

The Effect of Culturally Appropriate Self-Care Intervention on Health Literacy, Health-Related Quality of Life and Glycemic Control in Iranian Patients with Type 2 Diabetes: A Controlled Randomized Clinical Trial

Abstract

Background: Cultural and language differences are necessary factors for diabetes management and self-care education programs in patients suffering from diabetes. This study aims to investigate the effectiveness of culture-based self-care intervention on health literacy, quality of life, and glycemic parameters in patients with type 2 diabetes. **Materials and Methods:** This randomized clinical trial has been carried out in selected centers in Darreh Shahr, Iran; 80 participants were randomly assigned into intervention and control groups. The intervention group received an educational program for 6 sessions twice a week, but the control group only received routine services. Data were collected using health literacy and life quality scales for diabetic patients, which were completed by both groups before, immediately after, and 3 months after the intervention; hemoglobin A1C (HbA1c) was checked before and 3 months after the intervention. SPSS software was also analyzed data using χ^2 , Fisher's exact, independent t , and repeated measures analysis of variance tests. **Results:** There were no significant differences between the 2 groups before the study ($p > 0.05$) goes forward. But, mean scores of health literacy ($F_{2,40} = 5.61, p = 0.007$), quality of life ($F_{2, 40} = 4.09, p = 0.01$), and HbA1c levels ($t, 39 = 6.91, p < 0.001$) have shown significant differences between the 2 groups immediately and 3 months after the intervention have been applied. **Conclusions:** Culturally appropriate intervention should be offered as a part of the nurse's care program for diabetic to control HbA1c, and improve their life quality and health literacy.

Keywords: Culture, diabetes mellitus, education, health literacy, quality of life, self care

Introduction

Type 2 Diabetes Mellitus (T2DM) is the most common health problem globally among chronic diseases, especially in moderate- to low-income countries.^[1] The World Health Organization declared that the population of diabetic patients would reach over 6 million in Iran by 2030.^[2] Statistics indicates that 11.4% of Iranian adults have diabetes.^[3] The high prevalence of death and morbidity due to diabetes affects patients' Quality of Life (QoL) and increases hospital care costs.^[4] The progressive nature of diabetes and its potential complications leads to reduction in self-care behavior and change the patient and his/her family lifestyle.^[5] Previous studies in Iran indicated that people with diabetes have a low QoL, fewer self-management behaviors, and insufficient knowledge of diseases.^[4,6] Self-care behaviors could be exclusively challenging problem, while limited Health

Literacy (HL) is a significant health concern. HL is defined as "the degree to which individuals can obtain, process, and understand basic health information and services needed to make appropriate health decisions."^[7] Limited HL negatively affects patient health status, decreases medication adherence, and results in failure in physician instructions following, poor disease control, and greater use of emergency units and hospital services.^[8] In a study, which have been conducted in Iran, more than half of diabetic patients have an insufficient HL level.^[9] Low HL is a severe obstacle to self-care behaviors in diabetic patients.^[10] Self-care promotion is feasible through training. It is believed that self-care education is the basis for treating diabetes and preventing from its complications. Therefore, the relevant study results have shown that it could effectively change health behavior, helps understand

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the disease, reduce cholesterol, low-density lipoprotein, HbA1c levels, and improves patients' QoL.^[11-13] Researchers have also suggested a variety of interventions to improve self-care behaviors, reduce health complications, which consequently leads to stable improvement in the levels of glycated hemoglobin (HbA1c). One of the strategies frequently recommended to health care providers is culturally sensitive approaches.^[14] Culture is one of the determinants of health that influences the shaping attitudes and beliefs influential in interaction of patients with a health care provider.^[15] Misunderstanding of culture results in communication conflict between the patient and the nurse.^[16] Several studies indicated that language barriers, difficulty in lifestyle transitions^[17], and inappropriate acculturation have been cultural barriers for achieving optimal management of diabetes among patients.^[18] Overall, studies have shown that culturally appropriate interventions, the usage of cultural knowledge of health behaviors to change an intervention could improve participants' knowledge, physical and psychosocial health, clinical biomarkers, glycemic control, and disease self-management in patients with diabetes^[19] also would help participate in day-to-day self-care.^[20]

