

Effect of Empowerment Model-Based Program on Quality of Life in Patients with Type 2 Diabetes: A Randomized Controlled Trial

Abstract

Background: Type 2 diabetes (T2D) is a chronic disease with a high prevalence globally, which is in the second place of importance for the investigation of chronic diseases. According to previous studies, Quality of Life (QOL) is low in diabetic patients. Hence, this study was conducted with the aim to evaluate the effect of the empowerment model on the QOL of patients with T2D. **Materials and Methods:** A randomized controlled trial was performed on 103 T2D patients over 18 years of age, with a definitive diagnosis of diabetes and medical records in a diabetic center. Patients were randomly assigned to either the intervention or the control groups. Routine education was presented to the control group, and the empowerment model was used for education in the experimental group for 8 weeks. The data collection tools used consisted of a demographic characteristics form and the diabetic clients QOL questionnaire. The one-way analysis of variance, Chi-square test, paired *t*-test, and independent *t*-test were used for data analysis. **Results:** After the intervention, there were significant differences between the two groups in terms of the physical ($p = 0.003$), mental ($p = 0.002$), social ($p = 0.013$), economic ($p = 0.042$), and illness and treatment dimensions of QOL ($p = 0.033$), as well as the total QOL score ($p = 0.011$). **Conclusions:** According to the results of this study, the training program based on empowerment significantly increased the QOL of patients with T2D. Therefore, using this method can be recommended in patients with T2D.

Keywords: Diabetes Mellitus, Type 2, education, empowerment, quality of life

Introduction

Diabetes Mellitus (DM) is a global public health concern associated with mortality.^[1] DM is undoubtedly one of the most challenging global health problems in the 21st century.^[2] The prevalence of DM has been reported to be about 11.4% in Iran, and it is estimated that 9.2 million Iranians will have diabetes by 2030.^[3] People with chronic diseases like diabetes require many behavioral and psychological changes to fight the disease.^[4] DM is known to impair health-related Quality of Life (QOL) and is associated with multiple medical complications.^[5] Moreover, increased self-care, adherence to treatment regimens, and positive lifestyle changes are associated with improved QOL in patients with diabetes.^[6] Therefore, QOL is one of the significant endpoints of recent clinical trials in people with diabetes.^[7] Healthcare providers can affect the QOL of patients with chronic conditions by examining their health status and changing their

lifestyles to improve the management and treatment of the disease.^[8] Empowerment is an influential concept in education, management, performance, and research in nursing^[9] and results in improved self-care. Patient empowerment is a continuous process in which the knowledge, motivation, and ability to control one's illness are developed.^[10] Empowerment is generally regarded as a method in which people gain greater control over their decisions and actions influencing their health.^[11] Many studies have investigated the effect of the empowerment program on several dimensions of diabetic patients' lives, such as self-efficacy,^[12] psychological distress, self-stigma, role strain, and QOL.^[13]

Empowerment-based education is needed to determine whether patients can take control of their day-to-day diabetes self-management. Such a new approach should be based on "empowerment and

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engagement” to be effective in the daily activities of diabetic patients. Empowerment-based education provides individuals with insight that helps them change their behavior.^[14] It should be noted that one of the factors that affect patients’ QOL is the inadequate understanding of high-risk people about the consequences associated with their condition, and it increases any positive change in conditions such as proper education, health care, family support, etc., In addition, as people become more sensitive to complications, their motivation for preventive measures increases, highlighting the importance of empowerment-based education. To the best of the authors’ knowledge, at present, empowerment model education in clinical conditions is not organized for Iranian patients with diabetes, and it is necessary to evaluate its effectiveness in improving QOL. Furthermore, implementing this program does not require the utilization of experts, and nurses will be able to implement it according to their job descriptions. Therefore, the present study was conducted with the aim to determine the effect of the empowerment model-based program on QOL in patients with type 2 diabetes (T2D).

Materials and Methods

This clinical trial (IRCT2013082614484N1) was conducted on patients with T2D who were referred to the Diabetes Center of Imam Hossein Hospital of Shahroud, Iran, from October 2016 to December 2016. The study participants included individuals over 18 years of age with a definitive diagnosis of diabetes and medical records in a diabetic center. Moreover, they had no specific psychiatric disorder. The physical and mental ability to participate in the educational program was considered an inclusion criterion. The exclusion criteria included withdrawal from the study and the incidence of any severe stressful condition. The sample size was determined based on the study by Pibernik-Okanovic *et al.*^[15] With the consideration of 95% confidence interval and 90% power, the required sample size for the two groups were obtained to be approximately 98 individuals.

