

The Effect of Family-Centered Intervention on Key Indicators of Diabetes Management and Control in Patients with Type-2 Diabetes

Abstract

Background: This study is to determine the effect of the family-centered intervention (FCIS) on the key indicators of diabetes management and Control control in patients with type-2 diabetes. **Method:** The present study is a quiz- experimental study with a randomized control group. Participants were 64 patients with type-2 diabetes visiting Ali Asghar Hospital of Isfahan in 2018. The eligible patients were assigned to either the intervention group or the control group (i.e., patient-center care) through block randomization. FCIS were implemented in 4 two-hour sessions as home visits while the patients and their caregivers were present. Data were collected twice-*i.e.* before the intervention and 12 weeks after it- and were analyzed, by running a t-test ($\alpha = 0.05$), using SPSS-21. **Results:** The mean \pm SD age of participants was 50.4 ± 8.5 . There was no significant difference between the two groups in the mean weight, serum levels of FBS and A1C, physical activity, energy intake, and BMI before intervention. But, a significant improvement in the mean values of these variables in the intervention group after the intervention, compared with the control group was indicated ($P < 0.05$). **Conclusions:** This study suggests that FCIS are more effective than patient-center care in the management and control of type-2 diabetes. Therefore, it is recommended that the family be considered in educational interventions.

Keywords: Diabetes mellitus, diet, exercise, family-centered nursing, family Nursing, home calls, type 2

Introduction

Type-2 Diabetes Mellitus is one of the most common diseases in the world with an increasing incidence.^[1] Type 2 diabetes accounts for about 90 percent of the world's cases of diabetes and is projected to affect about 8.5 percent of the world's population by 2040.^[2] Diabetes causes serious damage to patients, including cardiovascular and cerebrovascular damage, sexual dysfunction, skin changes, neuropathy, and nephropathy.^[3-5] Blood glucose control can reduce chronic and progressive complications and the mortality rate in patients with T2DM.^[6] If diabetes is not properly controlled, vascular problems develop in patients less than three years after diagnosis. However, if there are effective arrangements in place to control the disease, these adverse effects can be delayed for up to 20 years or even longer^[7] The approximate status of diabetes control by diabetic patients can be measured by Glycated Hemoglobin (HbA1C).^[8]

Various interventions have been proposed to control diabetes in primary care, none of which have produced satisfactory results. Therefore, there is a dire need for adopting effective strategies to manage diabetes.^[6] The three general approaches to T2DM management include nutrition management, physical activity, and medication adherence.^[2] Patients with diabetes require sufficient knowledge and skills in diabetes management to be able to live a healthy and comfortable life.^[9] Social and family support provided for patients helps them better manage and control T2DM.^[1] Given that patients with diabetes are mainly cared for by their family members at home, the engagement family members in the treatment process may contribute to diabetes management.^[6]

Family-centered care is defined as the provision of health care for patients by involving their families and the recognition of the role of the family in the treatment of individuals with chronic diseases, especially diabetes.^[10] A key strategy for mobilizing family support for patients with chronic

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illness is to guide family members to set goals for a patient's self-care behaviors. With the support of a diabetic patient, family members can often play an important role in the mental well-being of the diabetic patient, disease management, adherence to treatment recommendations, and maintaining changes in the diet and physical activity of the patients.^[11]

Keogh *et al.*^[12] reported that psychological family centered intervention (FCIS) could significantly reduce the HbA1c level in patients with type-2 diabetes. In another study by Withidpanyawon, it was found that FCIS by pharmacists reduces the HbA1c level and the level of family support, self-efficacy, and self-management.^[13] However, in the study by Hu *et al.*,^[14] FCIS improved the diet, body mass index (BMI), blood sugar, and HbA1c of diabetic patients, but the level of their physical activity did not improve. Likewise, in a study by Garcia-Huidobro *et al.*,^[6] FCIS did not help decrease HbA1C over a period of 12 months. Given the above studies, in a number of studies, an attempt has been made to study the effect of the FCIS on the control and management of type 2 diabetes, but they have produced conflicting results.

Considering the contradictory results of various studies into the effect of FCIS on key indicators of diabetes management, and diabetes control, this study aims to determine the effects of FCIS on the key indicators of diabetes management and control in patients with type 2 diabetes.

Methods

This was a field trial study with a control group, seeking to compare two groups of diabetic patients receiving FCIS (i.e., intervention group) and patient-centered care (i.e., control group) in terms of the type-2 diabetes management indicators before and after the intervention. The population of the study consisted of patients with type-2 diabetes who were referred to the outpatient diabetes clinic of Ali Asghar Hospital of Isfahan, Iran in 2018.