Iran, a country with cultural diversity and different religions and ethnicities, necessitates paying close attention to patient education and care. Cultural diversity refers to differences in lifestyles, languages, values, norms, and other cultural aspects within and between different groups.^[21] Based on a previous study, in order to change the lifestyle of diabetic patients, culture-based education is essential.^[22] Although it is well established that cultural appropriateness is beneficial for some

patients with diabetes,^[15,18,19] there have been limited studies on the outcomes of these approaches among diabetic patients in Iran. So, choosing educational strategies appropriate to an in-depth understanding of the patient's beliefs and cultural competencies could help nurses to enhance care quality and effective communication with patients. Therefore, the aim of this study was to investigate the effectiveness of culture-based self-care educational intervention on HL, QoL, and glycemic parameters in patients with T2DM.

Materials and Methods

This randomized clinical trial IRCT20170819035769N3 was conducted over a 9-month from December 2017 to August 2018. The study was carried out in the 2 health service centers and the diabetes clinic in Darreh Shahr hospital in Iran.

The sample size based on previous studies were^[10] $\alpha = 0.05$ and $\beta = 10\%$ and test power of 90% and standard deviation = 1 and 5% drop rate in each group, 40 participants were estimated and entered the study without dropping out. One hundred and twenty diabetic patients were referred to the study setting and 100 patients were evaluated for eligibility. Therefore, patients were recruited into this study consecutively. Before allocating randomly, 15 patients did not meet inclusion criteria and 5 patients refused to participate in. Finally, 80 diabetic patients were randomly allocated to 2 equal groups (each group = 40 participants) [Figure 1].

In order to participate in this study, patients considered qualified provided that they were aged more than

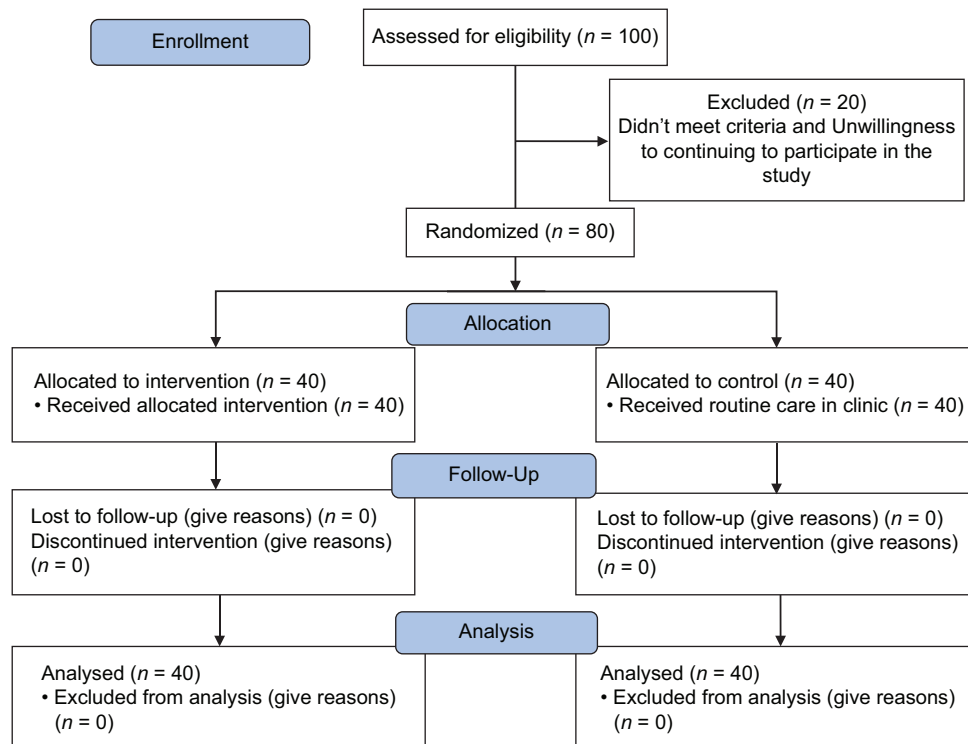


Figure 1: The process of study according of Consort Flow Diagram (2010)

40 years (poorly controlled [HbA1c >7%]), whom diagnosed with T2DM for 6 months or more based on medical diagnosis, being literate (ability to reading and writing skills), having no severe diabetes complications including nephropathy, retinopathy, and neuropathy, no formal intervention and history of participation in similar research, no problems in cognitive and physical conditions (according to the clinical diagnosis by the physician), and being appropriate for answering questions and attending training sessions.