The final sample size was determined to be 106 participants who met the inclusion criteria in order to obtain more efficient and generalizable results. A convenience sampling technique was adopted. After obtaining written consent from participants, they were randomly allocated to either the intervention ($n = 53$) or the control ($n = 53$) groups using the flip coin technique. The trainer and patients were not blinded in this study, but data collectors and analyzers were blinded.

After obtaining the necessary permissions, participants were asked to complete the data collection tools, including a demographic characteristics form and the diabetic clients QOL (DCQOL) questionnaire. The demographic data included age, gender, educational level, marital status, economic status, and occupation.

The DCQOL questionnaire is used to assess the QOL of diabetic patients. This questionnaire has 44 items in

5 dimensions and 1 general question. It consists of the physical (9 items), mental (11 items), social (7 items), economic (5 items), and illness and treatment dimensions (13 items). The validity and reliability of the DCQOL questionnaire have been approved in an Iranian study on patients with T2D. The results of criterion-related validity revealed a linear, positive, and significant association between DCQOL and the SF-36. The internal consistency results revealed Cronbach’s alpha of 0.88–0.93 and 0.95, and test–retest reliability of 0.86–0.90 and 0.92 for the DCQOL.^[16]

During the preintervention phase, patients completed the DCQOL questionnaire. After completing the questionnaire and randomly allocating patients to two groups, the intervention group received the empowerment training program, and the control group continued to receive routine training at the Diabetes Center. The educational content was provided based on the recommendations of the American Diabetes Association (2012) and according to the diabetic patients’ needs^[17] with the cooperation and consultation of a specialist and a dietitian. The diabetic patients participated in the study under the supervision of a specialist and a dietitian considering their four-drug regimen, nutrition, activity, exercise, and foot care based on a template consisting of the steps of understanding the threat, problem-solving, and evaluation. The empowerment model was designed to improve the care of patients with chronic diseases and their outcomes, and has been previously used for several chronic diseases.^[18,19]

In the first step (understanding the threat), department meetings were performed on 2 days to sensitize the patients and raise the patients’ knowledge and awareness. After a week, the second step (problem-solving) was performed as group discussion sessions in groups of six to eight individuals. In these sessions, the patients discussed their problems and solutions under the supervision of a researcher. Moreover, they received training for the required practical skills. Each session lasted about 60–90 min. In this step, we tried to teach the required skills, including group discussion and group problem-solving, to enhance patients’ self-efficacy. The patients in the control group only received routine training. In the third step (evaluation), the two previous steps and the empowerment process were evaluated. During the empowerment sessions, patients’ knowledge was assessed by raising two questions orally about the topics taught in the previous training sessions.

Moreover, the effect of the intervention in the prior session was assessed. To determine the effect of the empowerment program, patients were released for 3 months so that the clinical indicators could be measurable. Moreover, patients received essential guidance associated with different aspects of behavior toward diabetes. This resulted in a reliable relationship with the researcher. Although the researcher supported the patients based on the definition of empowerment, he only played the role of a facilitator and avoided providing

the patients with any ultimate solutions. Notably, three patients were excluded during the empowerment programs due to exacerbations and hospitalizations. After 3 months, the QOL of patients in both groups was assessed using the DCQOL questionnaire [Figure 1].

The empowerment approach training was conducted for the experimental group during 8 weeks in three phases, including the preintervention, intervention, and postintervention phases, based on the steps of the model: 1) understanding the threat, 2) problem-solving, and 3) evaluation. The Family-Centered Empowerment Model was designed by Dr. Fatemah Ahlani at Tarbiat Modares University, Iran.^[20]

All data were analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA). Descriptive statistics, including mean, standard deviation, and absolute and relative frequencies, were used to categorize and summarize the findings. Furthermore, two-sample *t*-test and one-way analysis of variance were applied for continuous variables. The Chi-square test was used for categorical variables to compare the characteristics of patients in the study groups before performing the empowerment model. Paired *t*-test was used to compare the mean QOL of diabetic patients in the experimental and control groups before and after the intervention.

Ethical considerations

The study was in accordance with the Declaration of Helsinki. The Ethics Committee of Shahroud University of Medical Sciences approved this study (IR.SHMU.

REC.1392.920.07). Accordingly, written informed consent was obtained from all participants before any intervention.

