

The Effect of a Multimodal Educational Intervention on Health Literacy in Patients with Ischemic Heart Diseases

ABSTRACT

Background and Objective: Studies investigated the relationship between Health Literacy (HL) and quality of life, medication adherence, and frequency of hospitalization. However, few studies are available on the effects of patient education strategies on the HL of patients with ischemic heart disease (IHD). We investigated the effect of a multimodal educational intervention on HL in patients with IHD.

Materials and Methods: This quasi-experimental study was conducted on 50 patients with IHD referred to Shahid Beheshti Hospital in Kashan, Iran, from February to September 2020. Patients were consecutively selected and randomly divided into two groups that either received a multimodal HL intervention or were treated as usual. The multimodal HL intervention included an educational booklet, two individual face-to-face training sessions, and enrolling in one of the groups created in WhatsApp and Telegram messengers. Patients were assessed at baseline and at the end of the eighth week using the HL questionnaire for patients with cardiac diseases. Data were analyzed by the Kolmogorov-Smirnov, independent-samples t, paired-samples t, Chi-square and Fisher's exact tests, and analysis of covariance.

Results: The mean HL scores of the intervention and control groups did not differ significantly at baseline. At the end of the study, the mean HL score in the intervention group increased by 98.12 points to reach 169.04 ± 8.36 , whereas in the control group it increased by only 10.32 points to reach 84.12 ± 12.21 . The mean scores of the two groups were significantly different at the end of the study ($P < 0.001$).

Conclusion: After the intervention, the mean HL score in the intervention group increased 2.4 times, whereas the mean score of the control group changed slightly. Nurses and physicians are recommended to use additional modalities, such as digital social networks, in addition to in-person education to strengthen their interactions with their IHD patients and improve patient HL.

Paper Type: Research Article

Keywords: Education, Health literacy, Coronary Artery Disease, Patient education

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Introduction

Cardiovascular diseases, especially ischemic heart disease (IHD), are of the leading causes of death worldwide and account for a major part of health care costs (1). IHD is a condition in which part of the heart muscle does not receive sufficient blood and oxygen (2). IHD was responsible for the death of 18.6 million people worldwide in 2019, accounting for 32.9% of all global deaths (3). In the same year, IHD was the first leading cause of mortality (46% of all deaths) and accounted for 20% to 23% of the disease burden in Iran (4). Primary prevention, appropriate treatment, and prevention of recurrence of IHD require serious lifestyle changes and high treatment adherence, which are highly dependent on the patient's health literacy (HL) (5).

HL means the ability to access, understand, appraise and exchange health information, actively interact with health professionals, and participate in health-related decisions (6, 7). HL is an important factor in the effectiveness of health interventions, treatment adherence, self-care, disease self-management, health behaviors, and utilization of preventive services (8). However, most studies have reported that the public HL as well as HL of patients with chronic diseases, including IHD, is not satisfactory (9, 10). A systematic review found that few studies have investigated the HL of patients with IHD and that at least 30% of patients have low HL, resulting in frequent hospitalizations, low quality of life (QOL), higher anxiety, and less access to social support (11). Another study examining HL and its association with medication adherence and QOL in patients with IHD has reported that more than 73% of patients with IHD had inadequate HL (12). A descriptive study in Iran examined HL in patients with IHD and reported that only 5.3% of the patients surveyed had good HL, while 81.8% and 13% of the patients had moderate and weak

HL, respectively (13). Another study from Iran reported that patients with cardiac disorders seek to improve their health-related knowledge and believe that acquiring this knowledge can improve the treatment process. However, most patients were dissatisfied with the limited resources and difficulties in accessing applicable health knowledge. Therefore, health care team members, especially nurses, are recommended to develop and implement programs to improve HL in patients, especially those with IHD (14).

Some studies have examined the effect of particular methods to promote HL in a variety of patients. However, limited interventional studies have been performed on patients with IHD. In one of these studies, Crengle et al. (2018) in Australia examined an HL intervention on pharmacological knowledge in patients with cardiac diseases and reported that the program significantly improved their pharmacological knowledge (15). In another study, Falahi and Miri examined the effect of e-learning (using compact disks) on HL in patients with IHD and reported that the educational intervention significantly improved patients' HL in terms of disease awareness, activity and exercise, diet, and medication regimen. However, the intervention lasted only two weeks, and the patients' HL was re-evaluated immediately afterward (16).