Reasons for participant's exclusion from study were as follows: (1) if they were reluctant to continue participating in research, (2) being absent for more than 2 sessions in the training program, and (3) incidence of disease and severe health problems.

Patients were selected through purposeful sampling method, while referring to the diabetes clinic and health service centers. According to online research, randomizers are allocated into 2 groups; an intervention or control groups through block randomization. Numbered opaque envelopes were used for allocation concealment. Subsequently, cards A (intervention) and B (control) were placed in an opaque envelope according to the generated random sequence. Then, envelope number 1 was opened for the first participant and his/her group was selected based on the envelope card. The same method was implemented for each patient.

The sampling and group allocation was continued until 40 patients were allocated to the intervention and control groups. To allocate concealment and sampling, we used one independent person not to be involved in the study.

The educational program's content was determined based on qualitative needs assessment, the self-care program, and the patients' cultural and health beliefs.^[15,19,23] The intervention group received a training program for 6 sessions lasting 30 to 40 minutes.^[12] The educational sessions were delivered in groups (6-8 persons) twice a week in the study setting [Table 1].

The educational program was carried out by 3 educators, which included a community health nurse (BA), a nutritionist, and a psychologist who fluently speaks Larry and has a rich experience of the local people's culture. In order to facilitate effective communication and learning for patients, the researchers demonstrated part of the training program in terms of practical display, hands-on activities, and PowerPoint videos. During the intervention, patients were also persuaded to ask questions and to share their experiences with the group.

After completing the intervention program, the patient was followed-up by a researcher for 3 months by phone or face-to-face in health service centers and diabetes clinics to monitor changes or to make sure about the implementing the proposed instructions. The control group received the usual medical care from the clinic or health service centers. Moreover, an educational pamphlet containing a summary of the content of the educational materials was given to the control group participants 3 months after the intervention.

Table 1: Objectives and content of educational sessions

Sessions	Object	Content
1	Understanding the disease and complications	Introductory sessions about objectives, teaching methods, and evaluation. Basic definition of diabetes mellitus, diabetic patients' needs, significance of self-care behaviors, recognition of complications, and foot ulcers.
2	Explain the importance of culture and health beliefs	The meaning of culture, misconceptions about diabetes, and how to replace them, while maintaining respect for the client's cultural values and priorities. Modify participants' diets and teach them how to choose healthy food and cooking tips. Talking about health beliefs and their effect on diabetes control, common traditional beliefs about herbal medicines. Ask participants to share their experiences in the group.
3	Demonstrate healthy diet and food choice	Explain about food pyramid, overview of traditional, local foods, and understanding their nutritional value. Improving unhealthy eating habits and the importance of snacks. Ask participants to share peer-to-peer experiences in the field of traditional, local foods.
4	Learning nutritional issues	Providing a dietary guidance during meal times and unhealthy snacks and eating habits, and how to replace them with each other (particularly carbohydrates) in meals and snacks, and proper use of fruits, vegetables, and grains as sources of dietary fiber.
5	Demonstrate self-monitoring and self-care	Explain the need for periodic examinations, control of blood sugar and HbA1c levels, normal blood glucose ranges. Importance of medications, injecting insulin, the side effects of medications. Positive effects of exercises and importance of foot care. Familiarize patients with supportive and information resources. Summarize the benefits of exercise and physical activity.
6	Demonstrate skills of stress management	How to manage stress and the benefits of stress management. Review the contents of previous sessions and group discussions any problems related to previous sessions.

The data collection tools included a demographic information form, which included age, gender, marital status, employment status, educational level, income level, duration of disease, and type of treatment, hemoglobin A1C (HbA1c) test, QoL, and HL Questionnaire.

A biochemical blood test was conducted in a single laboratory to estimate HbA1c once before the intervention and 3 months after the intervention. HbA1c level was measured through an enzymatic method using a BT3000 auto analyzer made by Pishtaz Teb Zaman company in the laboratory of Valiasr Hospital in Iran.

