The Effect of Empowerment Program on Health-Related Quality of Life of Type 1 Diabetic Adolescents

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Abstract

Background: There is a growing interest on the study and improvement of health-related quality of life (HRQOL). Type 1 diabetes can severely affect HRQOL. Iraqi adolescents with type 1 diabetes mellitus (T1DM) have lower quality of life (QOL) compared to their healthy peers.

Aim: The present study was performed with aim to assess the effect of an empowerment program on the HRQOL of type 1 diabetes adolescents.

Method: This clinical trial study was performed on162 adolescents with T1DM referred to the Al-Hassan Diabetes Center of Karbala/Iraq in 2021-2022. Firstly, the adolescents' Empowerment Package was compiled. Then sampling was taken via simple randomization method. The Kidscreen Questionnaire was used for data collection. The implementation of the empowerment program began for the intervention group in the groups of 10 to 15 people and in 10 sessions, three sessions per week. The control group received the routine care. Four weeks after completion of the intervention, the QOL score was again measured and compared in the two groups.

Results: Before the intervention, there was no significant difference between the Kidscreen scores of the control (88.70±10.80) and intervention (87.89±9.50) groups (p=0.62), but this difference was significant in the post-intervention stage (82.90±8.00 vs 89.70±8.80) (p<0.001). In the inter-group comparison, paired t-test showed a significant difference in Kidscreen score before and after the intervention in the intervention group (p<0.001) and in the control group (p<0.001).

Implications for Practice: We could suggest empowerment in diabetes self-care as a way to increase the QOL of adolescents with type 1 diabetes.

Keywords: Adolescents, Diabetes Type 1, Empowerment, Health-Related Quality of Life

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Introduction

Quality of life (QOL) is a broad multidimensional concept which usually includes subjective evaluations of both positive and negative aspects of life. Health-Related Quality of life (HRQOL) includes those aspects of overall QOL that could affect health either mentally or physically (1). On the individual level, HRQOL includes physical and mental health perceptions and their relationship (2). Health status that is self-assessed is also a powerful predictor of mortality and morbidity than the objective measures of health. HRQOL measures make it possible to scientifically demonstrate the impact of health on QOL (3).

Globally there is a growing interest in the study of HRQOL and many studies have focused on this concept (4,5). It has become an important measures from the clinical and epidemiological point of view (6). Diabetes type 1 is one of the chronic diseases that could deeply affect HRQOL. Type 1 diabetes mellitus, previously known as insulin dependent diabetes, is a heterogeneous disorder that usually develops during adolescence. The disease is characterized by a deficit of insulin production secondary to destruction of pancreatic b-cells and requires lifelong administration of insulin for survival (7). The results of a meta-analysis showed that the incidence of type 1 diabetes was 15 per 100,000 people and its prevalence was 9.5% (95% CI: 0.07 to 0.12) in the world which was statistically significant (8). The average annual incidence rate of type 1 diabetes in Iraq was 7.4 per 100,000 and in the intermediate group was 87 per 100,000. The overall mean age at first diagnosis was 15.3 ± 9 years and it was significantly higher in men (9). Type 1 Diabetes (T1Ds) has a greater negative impact on physical status than other type 2. Insulin helps the body use glucose from food for energy. People with T1Ds need to take insulin every day. Patient and families need to understand what causes diabetes and how nutrients, physical activity, and insulin interact and how these factors can effect on blood glucose levels (10). Due to the need for frequent insulin injections, dietary restrictions, activity restrictions, limited social relationships due to the need for ongoing care, concerns about complications and the lifelong nature of this disease, type 1 diabetes has a significant impact on the QOL of affected people (11).