Based on parameters including; $\alpha = 0.05$, $\beta = 0.2$, $Z_{1-\alpha/2} = 1.96$, $Z_{1-\beta} = 0.85$, $d = 0.8$, $s_1 = 2$, $s_2 = 1.6$ (for HbA1c)^[6] the sample size was estimated to be $n = 64$. Eligible patients were selected through the convenience sampling method and were subsequently assigned to either the intervention group (FCIS) or the control group (patient-centered care) through block randomized allocation.

The inclusion criteria were being diagnosed with type-2 diabetes, HbA1c level $>$ or equal to 7% over the previous six months, blood glucose level of 140 mg/dL or higher, and aged 20 years or older. Exclusion criteria included cognitive impairment, pregnancy, and participation in diabetes self-management interventions prior to the study.

Data collection instruments

In this study, 24-h dietary recall (assessment of energy intake), physical activity, weight, BMI, and serum levels of HbA1c and FBS were determined as type-2 diabetes management indicators. The Physical Activity Scale consists of nine grades based on the intensity of physical activity (Metabolic Equivalents: MET) from inactivity (MET = 0.9) to intense activity (MET >6) (16). The obtained score multiplied by the duration of the activity shows the intensity of the activity performed per unit of time (MET). The validity and reliability of this questionnaire had already been confirmed.^[15,16]

The reliability of the scale was re-established through the inter-rater reliability method, and the index of Cronbach's alpha was 0.87 for the present study.

After fasting for at least 8 h, 5cc of blood was taken from the patient's arm vein in the laboratory by an expert. Use was made of the glucose oxidase method to measure blood glucose, and the capillary electrophoresis method was adopted to measure HbA1c. All tests were performed by an expert in a laboratory. The calibration of the devices was carried out according to the guidelines provided by the respective manufacturer.

If their blood glucose level was more than 140 mg/dL and their HbA1c level was more than 7%, they were randomly assigned to either the intervention group FCIS or the control group (Patient-centered care). In addition, they completed a 24-h dietary recall and a physical activity scale. To complete the 24-h dietary recall, the participants in both groups were asked to list all the foods and beverages they had taken over the previous 24 h. The first recall was completed in the first session and, the second recall in the second session before the intervention. Their weight was measured, using a digital scale with an accuracy of 100 gr, and their height was measured by a tape measure with an accuracy of 0.5 cm installed on the wall. Following that, the BMI of the patients was also measured.

Twelve weeks after the end of the intervention (week 16), 24-h dietary recall (energy intake assessment), physical activity, weight, and HbA1c and FBS serum levels were measured as a posttest.

Post test?

The information about diabetes and diet (3 sessions), and physical activity (1 session) was provided for the participants at home by one of the authors, who was a community health nurse, a nutritionist, and an exercise therapist, respectively, in four 2-h sessions (once a week) in the presence of at least two main caregivers. These training were provided through face-to-face education, question and answer sessions, group discussion, and using video. Subsequently, in the final session, educational content in

the form of pamphlets and booklets was handed out to the patients and their families. For the purpose of improving the participants' diet, the amount of energy needed by each person was calculated and the diet was adjusted according to the dietary guidelines of diabetic patients.

Aerobic exercises were performed by an exercise therapist at home in the presence of the participants' main caregivers, and then participants were instructed to continue the exercises 3 times a week for 20 min. The role of the family was to help the patient in the implementation of interventions, prepare diet, remind the patient to take medicines and have physical activity, and control and monitor the implementation of interventions by patients.

Participants in the control group received interventions similar to the FCIS including exercise, physical activity, and diet for four weeks, one two-hour session per week in Ali Asghar Hospital of Isfahan, Iran without caregivers in the family. Following the interventions which were provided by the researcher (a community health nurse) and the specialized team (a community health nurse, a nutritionist, and an exercise therapist) the participants were asked to continue the interventions.

In each intervention session, questions were asked of the patients and their families in both the intervention and control groups about the implementation of research interventions. The community health nurse followed up with the participants in two groups for 12 weeks through weekly telephone calls for Participants' adherence to nutritional and exercise interventions.

Ethical considerations

This study was approved by the Ethics Committee of Yasuj University of Medical Sciences (920602701). The principles of voluntary participation in the study and confidentiality of the collected information were ensured. In addition, no costs were imposed on the patients participating in the study. In the final session, educational content in the form of pamphlets and booklets was given to the patients and their families.

Statistical analysis

Food and drinks were coded according to the protocol. Nutritionist IV software was used to measure the amount of energy and nutrients. Using this, the average amount of each food item in grams, and the amount of energy and nutrients consumed daily, was entered into the SPSS 21 program.