Therefore, the observed effect may be short-lasting and reflect only people's knowledge. Barkhordari-Sharifabad et al. also implemented an HL promotion intervention through the WhatsApp social network. For one month, they sent texts, images, videos, and educational animations about heart failure to patients. Immediately after the intervention, they reassessed patients and concluded that the HL intervention could improve patients' self-care (17). However, in the latter study, patients did not actively interact

with each other or with the trainer; moreover, the longevity of the effect of the intervention was not determined. In addition, none of the aforementioned studies examined the effects of the interventions on patients' HL. In a recent study, Tavakoly Sany et al. examined the effects of educational interventions on HL in patients with heart failure. They conducted focused group discussions and three educational sessions for 40 patients and concluded that the educational interventions significantly improved patients' HL compared with the control group (18). Yadav and Khokhar also examined the effect of information, education, and communication activities on HL of cardiovascular diseases (CVDs) among adolescents in Delhi and reported that the intervention improved HL of people regarding CVDs (19). Another study, although not on patients with IHD, compared the effect of lecture-based and peer-led education on HL of patients and concluded that peer-led methods were more effective than lecture-based education in improving HL (20).

However, a recent review of patient education interventions criticized current patient education methods and recommended that HL interventions should provide patients with understandable and accessible information. Such interventions should avoid medical jargon, break information into small, concrete pieces, include teach-back cycles, and use a combination of audiovisual and printed channels to enhance patient understanding and effectively improve their HL (21).

Multimodal education refers to the use of "multiple" modes of presentation, with combined elements of print, visual images, videos, text, and lectures (22). A multimodal educational intervention may also combine educational posters, small-group teaching sessions, and the use of social media (23). These modes strengthen each other, improve the dynamicity of learning, and enhance the learners' learning experience (24).

Because of the great importance of education in promoting HL, the fact that different educational methods may have different effects (25), and due to the shortcomings of the studies, and the fact that none of them reported the effects of interventions on HL, the present study was conducted to determine the effect of a multimodal educational intervention on HL of patients with IHD who referred to Shahid-Beheshti Medical Center in Kashan, Iran.

Materials and Methods

Study design

This was a quasi-experimental study conducted between February and September 2020. The study population was patients with IHD who referred to Shahid Beheshti Specialty and Subspecialty Medical Center in Kashan, Iran, for follow-up or treatment of recurrent cardiac symptoms.

Sample size and sampling method

The sample size was calculated based on a study by Crengle et al. (2018) that examined the effect of a health literacy intervention on knowledge about cardiovascular disease medications. In this study, 34% of patients had good knowledge of statins before the intervention, and this frequency increased to 90% after the intervention (15). Therefore, considering an alpha of 0.01, power of 90%, $p_1 = 0.34$, and $p_2 = 0.9$, 23 subjects were estimated to be needed per group. However, with a 10% loss probability, the sample size in each group was increased to 25.

$$n = \frac{2(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 pq}{(p_1 - p_2)^2}$$

Inclusion and exclusion criteria

Inclusion criteria were age 18 years and over, medical diagnosis of IHD, lack of identified cognitive impairments (expressed by the patient or based on the patients' files), willingness to

take part in the study, ability to take part in the training sessions, having a Smartphone, and being able to exchange experiences in the WhatsApp or Telegram social networks, ability to speak, read, and write in Persian, stability of clinical condition, and lack of pain during the study. Exclusion criteria were a decision to leave the study, partaking in the same training courses during the study, absence in one of the educational sessions or withdrawing from the social network, death, or the occurrence of critical conditions that make the patient's condition unstable and require hospital admission or prevent participation in the study. Eligible patients were enrolled consecutively and divided alternately into two equal groups (i.e. 25 patients in the intervention group and 25 in the control group) (Figure 1).