Result

General characteristics of patients have been presented in our previous article.^[21] The mean age of the patients was 47.26 (6.21) years; most patients were women (62.50%) with primary education (64%), housewives (54.50%), and married (83%), and there was no significant difference between the two groups in terms of the demographic variables [Table 1].

According to the results, there was no significant difference in the QOL dimensions [physical ($p = 0.752$), mental ($p = 0.235$), social ($p = 0.315$), economic ($p = 0.098$), and illness and treatment dimensions ($p = 0.361$), as well as the total score ($p = 0.627$)] between the intervention and control groups before the intervention. However, after the intervention, there was a significant difference between the two groups in terms of physical ($p = 0.003$), mental ($p = 0.002$), social ($p = 0.013$), economic ($p = 0.042$), and illness and treatment dimensions ($p = 0.033$), as well as the total DCQOL score ($p = 0.011$) [Table 2].

Discussion

This study was conducted to evaluate the effect of the empowerment model on the QOL of patients with T2D. According to the results of this study, the training program based on empowerment significantly increased the QOL

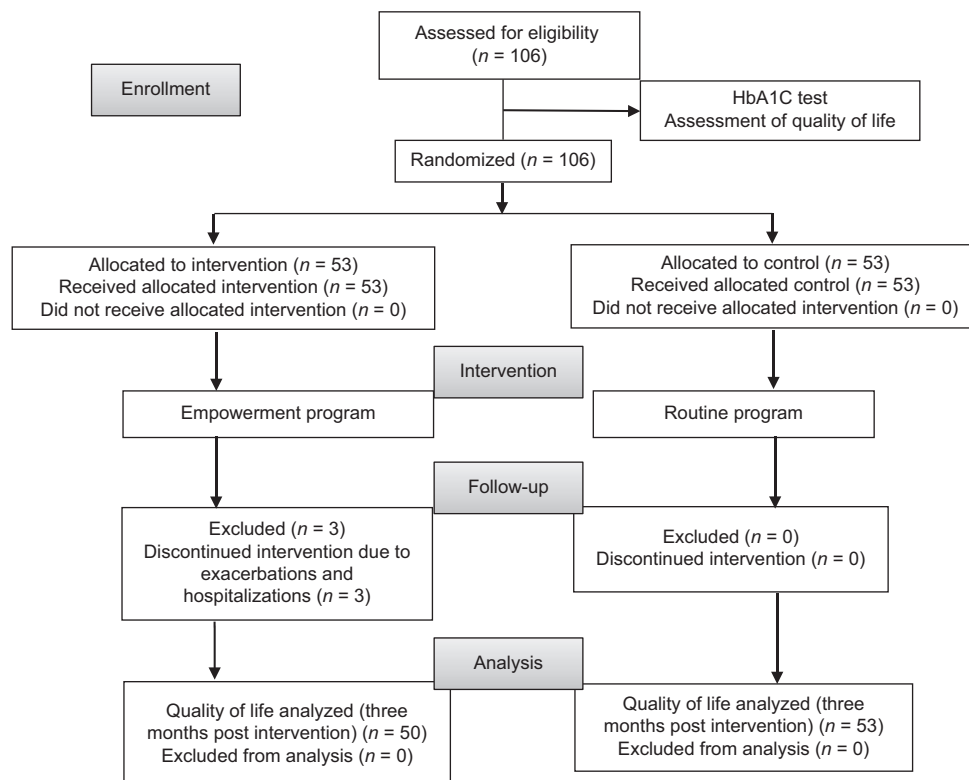


Figure 1: The process of study design

of patients with T2D. Diabetes education based on the empowerment model for self-management behaviors in physical, social, and psychological aspects is very different from the approach of persuading patients to adhere to the treatment regimen.^[22] In this study, all aspects of QOL in the intervention group differed significantly after the empowerment model compared to before the intervention.

The results of the study by Cheng *et al.*^[23] provided empirical evidence for the efficacy of the empowerment-based intervention program in enhancing empowerment and perceived QOL among patients with uncontrolled T2D. Furthermore, in a clinical trial, Nasrabadi *et al.*^[24] reported that the educational program based on empowerment could improve nutritional behaviors, hemoglobin A1C, and blood glucose in patients with T2D.

Moreover, a study by Cheng *et al.*^[25] showed that the empowerment-based intervention program resulted in a significant improvement in diet management and blood glucose self-monitoring. In addition, in the study by Shin and Park, a positive correlation was found between the empowerment and QOL of patients, and the empowerment of the survivors of breast cancer significantly influenced their QOL.^[26] Mamaghani *et al.*^[27] found that training based on empowerment models and emphasis on the strengths of clients in solving their own problems can play a major role in increasing self-efficacy and reducing HbA1c levels. Cheng *et al.*^[28] found that an empowerment-based intervention program increased the perceived QOL of patients with T2D.