The collected data were analyzed through descriptive and inferential statistics by using SPSS-21 ($\alpha = 0.05$). Mean and standard deviation were reported for quantitative variables and absolute and relative frequencies were reported for nominal variables. Data distribution was investigated, using the Kolmogorov-Smirnov test. Given the normal distribution of the quantitative dependent (outcome)

variables, the independent sample t-test and the paired sample t-test were run for inter-group and intra-group comparisons, respectively. Moreover, the Chi-square test was used to compare the nominal variables.

Results

64 patients with type 2 diabetes participated in the study. However, 55 patients, 28 in the intervention group and 27 in the control group, completed the study. In the intervention group, two participants dropped out, which was due to their unwillingness to continue the study, and in the control group, three participants failed to complete the study, which was due either to migration or hospitalization [Figure 1].

The mean \pm SD of participants was 50.4 ± 8.5 (with a minimum and maximum of 37 and 70 years, respectively). Most of the participants were male and employed and held a high school diploma [Table 1].

There was no statistically significant difference between the two groups in terms of mean weight, serum levels of FBS and A1C, physical activity, energy intake, and BMI before the interventions. However, the independent t-test results showed that there was a statistically significant decrease (i.e., improvement) in the mean body weight ($P = 0.001$), FBS ($P = 0.04$), glycosylated blood glucose ($P = 0.03$), energy intake ($P = 0.03$) and BMI ($P = 0.001$) and a statistically significant increase (i.e., improvement) in physical activity ($P = 0.04$) after FCIS in the intervention group, as compared with the control group [Table 2].

Table 1: Baseline characteristics of the participants

Group variables	Intervention	Control	P*
Gender n (%)**			
Female	14 (50)	12 (44.4)	0.4
Male	14 (50)	15 (55.6)	
Job n (%)			
Unemployed	3 (10.7)	5 (18.5)	0.6
Home-keeper	10 (35.7)	8 (29.6)	
Employed	15 (53.6)	14 (51.9)	
Education level n (%)			
Under Diploma	18 (64.3)	16 (59.3)	0.4
Diploma or higher	10 (35.7)	11 (40.7)	
Oral anti- hypoglycemia; n (%)			
Yes	9 (32.1)	11 (40.7)	0.3
No	19 (67.9)	16 (59.3)	
Insulin n (%)			
Yes	17 (60.7)	16 (59.3)	0.5
No	11 (39.3)	11 (40.7)	
Age; M \pm SD*** (year)	51.4 \pm 8.4	49.3 \pm 0.8.7	0.3

*Based on Independent Samples t-test for age variable, Chi-square test for other variables. **n (%): Number (percent).

***M \pm SD: Mean \pm Standard Deviation. *Based on Independent Samples t-test for age variable, Chi-square test for other variables.

n (%): Number (percent). *M \pm SD: Mean \pm Standard Deviation

The intragroup comparison results showed that there was a statistically significant decrease (i.e., improvement) in weight (mean difference = -2.39), FBS (mean difference = -51.78), HbA1c (mean difference = -2.11), energy intake (mean difference = -148.28), and BMI (mean difference = -.80) and a statistically significant increase (i.e., improvement) in physical activity (mean difference = 29.30) in the intervention group after FCIS compared to before. However, no statistically significant changes were observed in the mean difference of the above-mentioned indices in the control group [Table 3].

Discussion

In global discussion, no needs to mention results in other studies, you focus on points and differences and similarities and then compare.

This study investigated the effects of family-centered intervention (FCIS) on diabetes management indicators in patients with type-2 diabetes. The findings indicated improvement in energy intake or nutritional behaviors, weight, MBI, physical activity, blood sugar, and HbA1c, after FCIS.

Similar to the present study, In Sheikhi *et al.*'s^[17] study, the family-centered educational intervention improved self-care and subscales of nutrition, physical activity, and blood sugar control in patients with diabetes. In addition, consistent with the results of this study, Hu *et al.*^[14] reported the positive effects of FCIS on BMI, diet, blood sugar, and HbA1c of diabetic patients after one month. Although similar results were shown in the present and above studies,

both are pre-test and post-test designs without a control group which probably had some confounding variables.

