve replacement surgery to enhance their treatment adherence. The results obtained by this research are beneficial for healthcare providers in planning and implementing education programs.

Conclusion

The findings of this research confirm the effectiveness of the HBM-based education in promoting treatment adherence in the patients with heart valve replacement surgery. HBM-based education increased the patients' knowledge on the significance of treatment adherence. Additionally, following the education, the patients' perceived severity, perceived benefits, perceived barriers,

and cues to action improved. Moreover, in this research, the mean scores of perceived susceptibility and perceived self-efficacy for treatment adherence increased a lot, although not significantly, following the education program in the intervention group as compared with the control. Overall, it is suggested that the HBM-based education be implemented to promote treatment adherence in patients with heart valve replacement surgery.

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Authors' Contribution

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Competing Interests

The authors have no conflicts of interest to declare.

Ethical Approval

This study was approved by the Ethics Committee of Hamadan University of Medical Sciences (IR.UMSHA.REC.1399.871).

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