Key aspects to succeed in type 1 diabetes control are a multidisciplinary team work, disease management education and enhancing decision-making capabilities, and implying new technologies without forgetting the emotional sphere of the patient and family (12). In fact, treatment guidelines recommend that routine screening for emotional status and family relationships is crucial in diabetes management. Moreover, psychosocial and hormonal changes of puberty make this stage a difficult one with higher metabolic instability, and many adolescents experience deterioration in metabolic control. Assessment of HRQOL is important in clinical practice in diabetes type 1 in order to evaluate the course of the disease, early detection of the problems, and determine what type of insulin therapy would be adequate to maintain acceptable metabolic control with less impact on HRQOL in each patient. Previous studies have shown that girls, older children, and specific sociodemographic factors such as single-parenthood, lower family income or minority status would be associated with poor metabolic control and worse HRQOL (7).

Aljallad et al. (2020) showed that Iraqi children and teenagers aged 12-18 years with T1DM who live in Karbala governorate had poorer QOL than healthy peers (11). Also, Murillo (2017) confirmed low HRQL in pediatrics with diabetes type 1; they showed some factors should be taken into account to improve HRQOL (6). Such studies addressee low QOL in this population and these parameters would be better with concentrating on their education, awareness and skills. Moein et al. (2016) assessed the effect of an empowerment program on self-efficacy of patients with Type 2 Diabetes. They showed that an empowerment program had positive effects on self-efficacy in these patients (13). So, considering low HRQL of children with type 1 diabetes and the potential effect of empowerment programs on clinical outcomes of type II diabetes, this study was performed with aim to assess the effect of an empowerment program on HRQL of children with type 1 diabetes.

Methods

This clinical trial study was performed on 162 adolescent patients (age 12–18 years) with T1DM referred to the Al-Hassan Diabetes Center of karbala hospital in Iraq, 2021-2022. This study was blinded at the statistical analyst level. Adolescents aged 12-18 years with type 1 diabetes who had the inclusion criterion entered the study. Inclusion criteria were satisfaction with participation in the study, age 8-12 years, at least 4 months passed since the child's illness, no other diseases such as

congenital anomalies and learning disabilities (as approved by the treating physician), no participating in the training programs during the last 6 months, a minimum literacy of parents and children, no suffering from complications of diabetes. Dissatisfaction with the continuation of the research in each of the stages of the study and hospitalization for more than one week were considered as the exclusion criteria. To determine the sample size, confidence level and test power were considered as 95% and 80%, respectively. Sample size in this study was calculated using the formula of comparing two community means and according to the results of Ebrahimi et al.'s (2023) study (14) as 20 participants in each group. Sampling was done via convenience method and participants were assigned to the control and case groups via simple randomization method. Children with type 1 diabetes were registered in the Imam Hussein (Peace be upon him) hospital of Karbala holly city, and the selected participant were assigned to the two groups via simple randomization method. Out of about 502 registered patients, 162 patients met the inclusion criteria. Among them, 54 patients (sample size + 34 more because of the possible loss) were selected as the control group using a random number table. Accordingly, 108 patients were selected as the intervention group (Figure 1). Since the intervention in the present study had no ethical challenges and it did not cost much for the researchers, therefore, a larger sample size was included in the study.

The tools used in this study included demographic characteristics form and Kidscreen-27 tool for assessing health related quality of life in children. Sampling tool that includes inclusion and exclusion criteria and demographic characteristics form which have been made based on text review and our experiences in order to orient the sampling, eliminate the confounding variables and collect background information from patients. These tools have been validated through content validity but did not require reliability testing. Kidscreen-27 for assessing HRQOL is a standardized questionnaire designed to measure subjective HRQOL in children and adolescents, and is conceptually based on the definition of QOL as a multidimensional construct including physical, emotional, mental, social, and behavioral components of well-being and functioning as perceived by children and adolescents (10). Kidscreen-27 has been used in many countries for large-scale population-based studies (15). Nik-Azin et al. (2013) showed that Kidscreen-27 has an appropriate validity and reliability in Iranian population. They reported that Cronbach's alpha coefficients for all dimensions, except for school environment dimension, were above 0.70 and test-retest reliability coefficients for all dimensions were strong ($p<0.01$) (16). In the present study, the validity of the tool was done by translation validity and content validity. First, the tool was translated from English into Arabic. Then the translation validity was done by Arabic-English translation specialists. At the next step, the Arabic version was given to 10 Arabic-speaking medical and nursing professors to be assessed in terms of content validity. The reliability was assessed by internal consistency and Cronbach's alpha detection ($\alpha=0.72$) and test retest method ($r= 0.8$, $p<0.001$).