Unlike the results of this study, Hu *et al.*^[14] observed no improvement in physical activity until one month after the intervention. However, in the present study, FCIS promoted the physical activity of the patients. The differences in the results could be attributed to short follow-up time, differences in research design, and different cultural contexts in which the studies were carried out. In Hemmati Maslakkpak *et al.*'s^[18] study, two indicators of diet adherence and physical activity enhanced after face-to-face and telephone-based family-oriented education, although face-to-face family-centered education increased diet adherence, physical activity, and self-care scores, as compared with telephone-based family-oriented education. As in the present study, they used face-to-face FCIS, and obtained similar results. In addition, the results of the present study are similar to the effect of FCIS on adherence to nutrition and restriction of fluid by patients with hemodialysis, compared with patient-centered education in the study by Asgari *et al.*,^[19] Although the nature of the disease is different in the two studies, nevertheless they produced similar results. This suggests that FCIS can be effective in improving disease management in other chronic diseases as well.

Similar to the results of the present study, in a study in Japan, Horikawa *et al.*^[20] showed that raising the awareness of patients and their families about the diabetic diet along with family support can improve patients' dietary intake. Therefore, based on the results of the study above, family-centered education can help increase family awareness and promote family involvement in the

Table 2: Comparison of mean difference of diabetes management indices between the study groups

Groups Variables/Time	M±SD		Mean Difference (Test - Control)	Std. Error Difference	P*
	Intervention	Control			
Weight					
Before	77.5±10.02	78.66±8.66	-1.16	2.53	0.66
After	75.26±9.39	77.77±8.24	-2.5	2.38	0.001
FBS					
Before	237.85±79.49	241.70±62.45	-3.84	19.32	0.84
After	186.07±68.46	220.22±48.96	-34.15	16.10	0.04
A1C					
Before	9.62±2.22	9.48±1.71	+0.13	0.53	0.80
After	7.511±2.20	8.559±1.27	-1.04	0.48	0.03
Physical Activity					
Before	40.28±24.84	46.87±28.01	-6.58	7.13	0.36
After	69.59±22.69	56.4530±23.61	+13.14	6.24	0.04
Energy Intake					
Before	2903.57±525.97	3051.85±578.04	-148.28	148.92	0.32
After	2382.14±507.02	2748.15±745.94	-366	171.42	0.03
BMI					
Before	27.54±3.45	27.31±3.12	+0.8	0.63	0.5
After	26.74±3.30	27.36±3.06	-0.41	0.05	0.001

*Based on Independent Samples *t*-test; M±SD: Mean±Standard Deviation

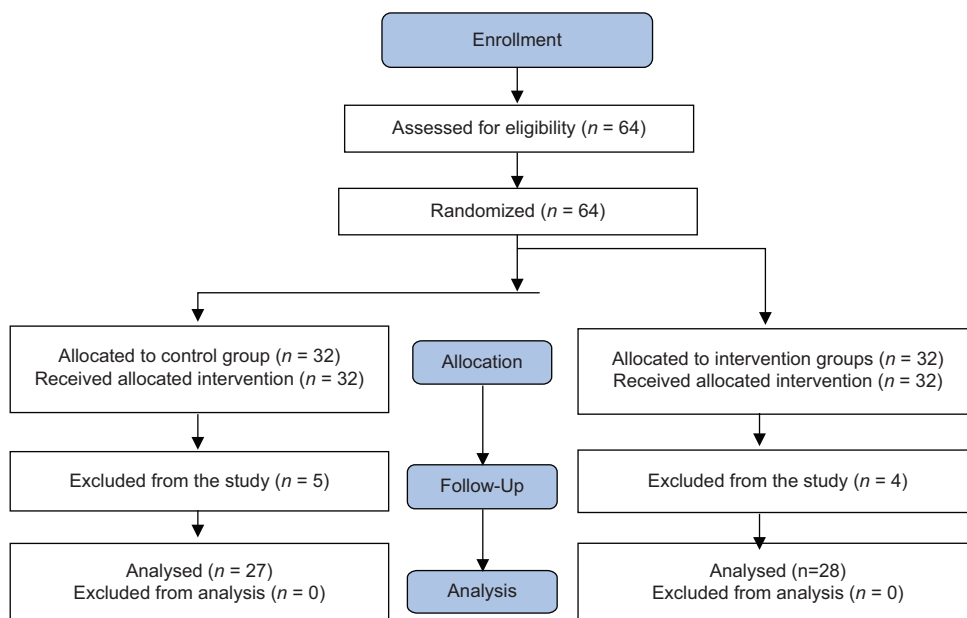


Figure 1: Flow diagram of patient's enrolment and study progress

Table 3: Comparison of mean difference of diabetes management indices within the study groups

Variables	Group	Mean difference±SD (After - Before)	P*
Weight	Intervention	-2.39±1.87	0.001
	Control	0.98±1.16	0.46
FBS	Intervention	-51.78±28.94	0.001
	Control	-21.48±28.1	0.91
HbA1C	Intervention	-2.11±0.99	0.001
	Control	-0.92±0.89	0.26
Physical Activity	Intervention	+ 29.30±19.63	0.001
	Control	+ 9.57±11.43	0.83
Energy Intake	Intervention	-148.28±148.92	0.001
	Control	-366±171.42	0.56
BMI	Intervention	0.80±0.63	0.001
	Control	0.41 ± -0.05	0.50

*Based on Paired sample *t*-test

preparation of healthier foods for diabetics, which, in turn, brings about improved diet, energy intake and body mass index (BMI) of these patients. As in the present study, three months after FCIS, there was a significant decrease in weight and BMI.