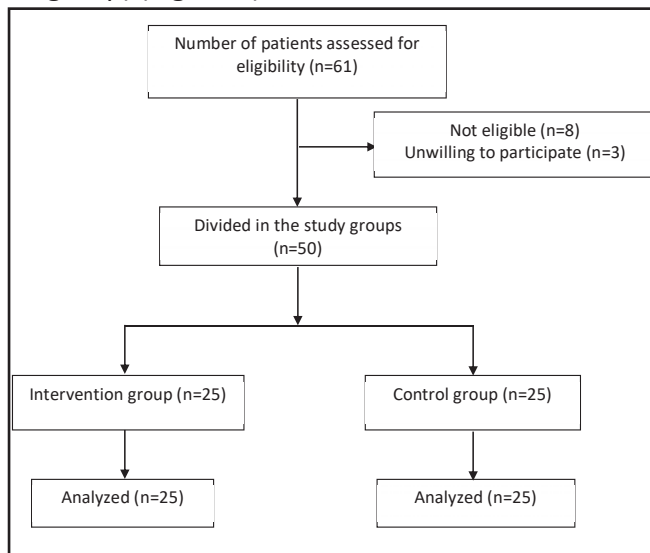


Figure 1. Flow chart of the study

Instrument

A two-part instrument was used to collect the study data. The first part includes questions about patients' characteristics such as age, sex, marital status, place of residence, education level, income adequacy, employment status, weight, height, body mass index, history of IHD and other diseases, number of physician visits and hospitalizations for IHD and other diseases

in the past 12 months, and source of health and disease information. The second part of the data collection instrument included the HL questionnaire for people with cardiac diseases (HLQPCD) developed by Falahi et al. (16).

The HLQPCD consists of 45 items in four subscales of Disease Awareness (14 items, e.g., "Swelling of feet and ankles may be a sign of heart failure," "Treating hypertension may prevent a heart attack"), Activity and Exercise (10 items, e.g., "Participating in sports activities is necessary to maintain health," "Light sports activities and walks are not dangerous for a cardiac patient"), Diet (12 items, e.g., "I buy dairy products such as milk, yogurt, and cheese according to their fat percentage," "Dietary fibers such as fresh vegetables reduce cholesterol levels"), and Medication Regimen (9 items, e.g., "I understand what is written on the package of the drugs about how to take the medicine," "I do not stop taking the medications prescribed by the doctor for my disease without permission, even if the symptoms of the disease have disappeared"). All items are answered on a 5-point Likert scale from always = 5 to not at all = 1. The sum of the scores for each subscale is calculated. Then, to obtain the overall score, the sum of all four subscales is calculated to produce a score between 45 and 225. The higher the score, the higher the HL.

The content validity of the HLQPCD was confirmed by Falahi and Miri after consulting 10 experts in the field of medical education and health care, and its reliability was reported to be 0.78 by calculating Cronbach's alpha (16). In the present study, the content validity of the instrument was confirmed by 10 faculty members of the Nursing and Midwifery School of Kashan University of Medical Sciences, and its reliability was assessed by Cronbach's alpha which was 0.82 for the whole instrument and ranged between 0.76 and 0.88 for the four subscales.

Intervention

Every day (on the morning and evening shifts), the first investigator visited the cardiac care wards of the aforementioned hospital, identified eligible patients, invited them to participate in the study, and, if they agreed, enrolled them in either the intervention or the control group. Sampling continued until the sample size was completed.

After each patient was enrolled in the study, s/he was provided with a copy of the study instrument (i.e. the patient characteristics form and the HLQPCD) and was briefed on the answering method. The first researcher (ZH) read the questions to illiterate or low-literate patients and entered the answers into the questionnaire. This pretest helped the researchers to identify the patients' educational needs and tailor the educational content. Patients' educational needs were almost the same because they mostly were at old age and the diploma level.

Accordingly, the educational content was designed based on the patients' educational needs and the guideline presented by Magnani et al. about HL in cardiovascular disease (26). According to Magnani et al., HL training interventions for patients with cardiovascular disease should include skills such as reading and writing about health and illness, gaining information about one's health, understanding health information received from different sources, the ability to perform calculations, and searching, processing, assessing, and interpreting health information. It should also prepare people to take responsibility for their health, empower them to make appropriate health-related decisions, and give them the confidence to direct and improve personal and public health and self-care (26).

In this study, the HL training intervention included an educational booklet, two individual 1-1.5 h face-to-face training sessions (as outlined

in Table 1), and registration of patients in one of the groups created in WhatsApp and Telegram messengers for continuing education and exchanging experiences and information (i.e. about the disease, diet and medications and related care, exercise, lifestyle modification, the introduction of health-related resources, addresses and links of websites containing useful information about self-care in IHD [i.e. the link of the healthy heart portal: <http://heart.kaums.ac.ir/>). Twenty-four hours after sending the useful links, patients were asked to share the most important thing they had learned with the researcher and other group members in a short message via WhatsApp/Telegram.

