

## Effect of family-centered empowerment model on treatment regimen of the school-aged children with diabetes: A randomized controlled trial

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### Abstract

**Introduction:** Diabetes is one of the chronic diseases. It is not curable but it can be controlled. The study aimed to determine the effect of family centered empowerment model on the treatment regime of school age children.

**Materials & Methods:** A clinical trial study was carried out on the school age diabetes children and their families. Considering ethical matter a total of 50 diabetes patients along with the parents who referred to the Golestan Hospital Diabetes Clinic have been contributed to the present study. They were divided randomly into two groups. Data were collected applying questionnaires, included demographics, physical activity, knowledge, adherence to dietary and medication before the intervention in the both groups and immediately after the intervention and 2 months after the intervention. The case group was completed and the data evaluated with SPSS software applying descriptive and analytical statistical tests .

**Results:** The study was completed and the extracted results for the case group, before and after intervention were obtained compiling; knowledge, (7.5,16.4) with the (p=0.0001), medication adherence (31.48, 41.2) with the (p=0.0001), the dietary regimen (31,45) with the (p=0.0001), sporting activities (13, 22) with the (p=0.0001) and parents knowledge (8.32,14.32) with the (p=0.0001).The statistical calculation indicated a significant difference in the control group however, there was no difference in control group (p=0.2).

**Conclusion:** Teaching children with diabetes and their families regarding compliance with the treatment regimen through family-centered empowerment model can increase adherence of treatment regimens and better control diabetes through it and helped make possible delayed complications of diabetes.

**Keywords:** Family centered empowerment model, Diabetes school age children, Treatment regime.

### Introduction

Diabetes is one of the most common metabolic diseases in the world and, including Iran (1, 2). Chronic and progressive nature of the disease and its management are challenging for children, adolescents and their parents (4, 3). Although the disease is not treatable, it can be controlled. The avoidance of premature death and coma were the premium application for diabetes control by 1921, however, for the time being it

means keeping normal not only the blood sugar, but also other indicators such as blood pressure and blood lipids. Thus, diabetes control means the prevention and delaying of its complications. Diabetes Poor control can lead to high levels of blood sugar, which in the long term have a strong relationship with chronic complications such as cardiovascular complications, retinopathy, nephropathy, neuropathy, and several psychological effects, which are

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associated with high costs of health care and reduced quality of life (4).

To control the disease, which can be fully managed by parents and children at home, a lot of personage action is necessary (5); and effective care, treatment and control of diabetes depend on the participation of the patient and family in self-care programs (6).

The results of many studies have shown that, for diabetes proper control, adherence to a therapeutic regimen is required, which includes medication, diet, exercise, learning in the areas of disease, nutrition, exercise and medication regimen are the cornerstone of diabetes (2). The annual incidence of diabetes in Iran is estimated at 3.7 per hundred thousand this figure varies around the world in the range of 1-35 cases per hundred thousand of the population under 14 years (7). Statistics of diabetic children in Iran over the past 20 years have doubled. It should be noted that, there are no exact statistics on children with diabetes in Iran (8).

Successful management of diabetic children is a dynamic process that requires the use of medications and non-pharmacological measures. Effective control of diabetes requires a supportive relationship between children, their families, and the components of the health system (doctor, nurse, dietitian and social worker). Therefore, teaching patient and family is an essential component of the diabetes management and control.

Family-centered care programs allow patients and their families to apply predetermined treatment decisions for optimal control of the disease; and since it is the center for diabetes control and care in the home, the management and administration of therapeutic regimens are borne by the parents (2). Empowering children and families can help control the disease better than before. Many

experts believe that empowerment is a dynamic, interactive and social process and leads to improve quality of life for people with chronic diseases, accountability, better interaction with health authorities, better response to treatment, prevention of complications, reduced health care costs and a positive vision of the disease.

In recent years, the concept of the patient and family empowerment has a special place in medical and nursing research, and has been mentioned as the need for the nursing profession (9).