This research was performed in 2 stages. Firstly, the adolescent empowerment package was collected based on the necessities mentioned in the print and online sources. These dimensions were addressed in Table 1. In the second stage, after obtaining permission from the ethics committee of the Mashhad University of Medical Sciences, sampling was done in Imam Hussein (PUH) Hospital in Karbala according to the consort table. The empowerment program for the intervention group was implemented in the groups of 10 to 15 people, and in 10 session, tree session per week (13). The content of empowerment sessions is such that first the topic of that session is presented theoretically by giving examples through lectures, group discussions, questions and answers. Then practical exercises were provided for each title. At the end of each session, exercises were given to do at home. At the beginning of the next session, the exercises were reviewed. The adolescent's skills have been observed on each topic. Then a new topic was instructed. The content of the meetings is given in Table 1. Also to observe the ethical points, after completing intervention and data collection, this package was implemented for the control group. The control group received the routine care. Four weeks after completing the intervention (13), the HRQL score was again measured and compared in the two groups.

Data were analyzed using SPSS software (version 16). Normal distribution of quantitative variables was determined by the Kolmogorov-Smirnov and Shapiro-Wilk tests. Independent T test (and if the distribution was abnormal, Mann-Whitney test) were used to compare the quantitative variables between the two groups,. Paired tests (paired or Wilcoxon as well as repeated measures or Friedman tests) have been used to compare between group analysis in terms of quantitative variables.