The individual training sessions included presenting information about the nature of the disease, its complications, risk factors, principles of medication therapy, acceptance and adherence to medications and the drug regimen, diet and lifestyle modification, exercise and regular moderate physical activity, smoking cessation, methods of stress management and problem-solving, and appropriate weight and weight loss (Table 1).

At the end of the training sessions, each patient received a booklet containing the necessary information about IHD management and recommended treatments. Then, each patient was invited and enrolled in one of the educational groups we created via WhatsApp and Telegram messenger, through which for five weeks, they received daily educational information (i.e., text messages, educational videos, and animations) on self-care, nutrition, drug therapies, treatment, and follow-up processes, as well as other materials on topics similar to those covered in the training session. Each day 1-2 messages were sent to patients. Messages were sent at 11 a.m. but could be opened at the participant's convenient time. All patients in the intervention group also

had the opportunity to share information and experiences via social networks. The intervention group received the multimodal HL training intervention, but the control group did not receive this training intervention and was only treated as usual.

Eight weeks after the end of the intervention, each patient was contacted and an appointment was made to fill out the HL questionnaire again.

Table 1: Outline of the individual training sessions

Session	Detailed content of the session
1	Greetings, introducing the aims of the session Structure and function of the heart and the blood flow of the heart, The nature of IHD, Risk factors and complications of IHD, Principles of medication therapy in IHD, and common medications in IHD, Acceptance and adherence to medication and medication regimen, Summarizing the session, Asking the patient some questions and recommending him/her to read the educational book and ask his/her questions of the researcher if needed.
2	Greetings A brief review of the previous session, Introducing the aims of the session Heart-healthy eating and diet modification, The importance of appropriate weight and weight loss, The importance of exercise and regular moderate physical activity, The effects of smoking on the heart and the importance of smoking cessation, Stress and stress responses Problem-solving and stress management methods (exercise, deep breathing techniques, timely and adequate sleep, healthy relationships), Summarizing the session Asking the patient some questions and recommending him/her to read the educational book and ask his/her questions of the researcher if needed.

Statistical Analysis

Data analysis was performed using the SPSS software version 16 (SPSS Inc., Chicago, USA). Descriptive statistics such as frequency, mean, and standard deviation were calculated to describe the patients' characteristics. The Kolmogorov-Smirnov test was used to test the normality of quantitative variables. We compared categorical variables between the study groups using the chi-square test or Fisher's exact test. The paired t-test was used for within-group comparison of the mean HL whereas the independent samples t-test was used for between-group comparisons. Analysis of covariance was performed to control for the effect of information source, which differed between the two groups. The significance level was set at <0.05 in all tests.

Results

A total of 50 patients (25 in the intervention group and 25 in the control group) participated in this study and all completed the study. There were no illegible answers. The age of the participants ranged from 50 to 85 years. The mean (SD) age of patients in the intervention and control groups was 64.40 (11.22) and 67.88 (10.79) years, respectively, and did not significantly differ according to the independent samples t-test. The intervention and control groups were homogeneous in terms of their demographic characteristics except for the source of information (Table 2).

The independent samples t-test showed no significant difference between the mean HL scores of the intervention and control groups at baseline (i.e. 70.92 ± 24.83 vs. 73.80 ± 13.09 , $P = 0.610$). However, the mean HL of the intervention and control groups changed to 169.04 ± 8.36 and 84.21 ± 12.21 , respectively, at the end of the study, and these changes were significant according to the independent samples t-test ($P < 0.001$) (Table 3, Figure 2).