In a study was carried out by Heydari with aim the determine of impact of the empowerment model on Quality of Life in Adolescents with Type I Diabetes” in Tehran in 2005, results showed that the mean of quality of life between the patients and control groups had no significant difference before the intervention however; after the intervention, the difference was significant; and the implementation of empowerment model had improved the quality of life of adolescents (1).

Given the above, the researcher intended to investigate the control and management of diabetes in children, because the nature of the disease and its complications reduce the quality of life in patients and their families and impose an economic burden on the family and society. The present study purposed to assess the effect of family-centered empowerment model on the level of adherence to the therapeutic regimen in children of school age with diabetes.

### **Materials and Methods**

A clinical trial study was carried out. The study population consists of 50 children and their parents who had recorded at the diabetes clinic of Golestan Hospital. Obtaining consent from the contributors and conditions of the study were explained to them, sampling was performed

using the simple random method over during a month to reach sufficient sample size.

The inclusion criteria were: age of 7-12 years; having at least two months elapsed since their medical diagnosis; having no experiences of acute complications during the study and had no other specific disease. Introducing herself, explaining the objectives of the research and getting the satisfaction of individuals, the researcher asked them to complete research tools.

Analyzing the data obtained from the pre-intervention, limitations, needs, strengths and weaknesses of patients and their families were identified in different areas. Then, the contents of the designed empowerment model were implemented based on four steps (perceived threat, problem solving, educational participation, and evaluation) for samples of the study in the case group.

The first step is the perceived threat, which consists of two concepts of perceived severity and perceived susceptibility. "Perceived severity" means an individual understanding of the disease severity with knowledge of the risks or complications of a disease, and feels that there is the risk of disease. "Perceived susceptibility" means an individual feeling of disease risk for him/her, with knowledge of the situation and a correct definition of health.

In this study, an increase in the perceived severity is used to increase the perceived threat of the patients and their families. Increasing the perceived severity, the nature of the disease, complications and risks, and the management of the disease was discussed to the contributors.

The perceived susceptibility was the second concept patients who were susceptible to complications, and empower them about a question, "how much am I at risk of disease", so that they could recall threat that may create the

problem associated with the disease for children in the future; and their level of sensitivity to the problems can be identified. Their perceived severity was increased by raising awareness and learning the families and patients; and their perceived susceptibility was increased by providing the necessary information.

Training sessions (as a group discussion during two 2-hour sessions), instructional booklet and CD were used to raise awareness. Obviously, promoting the level of knowledge and understanding of the disease condition and treatment process will increase the self-esteem.

The second step is to promote self-efficacy, during which the researcher wants to understand the problem by the samples of the study, to offer and implement solutions, As well as to promote the level of self-efficacy through group discussion, which overall was held in two sessions with the group problem-solving method. At this stage, the children expressed their problems about glucose testing, insulin storage conditions, insulin extraction and injection method, diet and exercise.

Necessary comments were given by the researcher on the correct extraction of insulin and calculation of the units, the correct injection of insulin and its correct locations, the diet of useful food and its amount in terms of the unit (in a meal and a snack), the sports activity, useful exercises, including walking, swimming and cycling and how doing it. The children practically observed the measures, and then were consequently asked to repeat the procedure until the proficiency level was achieved (tutorial video was displayed on the sports activities). This step also helps to improve self-efficacy and self-esteem.

Third step: increasing self-esteem through teaching participation: teaching participation was carried out continuously during the first and

second steps. At this stage, the families and the patients were asked to read the given booklets at home, and write about their difficulties in the case of the learned material, and deliver them in a paper in the next session. The notes of patients and parents were reviewed at the next meeting; and the correct answers were given to them. In fact, the teaching sessions to the patients and their families was done through written materials; and increased knowledge of child and family and the use of the learned material improved self-esteem.