As, in the present study, three months after FCIS, weight, and BMI showed a significant decrease. Duncanet *et al.*^[21] also found that by targeting physical activity and nutrition, FCIS could result in weight loss.

In the present study, the FCIS reduced HbA1c. HbA1c level is the best indicator of metabolic control in patients with diabetes. Consistent with the results of this study, Withidpanyawong showed that the FCIS performed by pharmacists reduced HbA1c levels in diabetic patients.^[13] In addition, in the study carried out by Wichit *et al.*,^[22]

family-centered self-management programs significantly decreased HbA1c levels. In the studies above, the control group received routine care. However, in the present study, the control group received similar interventions without family involvement. Therefore, the improvement could be ascribed to family care.

Also, in the study by Parellangi, FCIS improved blood sugar levels.^[23] Although the intervention was able to improve blood sugar, it was a before-and-after study without a control group and with a small number of samples. Similar to the results of the present study, in the study by Cheraghi *et al.*,^[7] family-centered educational intervention resulted in significant improvement in the mean score of adolescent management behaviors and their supervisor in the family in terms of insulin therapy, blood glucose testing, diet, physical activity, HbA1c level, and blood glucose. Although the intervention was effective in improving blood sugar, it was a before-and-after study without a control group and with a small number of samples. However, the study above used a pre-and post-test research design without a control group and was carried out on patients aged 10 to 14 years with type 1 diabetes.

Moreover, Vesco *et al.*^[24] reported that sharing the responsibilities for the management and control of diabetes with adolescents and their parents helped control the disease. Also, in the study by Katz *et al.*,^[24] family-centered psychoeducational intervention improved HbA1c in adolescents Youth with type 1 diabetes more than Care Ambassador intervention^[25] Moreover, In Feldman's systematic review, the FCIS led to better diabetes control in most clinical trial studies.^[26] The difference between the above studies and the present study is in the type of diabetes and the results showed that FCIS can also control type 1 diabetes in adolescents.

Contrary to the results of the present study, in Kang's study, the FCIS could not improve lipid profile values, HbA1c, and self-care behaviors in the Patients with type 2 diabetes after six months.^[27] Also, in Hemmati Maslakpak *et al.*'s^[18] study, HbA1c and FBS did not improve. Despite the longer follow-up time in both studies above, no improvement was observed in the value of HbA1c. The conflicting results of the studies touched upon above and the results reported in the current study could be attributed to family culture, the age of the participants, and methodological issues such as differences in the design, research method, and the type of intervention used in the study.

Given that the findings of the present study confirm earlier findings reported in the majority of cases, it could be argued that FCIS has a positive effect on the management of type 2 diabetes. Since home visits are not provided by nurses and health care personnel in Iran, as in many other countries, these results also indicate the importance of home visits paid to diabetic patients by such personnel. So, it is recommended that in comprehensive health centers, authorities should hire nurses for home visits and apply FCIS in diabetes management.

A strength of the present study is using the patient-centered intervention in the control group, which is similar to the FCIS without the presence of the family. The improvement observed in the study can be attributed to family care and not to education alone.

Conclusions

The results of the study showed that FCIS were more effective than patient-center care in disease management in patients with type-2 diabetes, as FCIS managed to control weight, BMI, FBS, and HbA1c and improved energy intake and physical activity of participants in the experimental group.

It is possible to replicate the present study with a longer time intervals of 3, 6, and 9 or even 12 months between the intervention and the follow-up study to see whether the same results are obtained. In addition, given that home visits by nurses and health personnel are costly and may thus not be feasible all the time, future studies could compare the effects of such interventions on management indicators of diabetes when these services are performed at the patient's homes or in the medical centers in the presence of a family member.

Limitation study?

Given that there were some limitations in the study, the findings should be interpreted with caution. The first limitation was the short follow-up time. In addition, there were concerns about the researcher's safety during home visits.

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Conflicts of interest

There are no conflicts of interest.

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