In addition, empowerment programs for patients with T2D significantly improved self-care behaviors, adherence to medications, self-efficacy, and QOL.^[29,30] Similarly, the results of previous studies showed that implementation of the empowerment model improved QOL in a wide range of people, such as school-age children diagnosed with rheumatoid arthritis, transgender people under hormone therapy, and children with epilepsy.^[31-33]

In the present study, we investigated empowerment education as a dominant approach in the education of T2D patients. We used a QOL questionnaire that was culturally appropriate for Iranian patients. Based on the findings of the present study, it can be concluded that empowerment programs can increase T2D patients' awareness or knowledge of risks and encourage and motivate them to change their behavior to a more preventive and healthy behavior by increasing their knowledge and enhancing their self-awareness. By doing so and gaining the ability to control the factors that affect their health, these individuals can increase their QOL. Moreover, as clients become more involved in the empowerment program, they have a chance to practice and learn more. This way, they will become aware of the challenges and, thus, increase their self-esteem, which leads to improved QOL.

However, some limitations might affect the generalization of the results. First, this study was conducted on patients with T2D, and thus, the results cannot be generalized to T1D patients. Moreover, the following uncontrollable confounding variables should be considered: different cultural and social

Table 1: Descriptive characteristics of patients with type 2 diabetes

Demographic variable	n (%)		p*
	Control	Intervention	
Group			
Age (year)			
Less than 45	27 (51)	29 (58)	0.72*
45 and higher	26 (49)	21 (42)	
Gender			
Male	20 (37.50)	23 (46)	0.19*
Female	33 (62.50)	27 (54)	
Educational status			
Primary	34 (64)	33 (66)	0.76*
Middle school	13 (24.50)	10 (20)	
Diploma and higher	6 (11.50)	7 (14)	
Occupational status			
Employed	14 (26.50)	9 (18)	0.34*
Unemployed Retired	10 (19)	14 (28)	
Housewife	29 (54.50)	27 (54)	
Marital status			
Married	44 (83)	36 (72)	0.69*
Single	9 (17)	14 (28)	
Disease history (y)			
Less than 7	29 (54.50)	24 (48)	0.76*
7 and Higher	24 (45.50)	26 (52)	

*Chi-square test

Table 2: Comparisons of mean scores of quality of life in the study groups before and after the intervention

	Before intervention		p*	After intervention		p*
	Control	Intervention		Control	Intervention	
Dimensions of quality of life	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Physical	57.82 (6.21)	58.21 (5.67)	0.752	58.76 (6.21)	67.40 (5.99)	0.003
Mental	64.12 (8.47)	66.68 (8.49)	0.235	63.26 (8.62)	72.75 (8.53)	0.002
Social	58.32 (7.45)	60.25 (7.28)	0.315	58.78 (7.41)	67.66 (7.01)	0.013
Economic	49.98 (7.23)	52.64 (6.95)	0.098	51.78 (7.01)	59.19 (6.60)	0.042
Illness and treatment	48.82 (7.51)	50.64 (7.48)	0.361	49.70 (7.24)	58.27 (7.67)	0.033
Total score	59.14 (7.62)	60.34 (7.54)	0.627	57.02 (7.45)	63.65 (7.39)	0.011

*Independent sample t-test

backgrounds, different interpersonal interactions of patients, and the difference in motivations and interests of patients in the study, which might affect the learning of the individual. However, we should note that the random allocation of patients and homogenizing the two study groups reduced the effect of these factors to a large extent. Nevertheless, the possible transfer of data from the staff of the diabetic center to the members of both groups and the possible noncompliance with the empowerment educational program by the patients should be considered as other limitations of the present study. The invitation of the participants and the educational programs for the two groups were conducted on different days to reduce these problems.

Conclusion

Based on the findings of this study, the empowerment model-based program affected the QOL of patients with T2D. The research findings could be used in such areas as education and clinical research in the field of chronic diseases such as diabetes. It is recommended that all members of the health care team, especially nurses pay attention to this educational method in health education-related activities and use this approach in providing training programs for patients and in-service training. It is hoped that nurses will shift from traditional to modern educational approaches, especially empowerment-based training programs, which will reduce the burden of disease on the affected person, the family, and the community.

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Conflicts of interest

Nothing to declare.

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