QoL was measured using the Burroughs (2004) Fifteen-item Diabetes Quality of life Brief Clinical Inventory.^[24] It is scored based on a 5-point Likert-type scale from dissatisfaction to satisfaction (scores of 15–75). The reliability of the questionnaire was confirmed by calculating .77 Cronbach's α coefficient. The instrument was validated in Persian by Nasihatkon *et al.*, in 2012.^[25]

The second part of the questionnaire contained HL. This questionnaire was designed in 2008 by Ishikawa *et al.*,^[26] and validated for the Iranian culture by Reisi *et al.*, in 2016.^[27] HL in diabetic patients is measured in 3 categories as Functional (5 items), Communicational (5 items), and Critical (4 items). This self-administered tool contained 14 items responded using a 4-point Likert-type scale, ranging from 1 (never) to 4 (often) (scores of 14–56). The reliability of the questionnaire was confirmed by calculating a higher than .82 Cronbach's α coefficient.

IBM SPSS Statistics Version 16.0 (IBM, Inc., Armonk, NY, USA) was implemented for data analysis. In addition, the Kolmogorov-the Smirnov test was implemented for the average data distribution. Moreover, χ^2 test, Fisher exact test, independent sample *t* test, and Repeated measures ANOVA (analysis of variance) were also used.

Ethical considerations

The ethics committee approved the study of Baqiyatallah University of Medical Sciences, Tehran, Iran, with code number ID IR.BMSU.REC.1395.342. Clear explanations and written consent were provided to every participant before the start of the investigation.

Result

The mean age of the participants was 54.38 (7.38) years and the mean duration of diabetes were 7.35 (4.97) years. Chi-square test, Fisher exact test, and independent *t* test were no significant differences in sociodemographic profiles between the 2 groups ($p > 0.05$), and the groups were homogeneous [Table 2].

Before the intervention, there were no significant differences between the 2 groups regarding the mean score of HL and QoL ($p > 0.05$). Nevertheless, 3 months after the intervention, the mean score of Functional ($p = 0.001$), communicational ($p = 0.001$), criticality ($p = 0.005$) category, and total HL ($p = 0.005$) in the intervention group was significantly more than that of the control group. Also, the mean score of QoL in the intervention group was significantly more than that of the control group immediately ($p = 0.01$) and 3 months after the intervention ($p = 0.001$) [Table 3].

Also, repeated measure ANOVA in between groups comparison showed a significant difference in the mean score of the functional and communicational categories, total HL, and QoL at the 3 measurement time points were ($p = 0.002$), ($p = 0.007$), ($p = 0.7$), and ($p = 0.01$), respectively. However, there were no significant differences in the critical dimension at the 3 measurement time points ($p = 0.29$) [Table 4].

The results indicated no significant differences in HbA1c mean values between the 2 groups before and after the intervention ($p > 0.05$). In within-group comparison, there was a statistically significant difference in the intervention group in the reduction of mean values of HbA1c ($p < 0.001$), but these values differences were not significant in the control group ($p = 0.33$) [Table 5].

Discussion

This randomized controlled trial showed that culturally

Table 2: Characteristics of the participants in two groups of the study

Group characteristics	Categories	Intervention group, n (%)	Control group n (%)	χ^2	df	<i>p</i>
Gender	Male	20 (50)	27 (67.50)	2.52	1	0.08**
	female	20 (50)	13 (32.50)			
Type of treatment	Medication (Insulin or oral medication)	20 (50)	28 (70)	3.33	1	0.58**
	No medication	20 (50)	12 (30)			
Marital status	Single/Widowed	9 (22.50)	4 (10)	2.29	1	0.11**
	Married	31 (77.50)	36 (90)			
Educational level	Below diploma	18 (45)	25 (62.50)	2.46	1	0.08**
	Diploma and university	22 (55)	15 (37.50)			
Employment status	Employed	4 (10)	6 (15)	3.91	1	0.06**
	Unemployed, retired, or housewife	36 (90)	34 (85)			
Monthly income	Sufficient	7 (17.50)	7 (17.50)	1.14	2	0.56*
	Somewhat adequate	12 (30)	8 (20)			
	Insufficient	21 (52.50)	25 (62.50)			