Table 2: The demographic and clinical characteristics of the intervention and the control groups

Variables		Intervention group	Control group	P-value
		Mean±SD or n (%)	Mean±SD or n (%)	
Age		64.40 ± 11.22	67.88 ± 10.79	0.269
Weight		70.28±9.75	73.20±11.06	0.327
Height		163.84±7.94	21.69±4.33	0.600
Body Mass Index		26.49±3.01	25.66±3.48	0.375
Sex	Female	5 (20)	9 (36)	0.208
	Male	20 (80)	16 (64)	
Marital status	Single	1 (4)	1 (4)	0.999
	Married	24 (96)	24 (96)	
Employment status	Self-employed	3 (12)	3 (12)	0.856
	Unemployed	22(88)	22(88)	
Education level	Lower diploma	22 (88)	22 (88)	0.999
	High school diploma	3 (12)	3 (12)	
Adequacy of income	Sufficient	20(80)	13(52)	0.073
	Insufficient	5 (20)	12 (48)	
Place of residence	City	14 (56)	16 (64)	0.564
	Suburbs	11 (44)	9 (36)	
Other comorbidities	Yes	23(92)	23(92)	0.999
	No	2(8)	2(8)	
Source of information about illness and care	Physicians	12 (48)	16 (64)	0.006
	Internet	1 (4)	1 (4)	
	Radio and TV	0	2 (8)	
	Friends and books	4 (16)	4 (20)	
	None	8 (32)	2 (44)	
Frequency of hospitalization for heart disease in last 12 months	0-2 times	22(88)	23(92)	0.637
	3 or more times	3(12)	2(8)	
Hospitalization for other diseases in last 12 months	Yes	20(80)	17(68)	0.333
	No	5(20)	8(32)	
Number of medical visits for heart disease in last 12 months	0-5 times	16(64)	19(76)	0.355
	6 or more times	9(36)	6(24)	

Table 3: Comparison of the mean pretest and posttest health literacy scores between the intervention and the control groups

Time	Control group	Intervention group	P-value *
	Mean ±SD	Mean ±SD	
Pretest	73.80 ± 13.09	70.92± 24.83	0.610
Posttest	84.12± 12.21	169.04± 8.36	< 0.001
Difference score	10.32± 9.88	98.12± 25.98	< 0.001
P-value **	< 0.001	< 0.001	

* t-test, ** Paired t-test

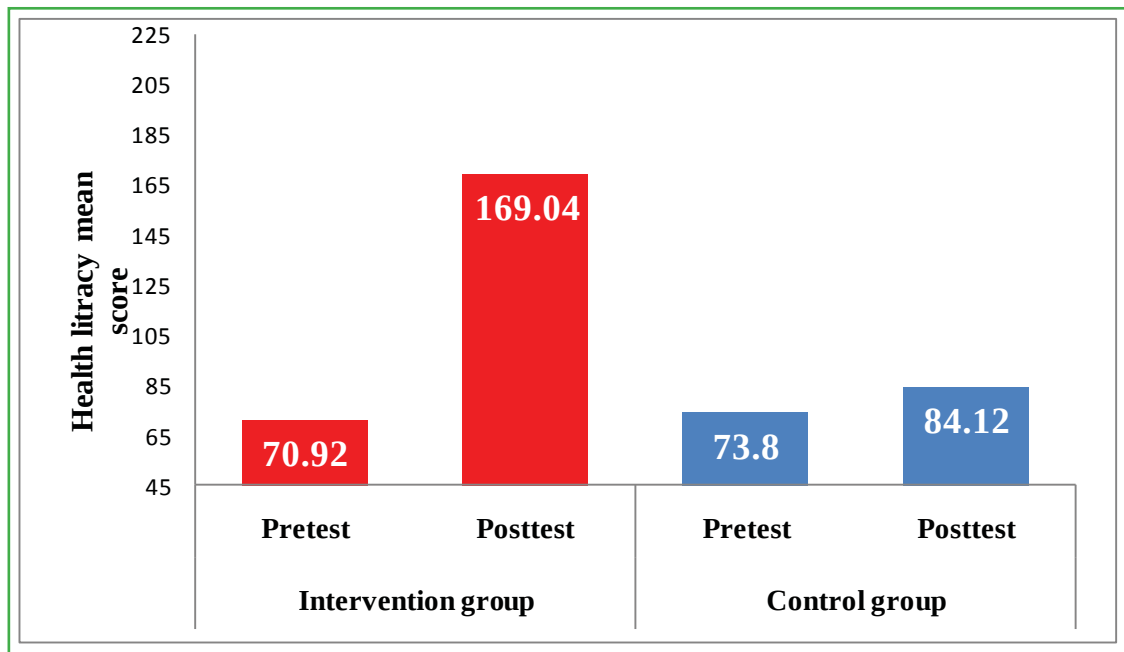


Figure 2. Comparison of the mean pretest and posttest HL scores in the intervention and control groups

Because the source of information about illness and care was different between the two groups, an analysis of covariance was done to control for the effects of this variable. The results showed that the source of information had no significant effect on the difference of HL in the two groups ($p = 0.083$).