Table 1. The content of adolescent empowerment program

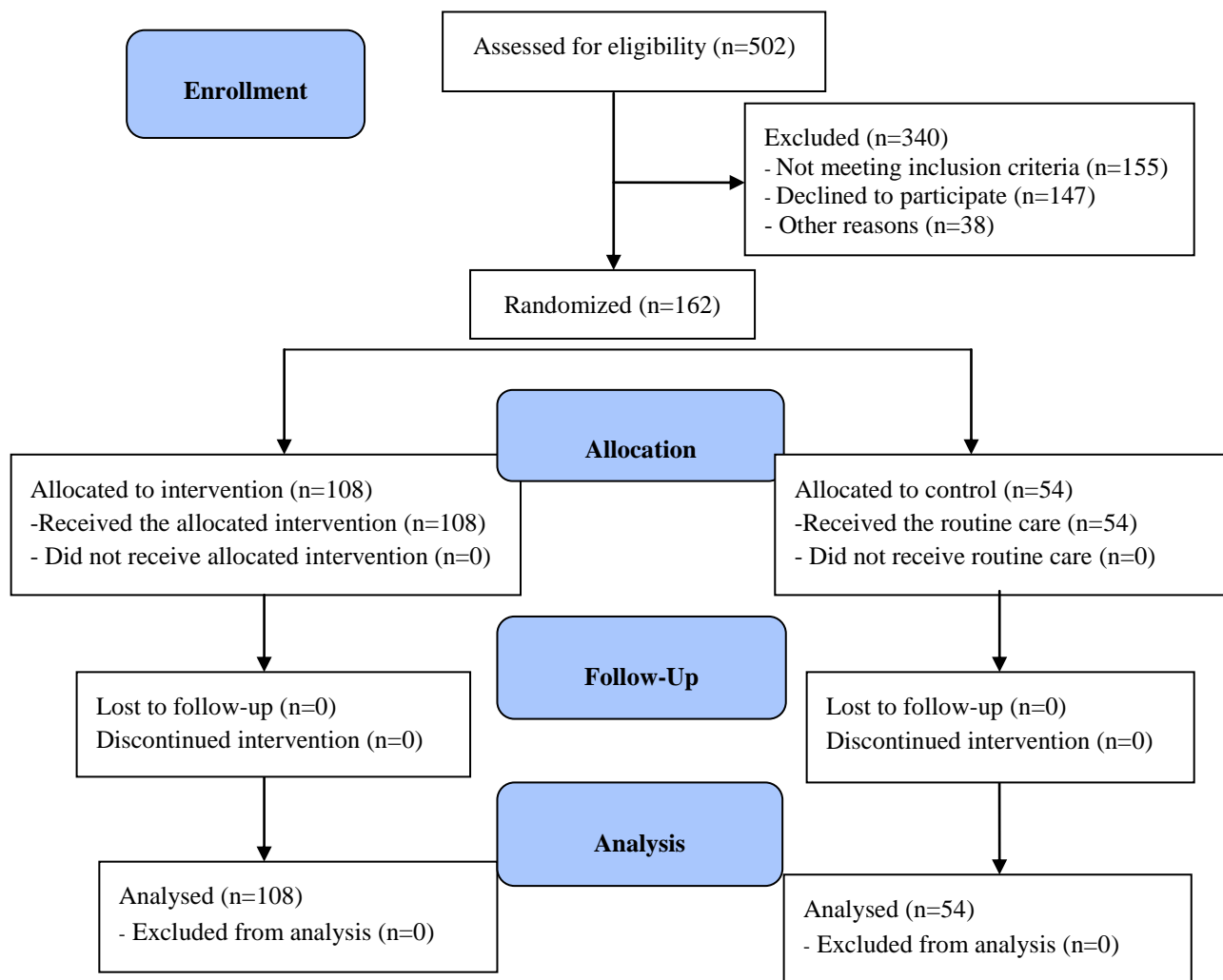| Session number	Beginning	Content	Practical exercise	Home work
1	Introducing researchers and participants	Diabetes Theory	Post-test and answer questions about content-based diabetes theory	Provide the first part of the package to the participants to study at home
2	Retest to review knowledge about diabetes theory	Limited knowledge of acute complications and how to prevent and deal with any of the acute complications	Post-test and answer questions about limited knowledge of diabetes complications based on content	Provide the second part of the package to the participants to study at home
3	Retest to review knowledge about the acute complications of diabetes and how to prevent and control complications	Insulin self-care: including insulin types, insulin syringes, dose calculation, drug drawing from the pockets, injection sites, injection method,	Practical training on different types of insulin shells, different types of insulin pens, different types of insulin, how to store insulin, how to draw and how to inject insulin	Provide third part of package to participants to study at home. Provide home practices about insulin injection and drawing techniques, use of insulin injection template, observe injection sites, and follow up injection site complications.
4	Receive documentation of exercises performed at home	Insulin self-care: including insulin types, insulin syringes, dose calculation, drug drawing from the pockets, injection sites, injection method,	Practical training on different types of insulin shells, different types of insulin pens, different types of insulin, how to store insulin, how to draw and how to inject insulin	Provide home practices about insulin injection and drawing techniques, use of insulin injection template, observe injection sites, and follow up injection site complications.
5	Receive documentation of exercises performed at home	Activity self-care: including recognizing the types of activities that are allowed in these patients, How to prevent hypoglycemia and hyperglycemia during activity, Adjustments of insulin dose during activity at the advice of the relevant physician.	Perform light practical activities in accordance with theoretical standards for the prevention of hypo and hyperglycemia	Provide practice activities at home and note the schedule of these activities, The amount of sugar recorded before and after the activity, Documentation of possible complications and possible intervention in special forms that have been prepared for this purpose
6	Receive documentation of exercises performed at home	Activity self-care: includes recognizing types of activities that are allowed in these patients, How to prevent hypoglycemia and hyperglycemia during activity, Adjustments of insulin dose during activity at the advice of the relevant physician,	Perform light practical activities in accordance with theoretical standards for the prevention of hypo and hyperglycemia	Provide practice activities at home and note the schedule of these activities, The amount of sugar recorded before and after the activity, Documentation of possible complications and possible intervention in special forms that have been prepared for this purpose
7	Receive documentation of exercises performed at home	Nutritional self-care: including recognizing the types of allowed and unauthorized foods, caloric calculations and glycemic index, setting a diet plan under the advice of a nutritionist	Perform food calculations for the basis of each child's weight with the participation of the child, Set proper diets for breakfast, lunch, dinner, Set snack diets	
8	Receive documentation of exercises performed at home	Nutritional self-care: including recognizing the types of allowed and unauthorized foods, caloric calculations and glycemic index, setting a diet plan under the advice of a nutritionist	Perform food calculations for the basis of each child's weight with the participation of the child, Set proper diets for breakfast, lunch, dinner, Set snack diets	Perform food calculations for the basis of each child's weight with the participation of the child, Set proper diets for breakfast, lunch, dinner, Set snack diets and document on special forms for class presentation
9		Limited knowledge of long-term complications and prevention of them.	Performing post-test on recognizing and prevention long-term complications	Provide long-term complications to the participants to study at home
10	Verbal post-test of late complications of diabetes	Questions and answers and bug fixes	Termination and introduction of communication paths with researcher	