*Fisher exact test. **Chi-square test

appropriate self-care intervention significantly improved health literacy, QoL, and HbA1c level of diabetic patients. In this study, the Functional, Communicational, and Critical Health Literacy questionnaire was used to assess the HL of diabetic patients, which unlike other studies of patients' HL, has been evaluated in 3 functional, communication, and critical domains. The tool assesses the necessary skills and the patients' communication, cognitive, and social skills. These results concur with previously published report findings.^[10,18,28]

Similarly, a study investigating a women with T2DM in Iran found that small group training increased knowledge and the HL of diabetic patients.^[12] In contrast, however, another study indicated that the HLof diabetic patients in

of communication and criticism domain had a higher score than functional domain. In fact, one reason for the low level of patients' functional HL is due to the high age of the patients with visual impairment, which affected these patients' reading and writing skills and functional HL.^[27]

Also, in the present study, the educational program improved communication HL in the intervention group. Therefore, our results align with previous studies' findings.^[12,29] However, intervention in communication skills could improve the knowledge and HL of diabetic patients and control patients' clinical indicators.^[19,30] As in previous studies, culturally appropriate education intervention was feasible and effective regarding that participants showed improved QoL and

Table 3: Comparison of mean and standard deviation score dimensions of health literacy, and quality of life in the intervention and control groups

Variable	Time period	Mean (SD)*		Independent <i>t</i> test		
		Intervention group	Control group	<i>t</i>	df	<i>p</i>
Functional	Before the intervention	15.20 (3.30)	16.65 (3.67)	1.08	78	0.28
	Immediately after intervention	16.80 (2.80)	16.15 (3.31)	1.38	78	0.17
	Three month after intervention	17.40 (1.53)	16.00 (1.81)	3.73	78	<0.01
Communicative	Before the intervention	14.47 (4.16)	14.32 (4.29)	0.15	78	0.87
	Immediately after intervention	15.67 (2.97)	14.42 (3.29)	1.78	78	0.07
	Three month after intervention	15.27 (2.01)	12.05 (1.61)	5.45	78	<0.01
Critical	Before the intervention	10.87 (3.62)	11.12 (3.61)	0.54	78	0.75
	Immediately after intervention	11.82 (2.85)	11.45 (2.38)	0.63	78	0.52
	Three month after intervention	11.10 (1.67)	9.02 (1.64)	2.89	78	0.005
Total health literacy	Before the intervention	41.15 (7.87)	42.10 (7.61)	0.54	78	0.58
	Immediately after intervention	42.70 (5.91)	42.02 (6.04)	0.50	78	0.61
	Three month after intervention	42.37 (2.88)	38.47 (2.96)	2.9	78	0.005
Quality of life	Before the intervention	45.10 (7.13)	43.92 (8.68)	0.66	78	0.51
	Immediately after intervention	47.67 (6.37)	43.77 (7.35)	2.65	78	0.01
	Three month after intervention	47.50 (3.70)	40.92 (5.38)	7.32	78	<0.01

*Standard deviation

Table 4: Comparison of mean and standard deviation score dimensions of health literacy, and quality of life in between the intervention and control groups

Variable	Time period	Mean (SD)*		Repeated measures ANOVA**		
		Intervention group	Control group	<i>F</i>	df	<i>p</i>
Total health literacy	Before the intervention	41.15 (7.87)	42.10 (7.61)	5.61	1	0.007
	Immediately after intervention	42.70 (5.91)	42.02 (6.04)			
	Three month after intervention	42.37 (2.88)	38.47 (2.96)			
Quality of life	Before the intervention	45.10 (7.13)	43.92 (8.68)	4.09	1	0.01
	Immediately after intervention	47.67 (6.37)	43.77 (7.35)			
	Three month after intervention	47.50 (3.70)	40.92 (5.38)			

*SD=standard deviation, **ANOVA=analysis of variance

Table 5: Comparison of the mean values of HbA1c* levels before and three months after intervention

Variable	Intervention group, mean (SD**)	Control group, mean (SD)	Independent sample		
			<i>t</i>	df	<i>p</i>
Before intervention	10.00 (2.18)	9.04 (1.78)	1.04	78	0.30
Three month after intervention	9.45 (2.57)	9.58 (2.44)	1.11	78	0.26
Paired <i>t</i> test			6.91	39	<0.001
			2.13	39	0.33