The fourth step, process evaluation during the work and final evaluation: the process evaluation was made orally during empowerment sessions (first, second, and third steps) by asking questions in the first step, showing a subject (italic please extracting insulin with a syringe, and insulin injection) in the second step, and delivering notes about the problems in the step of educational participation.

Following the last session of empowerment program for both groups and to assess the stability, the empowerment program was completed for the case group through questionnaires, the results were collected two months after the last session of the final evaluation at the end, training materials as booklets and CDs were given to the control group.

During the two-month follow-up, researchers were in contact with the patients of the training group; and their problems were solved in the process of implementing the program such that they were very satisfied with the contacts, and felt secure.

Ethical considerations of the study were included: the research permission was obtained from the University Ethics Committee; the

objective of the study was explained to patients and their families; written participate consent in the study was obtained from the child and primary caregiver. Patients and their families were assured that all the information will remain confidential; right to withdraw from the study were explained to them; they were explained that educational programs for patients and their families will not entail any financial loss; and educational booklets after the study were given to the control group.

#### **Ethical considerations**

This study was conducted after obtaining the confirmation of the Ahvaz Jundishapur Ethics Committee and the informed consent from all subjects participating in the study.

#### **Results**

In terms of age, in the training and control groups, children participating in the study had a mean age of  $9.64 \pm 2$ ; and in terms of gender, the percentage of females in both groups were higher than males.

In terms of the first involvement age in both groups, the highest and lowest frequencies were related to 4-8 years and of 0-4 years, respectively (Table 1). According to the extracted results from the table in the control and case groups, a statistically significant difference was observed between the average knowledge, (7.5, 16.4) ( $p = 0.0001$ ), diet adherence (31, 45) ( $P = 0.0001$ ), sports activities (13, 22) ( $P = 0.0001$ ), medication regimen (31.48, 41.2) ( $P = 0.0001$ ), self-efficacy (13, 18) ( $p = 0.0001$ ) before and after the intervention in the case group however, this difference was not significant in the control group (Table 2).

**Table 1: Comparison of frequency of onset age and children sex in the two groups**

Variable	Control N(%)	Case N(%)	p value
Male	12(48)	11(44)	0.5
Female	13(52)	14(56)	
Onset age(years)			0.99
(0-4)	4(16)	3(12)	
(4-8)	13(52)	14(56)	
8-12	8(32)	8(32)	

**Table2: Comparison of mean knowledge, adherence to diet, exercise, medication adherence and efficacy in two groups of children**

Variable	Intervention		p value	Control		p value
	Before the intervention	After the intervention		Before the intervention	After the intervention	
	Mean ± SD			Mean ± SD		
Knowledge	7.5±2.9	16.4 ± 1.9	0.0001	8.5± 2.8	8.88 ±2.9	0.1
Adherence to diet	31 ±5.9	45 ± 2	0.0001	30.4 ± 5.4	31 ± 5.5	0.11
Exercise	13(52%)	22(88%)	0.0001	8(32%)	8(32%)	0.2
Medication adherence	31.48 ± 4.9	41.2 ± 1.9	0.0001	30 ± 3.9	30.7 ± 3.4	0.1
Efficacy	13 ± 2.3	18 ± 1.7	0.0001	12.1 ± 2.9	12.5 ± 2.2	0.15

**Discussion**

Diabetes is one of the chronic diseases that accompany the patient to the end of life. Therefore, having power over the diabetes is necessary so that the person can have a normal life without any complications. Proper control of diabetes may need to continuously adhere to the therapeutic regimen, including medication, diet, exercise, and education, which are the cornerstone of diabetes (2). Education is the cornerstone of diabetes management, and helps families to be responsible for controlling the disease. In this study, 50 children aged 7-12 with diabetes (with an average age of 9.64 years) and

their mothers were studied. According to studies, the age of diabetes incidence in our country is 7-15 years (3). Therefore, given that the study is conducted on children aged 7-12, the average age is acceptable for the present study.