Figure 1. CONSORT flow diagram of the study

Results

A total of 162 adolescents included in the present study, 54 in the control group and 108 in the intervention group. The mean age of the adolescents in the intervention group was 14.70±1.83 year and in the control group was 13.80±1.74 year. Mann-Whitney U test showed that the difference was not statistically significant ($p=0.205$) and the two groups were homogeneous in this respect (Table 2). Also, 56.4% in the intervention group and 56.8% in the control group were female. Chi-square test did not show a significant difference between the two groups in the frequency of gender ($p=0.547$) and the two groups were homogeneous in terms of gender (Table 2). Other demographic parameters were presented in Table 2.

Before the intervention, the mean of Kidscreen score in adolescents in the intervention group was 87.89±9.50 and in the control group was 88.70±10.80, but the independent t-test did not show a significant difference between the two groups in this regard ($p=0.620$). In the post-intervention stage, the Kidscreen score was 89.70±8.80 in the intervention group and 82.90±8.00 in the control group. Independent t-test showed this difference was significant ($p<0.001$) (Table 3).

In terms of intergroup comparison, paired t-test showed a significant difference in Kidscreen scores before and after the intervention in the intervention group ($p<0.001$); this difference was also significant in the control group ($p<0.001$) (Table 3).

Table 2. Demographic characteristics of the study participants

Variable	Mean±SD		P-value
	Intervention	Control	
Age (Year)	14.70 (1.83)	13.80 (1.74)	0.205*
Duration of diabetes (months)	43.60 (35.90)	29.50 (23.00)	0.070*
Last Hg A1C	11.00 (2.50)	10.70 (2.20)	0.432*
Gender			
Male	47(43.5%)	21(36.2%)	0.547**
Female	61(56.4%)	33(56.8%)	
Occupation			
Student	97(89.80%)	54(93.10%)	
Leaving school	9 (8.30%)	0(0.00%)	0.520**
Not enrolled in school	2 (1.80%)	0 (0.00%)	
Economic status			
Poor	3(2.75%)	0 (0.00%)	
Bad	4(3.70%)	3(5.10%)	
Average	83(76.80%)	38(7.30%)	0.631**
Good	16(14.80%)	12(22.20%)	
Excellent	2(1.80 %)	1(1.80)	
Concomitant diseases			
None	99 (91.70%)	49(90.70%)	
Kidney disease	3 (2.70%)	1(1.80%)	
Celiac	2 (1.80%)	1 (1.80)	0.917**
Psoriasis	2 (1.80%)	2 (3.70%)	
Thalassemia	1(0.90%)	1 (1.80%)	
	1(0.90%)	0 (0.00%)	