*HbA1C=hemoglobin A1C, **SD=standard deviation

self-care behaviors.^[15,31] Similar to previous research, our results showed the importance of cultural factors and health beliefs, noting that health providers need to fit interventions to health beliefs.^[19] Moreover, in this study, most patients were older, but designing educational content based on health needs and cultural beliefs by simple language and local dialect had a significant impact on better understanding and improving patients' communication literacy and QoL. An important feature of our program was the language of instruction and participants' native language. This strategy could help facilitate communication and learning process. Also, our program was provided by the local health system caregivers based on "clear communication" HL strategies such as simple spoken language, answer and question, teach-back method, display the film, and using interactive strategies.

According to the results, patients with T2DM are generally older or have many complications of diabetes. However, health care providers do not rely solely on pamphlets or other print media to educate their patients. Therefore, this training method for older people who are likely to have lower HL would not be influential. However, using educational strategies increases patients' HL knowledge scores. However, according to present study, Negarandeh *et al.*,^[10] also concluded that HL is a multidimensional skill related to accessing, understanding, evaluating, communicating, and using health information to make the right health decisions. So, increasing knowledge of the disease may not improve his or her HL. Nevertheless, health care workers reinforce the knowledge of patients with inadequate HL by using simple language and understandable educational methods.

In this study, family members were involved in patient education sessions. This program improved patients' physical and psychological features, significantly affected understanding, and improved patients' QoL. In previous studies, like this study patients who reported a lack of psychological support or conflict-identified diabetes as a significant source of distress and had lower adherence to a diabetic diet, insufficient metabolic control, and lower QoL.^[30,32]

The results affirm that cultural factors and being culturally sensitive in the educational program's design effectively reduces A1C levels. Similarly, a randomized controlled trial reported a low level of glycemic control after a diabetes education program in the literature,^[17,19] which has been confirmed by current researchers.

One of the strengths of this study is regarding the prevailing cultural beliefs of the people in education. Based on the results, most patients believed that patient's self-monitoring has no therapeutic value and should be performed at the health centers or hospitals under health personnel's supervision. Therefore, they were not willing to provide glucometer and blood glucose control. Alternatively, herbal and home remedies were replaced without medical supervision. Patients also cooked and consumed local foods at festivals and cultural occasions because of respect for family traditions, which is often contradicting with their diets.

On the other hand, due to the local dialect and the lack of fluency of most patients in the country's official language, the language is one of the main barriers to communicating with health system staff, causing shame and embarrassment and effective relationship between patient and health care provider. Furthermore, these beliefs influence the dimensions of patients' HL and QoL.

Furthermore, communication and critical HL skills are essential factors for improving self-care behaviors in diabetic patients. This empowerment ultimately enables patients to receive and evaluate the information they need from a different communication channel and put them into practice; critical HL is a prerequisite for understanding these factors. Therefore, according to the results, communicating correctly is the most critical factor affecting how patients perform self-care behaviors. It can be said that proper communication between health care staff and patients results in better understanding of patients' desires and experiences, awareness of the program, on time diagnosis, and treatment process.

The present study was designed and implemented for the first time based on the cultural and health needs of diabetic patients using native language health care providers familiar with the people's culture in the region. Another critical point was to involve the patients' families in educational programs. Finally, a unique tool was used to measure HL and patients' QoL.

The study's limitations were the use of a self-report questionnaire and the content of this educational program; however, generalizing the study results to a wider patients' population, even in Iran, which is a multiethnic country, should cautiously be considered. In addition, the participant's physical and economic conditions were occasionally prevented from regularly attending group classes as scheduled. Finally, since most patients with T2DM are older and exposed to long-term complications of the disease, it is also suggested that culturally appropriate self-care intervention based on HL levels to be used for other chronic conditions.

Conclusion

Culturally appropriate self-care intervention may significantly increase HL, QoL, and causes reduction of HbA1c in diabetic patients. So, increasing the cultural knowledge of family members and health care providers was a practical approach to preventing and reducing chronic diseases' complications. Finally, considering the program's effectiveness, it should be suggested as a part of nurse' care program for diabetic patients to control HbA1c and improve their QoL and HL.

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Conflicts of interest

Nothing to declare.

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