Regarding the HL subscales, the independent samples t-test showed that the mean scores of

the four subscales did not significantly differ between the two groups at the beginning of the study ($p > 0.05$) (Table 4). However, at the end of the study, the mean scores of the four subscales were significantly higher in the intervention group than in the control group, and all differences were statistically significant according to the independent samples t-test ($p < 0.001$).

Table 4: Comparison of pretest and posttest mean scores of health literacy subscales between the intervention and control groups

Health literacy subscale	Time	Control group	Intervention group	P-value *
		Mean $\pm$ SD	Mean $\pm$ SD	
Disease awareness	Pretest	32.92 $\pm$ 6.71	30.88 $\pm$ 11.67	0.453
	Posttest	37.40 $\pm$ 4.69	76.58 $\pm$ 4.01	< 0.001
	P-value **	< 0.001	< 0.001	
Diet	Pretest	33.01 $\pm$ 5.55	32.39 $\pm$ 11.05	0.797
	Posttest	38.01 $\pm$ 7.19	74.80 $\pm$ 4.01	< 0.001
	P-value **	< 0.001	< 0.001	
Medication regimen	Pretest	4.04 $\pm$ 1.02	3.88 $\pm$ 1.92	0.715
	Posttest	4.48 $\pm$ 1.15	8.88 $\pm$ 0.88	< 0.001
	P-value **	0.126	< 0.001	
Activity and exercise	Pretest	3.84 $\pm$ 1.10	3.80 $\pm$ 1.32	0.908
	Posttest	4.24 $\pm$ 1.05	8.80 $\pm$ 1.04	< 0.001
	P-value **	0.086	0.037	

* t-test, ** Paired t-test

Discussion

The present study showed that the multimodal HL promotion intervention could significantly increase HL in the intervention group, so that the mean HL score in this group increased by 99 points, which was about 2.4 times compared with the baseline. However, the mean HL score of the control group increased by only about 10 points compared to baseline in this group. The slight increase in score in the control group does not appear to be substantial compared to the increase in score in the intervention group and may be attributed to the fact that participants had been exposed to the questionnaire earlier or had received some information over time.

Our results suggest that the multimodal intervention was effective in increasing HL in the intervention group. In a study of patients with IHD conducted by Falahi and Miri, 90% of the control group and 83% of the intervention group had moderate HL at baseline. However, after an HL training intervention, all patients in the intervention group had good HL, while 86% of the control group still had moderate HL (16). Crengle et al. (2018) also reported that an HL intervention in patients with cardiovascular disease could significantly improve their pharmacological knowledge. Although the latter study did not have a control group, in line with the present study, it shows the effectiveness of HL interventions (15). A study of fifty-six health ambassadors also showed that educational lectures on self-care for minor illnesses increased adequate HL from 25% to 50%. However, at the end of the study, 50% of people still had borderline and inadequate HL. The authors concluded that although lectures have some effect on improving HL, more effective and innovative methods are still needed to effectively improve HL (27). Some studies in patients with cardiac problems and diabetes mellitus have also confirmed the effects of HL- enhancing

interventions on self-care behaviors (17, 28) and treatment adherence (29, 30). Many studies have also reported that patients with better HL had higher health levels (6), better QOL (31), and lower mortality rates (32); and imposed lower costs on themselves and the healthcare system (33). However, in a recent systematic review of HL interventions for secondary prevention of coronary artery disease, Beauchamp et al. reviewed 21 studies and reported that 17 studies had positive outcomes.

The authors concluded that interventions are more effective if create social support networks, empower patients, develop interaction between patients and health professionals, and facilitate access to and appropriate use of health information and services (34). The multimodal intervention implemented in our study seems to have all the necessary features, because we not only trained and empowered our patients through face-to-face individual educations, but also created a supportive and interactive social network among them that allowed them to interact with each other as well as with the researcher as an expert nurse. In addition, the researcher not only provided patients with the information they needed through the network, but also provided them with links, addresses, and resources that facilitated their access to useful information and services.