* Mann-Whitney U test, ** Chi-square test

Table 3. Main results of the study in the control and intervention groups

Variable		Mean±SD		Intragroups analysis
		Intervention	Control	
Physical activity	Before intervention	15.17±3.05	16.10±3.08	t=-1.86
	After intervention	16.40±2.20	15.40±2.30	p=0.64*
	Intergroups analysis	t=-5.18 p<0.0001**	t=1.86 p= 0.67**	t=2.46 p=0.010*
General Mood and Feelings	Before intervention	18.35±3.00	18.87±3.10	p=0.240****
	After intervention	19.70±2.70	18.80±2.80	p=0.41****
	Intergroups analysis	Z=-6.17 p<0.001***	Z=-3.75 p=0.64***	
Variable		**Intervention**	**Control**	**Intragroup analysis**
Family and free time	Before intervention	26.20±4.20	26.10±4.10	t=0.159
	After intervention	24.80±3.70	22.60±3.20	p=0.31*
	Intergroups analysis	t=1.70 p<0.001**	t=6.69 p<0.001**	t=1.96 p=0.01*
Friend & Social Support	Before intervention	13.40±3.50	13.50±3.22	t=-1.97
	After intervention	24.70±3.70	13.40±2.70	p=0.84*
	Intergroups analysis	t=-5.18 p<0.001**	t=0.26 p=0.79**	t=2.59 p=0.01*
School Functioning	Before intervention	13.82±2.45	14.10±2.60	t=-0.197
	After intervention	13.60±2.10	12.70±2.20	p=0.50*
	Intergroups analysis	t=1.45 p=0.149**	t=4.60 p<0.001**	t=2.319 p=0.02*
Kidscreen total score	Before intervention	87.89±9.50	88.70±10.80	t=-0.496
	After intervention	89.70±8.80	82.90±8.00	p=0.62*
	Intergroups analysis	t=-6.68 p<0.001**	t=5.0 p<0.001**	t=4.65 p<0.001*

*Independent sample t test, **paired t test, ***Wilcoxon test, ****Mann-Whitney U test

Discussion

The purpose of this study was to assess the effect of an empowerment program on HRQL of type 1 diabetic adolescents. In order to achieve this purpose, specific goals were planned and research findings were determined in the direction of the mentioned goals. The results of the present study showed that the empowerment program significantly increased the physical activities and health score of the adolescents in the intervention group; while the child's physical activities and health score significantly decreased in the control group. Therefore, it can be concluded that the empowerment program has a significant positive effect on the health and physical activity of adolescents with type 1 diabetes. Moreover, the empowerment program was able to significantly increase the general mood and feelings score of the adolescents in the intervention group. While in the control group, the child's general mood and feelings score did not significantly change. Therefore, the empowerment program has a significant positive effect on the general mood and feelings of adolescents with type 1diabetes.

According to the results of the present study, the empowerment program didn't significantly increase the family and free time score of the adolescents in the intervention group. Therefore, it can be concluded that the empowerment program hasn't a significant positive effect on the family and free time of adolescents with type 1 diabetes. Also, the empowerment program was able to significantly increase the friend & social support score of the adolescents in the intervention group. While in the control group, the child's friend & social support score significantly decreased. Therefore, the empowerment program has a significant positive effect on the friend & social support domain of HRQL of adolescents with type 1 diabetes. Moreover, after the intervention, school functioning score decreased in the intervention group, but this decrease was not significant. In the control group, the child's school functioning score significantly decreased. Therefore, it can be concluded that the empowerment program hasn't a significant positive effect on the school functioning of adolescents with type 1 diabetes. In addition, the empowerment program was able to significantly increase the HRQL score of the adolescents in the intervention group. While in the control group, the child's HRQL score significantly decreased. Therefore, it can be concluded that the empowerment program has a significant positive effect on the HRQL score of adolescents with type 1 diabetes.