The results of this study showed that the implementation of family-centered empowerment model in the experimental group improved the participations. According to a systematic study of Koch et al educating children with diabetes causes an increase in knowledge and positive impact on the disease of

diabetes and metabolic control of the disease (10).

The study of Swift has shown that education of children and adolescents yield better control of blood sugar and increase their self-esteem, and that education was the key to diabetes care (12, 11). Haidari et al showed that the use of the empowerment model increased the knowledge of adolescents with diabetes and therefore increased their quality of life (1).

In the present study, diet adherence has increased in the contributors in the case group, after the implementation of family-centered the empowerment model. The researchers believe that the implementation of educational program for diabetic patients can be effective on their adherence to the diet (13). By using the clinical trial method, some other researchers have examined the role of educational intervention on rates of adherence to diet in diabetic patients (14). In addition, dietary modification is an important factor in the treatment of all types of diabetes (15), so that 30% of people with diabetes can control their disease by modifying the diet along with exercise (16).

The results of this study showed that after the implementation of family-centered empowerment model, the ratio of doing a sports activity increased in the study samples in the case group. Performing sports activity in this study means exercising three or more times a week, each time for 30 to 90 minutes at moderate intensity. Study of Robertson et al showed that exercise for 60 minutes was the best sports activity for metabolic control in diabetic children, which is consistent with the present study (17). In addition, a study by Christian et al showed that moderate-intensity exercise for 60 minutes as much as 75% reduced the need for insulin, which is consistent with the present study (18).

The results of this study showed that following implementing the model, adherence to medication regimen has increased in the case group participations. According to Allen's study, the use of self-care education in children increase adherence to medication regimen (19), which is granted by the present study. Study of Elizabeth showed that medication adherence in children with asthma was not related to the children's knowledge, which is not approved by the present study (20). Compliance with medication regimen is a case that can be improved with training (2) and was demonstrated in the present study.

In this study, self-efficacy of diabetic children in the study samples in the case group has increased after the implementation of the empowerment model. Study of Teymouri et al showed that the use of the empowerment model encouraged self-efficacy and thus improved the quality of life for children with asthma (10). Self-efficacy is one of the factors that can improve self-care behaviors (21, 22). In the old study, people with diabetes were inactive in care and did not participate in the decision making. The new approach is that diabetes and the self-management belong to the person (23). Sense of self-efficacy enables people to perform extraordinary tasks using the skills to deal with obstacles. Thus, self-efficacy is an important factor in the successful performance and basic skills needed to complete it (24). Based on the results of this research and other studies, self-efficacy is an important principle for the use of skills and self-care, which by using the empowerment model can help to strengthen the self-efficacy in person, and increase the self confidence.

This study was completed with the participation of all selected diabetic patients; and ultimately, patients and their families were satisfied with the final outcome and follow-up,



and asked about keeping going on the study period. Due to lack of physical space, the researcher did not conduct sports activities. Due to the lack of facilities the practical measurement of food units was not carried out by the researcher. This study was conducted on patients of 7-12 years old therefore; the results of this study cannot be generalized to the entire population of patients. To the extent possible within the framework of the research, communication limitation was controlled for the case and control groups (they were not visited by a physician on the same day), but other communications, through the media and out of place, were not possible to control.

### **Conclusion**

According to the results of this study, in diabetic children 7-12 years in the experimental group for which the empowerment model was implemented, the compliance with the therapeutic regimen have had a significant increase compared to the control group for which this model wasn't implemented. Finally, it must be said that the implementation of the

empowerment model increased the children's adherence to the therapeutic regimen, and therefore compliance with the therapeutic regimen, and ultimately improved the control of the child's disease and the prevention of early and late complications of the disease. The empowerment model has the capability of application the least facilities and widely ask over to be applied by parents and children. It is suggested that such methods be applied to other age groups and other chronic diseases in clinics and related centers.

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