In addition to the educational nature of the intervention implemented in the present study, the significant effect of the intervention may be attributed to the multimodality of the intervention and the longer duration of the intervention compared with other studies. Patients in our intervention group enjoyed a set of face-to-face training, written educations, and continuing education through a social network. However, former studies have mostly

used single training methods such as compact discs (16), social networks (17), or face-to-face training (15). Although all of these were effective, our intervention was more effective in the improvement of HL. This suggests that using a multimodal educational method may increase the effectiveness of the intervention by combining the strengths of different teaching methods.

In this study, all HL subscale scores doubled in the intervention group, whereas much less changes occurred in the control group. The largest increase was in the disease awareness subscale (2.48-fold increase). However, in the control group, two subscales (activity and exercise, and medication regimen) did not change significantly, and the other two subscales showed a slight increase of 4.5 to 5 points, although this was statistically significant in within-group comparison. However, this does not seem to matter much compared to the possible scores and compared to the intervention group. Similar results were obtained in a study by Falahi and Miri, who used the same instrument to assess HL (16). Our findings, together with those of Falahi and Miri, show that the HL promotion intervention can significantly improve all aspects of HL in patients with IHD.

As the study findings showed, all of our patients had poor HL at baseline so that possessed only about 32% of the HL score at the beginning of the study. Meanwhile, most patients identified their physicians as the primary source of information about their illness and health. These findings show that most patients did not receive adequate health and disease-related information from their physicians and other health care providers. These findings are consistent with the results of an earlier study on patients with IHD (13). A study in Iran reported that only 31% of patients with cardiovascular

disease received information about their illness and health from their physicians (14). A study in Pakistan also reported that only 5% of patients with cardiovascular diseases received adequate information about their illness and health status from health professionals such as doctors and nurses. Therefore, patients try to meet their information needs through the media, friends, magazines, and the Internet (35). Low HL may lead to inappropriate health behaviors (36), low treatment adherence (37), decreased self-care (38), anxiety, frequent medical visits, and frequent hospital admissions (39). On the other hand, appropriate patient training; especially multimodal training methods such as the methods used in the present study, is of great benefit in improving HL in patients with IHD. This would reduce patients' anxiety, improve self-care behaviors and treatment adherence, and reduce health care costs.

As strength points, we used a combination of methods to train patients with IHD. Also, we conducted the posttest 8 weeks after the end of the intervention, and the results showed that multimodal training was not only effective but also had a long-term effect on improving HL in patients with IHD. However, this study had some limitations. First, due to the nature of the intervention, it was not possible to blind the intervention group. Second, the small sample size may be considered a limitation. Therefore, it is advisable to conduct a similar study with a larger sample.

Conclusion

In this study, patients in both the intervention and control groups scored only about one-third of the HL score at the beginning of the study. However, after the intervention, the mean HL score in the intervention group increased by 2.4 times, whereas the score in the control group increased only slightly, which does not

appear to be considerable. These findings show that the implemented multimodal educational intervention was able to effectively increase HL scores in the intervention group. According to the findings, nurses, physicians, as well as health officials are recommended to pay special attention to the improvement of HL in their patients. They are recommended to use multimodal approaches to promote HL in patients with IHD. To this end, they are suggested to make their written and face-to-face patient education more effective through the use of new technologies such as mobile-based social networks. Nurses, physicians, and hospital authorities are recommended to establish mobile-based social networks for patient education and ongoing interaction with their patients. In this way, they can continue their interaction with patients, provide them with ongoing education, and improve patients' HL.

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Conflict of interest: The authors have no conflict of interest.

Ethical Considerations: This study was approved by the Research Ethics Committee of Kashan University of Medical Sciences, Kashan, Iran (Code: IR.KAUMS. NUHEPM.REC.1398.040). All patients were briefed on the purpose of the study, voluntary participation, confidentiality of data, and the right to withdraw, and signed a written informed consent form upon entry into the study.

Authors' contribution: ZH and MAH contributed to project conception, ZH and FR did the data acquisition; ZH and MAH did data analysis, literature review, and wrote the manuscript; MAH and FR critically revised the successive drafts. All authors read and approved the final manuscript.

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