Heidari et al. (2007) performed a semi-experimental applied research to estimate the effect of empowerment model on QOL of diabetic adolescents. They reported a significant difference before and after the intervention in the case group in terms of mean QOL and concluded that implementation of the empowerment–model intervention has been highly effective on the diabetic adolescent's quality of life (17). Sargazi Shad et al. (2016) in their research with aim to examine the effect of the family-centered empowerment model on QOL and self-efficacy in adolescents with type 1 diabetes reported that the implementation of empowerment significantly increased the mean scores of the self-efficacy and QOL at 1.5 months and 3 months after the intervention in the intervention group. They concluded that diabetes education with the patient empowerment approach which performed at the family level can improve patients' self-efficacy and increase QOL in adolescences with diabetes. This method can be implemented by nurses to assist the family and patient in medical care (18). Forlani et al. (2006) also conducted a study to examine the effect of an empowerment-based educational program on the psychological well-being and HRQL in Type 1 diabetes. Their results showed that the intervention group had a better metabolic control and a general improvement in comprehensive indices and most scales of PGWB and SF-36. They concluded that an educational empowerment-based intervention significantly improves the psychosocial aspects of diabetes and QOL of patients in active and effective self-care. Repeated educational interventions are the way towards a normal life with Type 1 DM (19).

As can be seen, the results of the above studies support the results obtained from the present study. In the present study, the empowerment program was able to improve the overall score of QOL and many of its dimensions. The following mechanisms can be proposed for the present result. In the present study, first, a coherent empowerment package was provided that covered the most basic needs of self-care to medication care. Thus, the researcher first equipped himself in terms of self-care knowledge in diabetes. The above care package was provided to experts in pediatric diabetes in order to best match the self-care needs of adolescents with type 1 diabetes. Prior to the intervention, the current status of each participant was determined using the Michigan Form to get the strengths and weaknesses of each. Each of these items was used in training sessions. So if adolescence was poor in one dimension of self-care based on the Michigan tool, we had this section for more emphasis. Conversely, if a child

was more empowered in some aspects of self-care, we would ask him or her as a role model to share his or her experiences with others. Also, during the implementation of the care package, we did not enter the next stage until the adolescent had reached the level of previous basic skills. The same gates that were placed to pass to the next stage, ensured that the teenager has achieved the desired competency.

Another reason that made the present intervention successful was the practice of practical exercises, that is, our criterion for passing to the next stage was to achieve practical adequacy and accurate implementation of self-care activities. For example, in the presence of the researcher, the child should be able to calculate the portion of insulin needed for an optional meal, such as a handful of bread, two cutlets, and a quarter cup of buttermilk, draw in a syringe, and inject at the appropriate location. Also, placing the child in a public environment where they all have the same problem and have tried different solutions and can pass on their knowledge to others can have a positive effect. Moreover, being in the group of learning and teaching can instill in the child that he is not alone and other people like him are also involved in this problem. This can reduce the psychological burden of the problem. The public nature of the empowerment package was predicted. However, unexpected results were also obtained in this study. The empowerment program wasn't able to significantly increase the family and free time score of the adolescents in the intervention group. Also in the control group, the child's Family and free time score decreased significantly. Also the empowerment program didn't significantly increase the school functioning score of the adolescents in the intervention group. School functioning score decreased in the intervention group, but this decrease was not significant. In the control group, the child's school functioning score decreased significantly. We did not find a specific logical reason for these phenomena, but there is a common ground between the two. The data of the first stage were collected before or at the beginning of the academic year and the data of the intervention group were collected in the middle of the academic year. It is likely that as school lessons and home works become more difficult, adolescents' school performance scores will also decrease. On the other hand, this employment in schoolwork has been able to affect the child's engagement and communication with the family.

Implications for practice
As evidenced by the results of the present study, the empowerment program was able to increase the QOL score of adolescents with type 1 diabetes. Given the importance of self-care in controlling type 1 diabetes and its complications, empowerment in diabetes self-care can be suggested as a practical way to improve the QOL associated with adolescent health with type 1 diabetes.

Acknowledgments

Conflicts of interest
The authors declared no conflict of interest.

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