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The Effects of Nutrition Education and Diet Therapy on Glycemic and Lipidemic Control in Iranian Patients with Type 2 Diabetes

Faezeh Askari[1], Samira Rabiei[1] and Reza Rastmanesh[2]*

[1]*Department of Clinical Nutrition & Dietetics, Shahid Beheshti University of Medical Sciences (SBMU), Tehran, Iran*
[2]*SBMU, National Nutrition and Food Technology Research Institute, Tehran, Iran*

Abstract

Objective: To evaluate the effects of nutrition education and adherence to a healthy diet on glycemic and lipidemic control in patients with T2DM.

Design: A randomized controlled trial.

Setting: Aliebneabitaleb hospital in Ghom.

Participants: There were 494 patients with T2DM, aged 14-87 years from both sexes who were selected by convenience sampling.

Intervention: The participants were divided into two 247 person groups by stratified randomization. Both groups received a diet adjusted based on ideal body weight and the intervention group was additionally educated about healthy food choices regarding to diabetes.

Main outcome measures: Information on medications, psychological factors, diet and physical activity was obtained from questionnaires. Blood samples were collected to measure FBS, 2 hPG, HbA1c, cholesterol and triglyceride. After 2 months, weight and biochemical parameters were measured again.

Analysis: Independent T-test, Mann-Whitney, Chi-square and Wilcoxon were used as appropriate. Logistic regression was used to determine the odds ratio of abnormal glycemic and lipidemic control according to the intervention.

Results: The mean weight, FBS, 2 hPG, cholesterol and triglyceride after intervention were lower than before that ($p<0.05$).

Conclusions and implications: Nutrition education plus a weigh reducer diet is more effective on glycemic and lipidemic control than a weight reducer diet, alone.

Keywords: Type 2 diabetes mellitus; Nutrition education; Glycemic control; Lipid profile

Introduction

Type 2 Diabetes Mellitus (T2DM) is the most common and costly endocrine disease [1] which is associated with increased morbidity and premature death, especially from cardiovascular diseases, myocardial infarction and stroke [2]. The prevalence of T2DM has increased dramatically over the past two decades. According to the most recent survey, the number of people who are currently affected by this disease is 230 million worldwide and it is estimated that it rises to 370 million people by the year 2025 [3]. The prevalence of this disease in Iran was reported to be 7.7% in people younger than 65 years [4]. Blindness, renal failure, and amputation are of the most important long term complications of T2DM [5].

Lifestyle modifications including alteration of diet and physical activity are the first lines of managements during diabetes [6]. Dietary modification is the basic principle for management of T2DM in the world [7], so that by shifting an unhealthy dietary pattern to a healthy one, desirable outcomes may be achieved [8]. There is not enough knowledge regarding the suitable food choices among diabetic patients; whereas education of healthy choices and consumptions is one of the most effective ways to control T2DM [9] and it has a pivotal role in encouraging and supporting these patients to the daily control of their condition [10-14]. So, educational efforts to improve self-management are central and integral components of any effective treatment plan [15]. On the other hand, evidence has shown that the costs for equipping hospitals and health service centers in developing countries are more than costs for educating diabetic patients in developed countries [16]. A recent review focusing on the cost-effectiveness of diabetes education also showed that diabetes education is likely to be cost-effective, especially for patients with the poorest glycemic control [17]. In Iran, there is not any cost effectiveness analysis for nutrition education. However, Aghili et al. [4] evaluated cost effectiveness of a structured Self Monitoring of Blood Glucose (SMBG) in Iranian people with type 2 diabetes. The average cost effectiveness ratio was 143.28 (USD) for 1% glycosylated hemoglobin (HbA1c) reduction and total complications and mortality cost saving was 154.8 USD. So, they introduced SMBG as a cost effective option for T2DM 4.

There are some studies that showed that nutrition education increase in knowledge, attitude and practice's score, but the effects of nutrition education on metabolic biomarkers was not assessed sufficiently [18,19]. On the other hand, so far as we know, there is not

***Corresponding author:** Reza Rastmanesh, Clinical Nutrition & Dietetics Department, Shahid Beheshti University of Medical Sciences, National Nutrition and Food Sciences Technology Research Institute, Shahrake Gharb, Farahzadi blvd, 1981619573, Tehran, Iran, Tel: 9821-22357484; Fax: 9821-22360660; E-mail: rezar@sbmu.ac.ir

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any study to evaluate the effects of nutrition education plus diet therapy on biochemical markers in Iran. We thought that one of the reasons for failure of many weight reducer diets may be poor awareness of importance of a healthy diet. We supposed that increase in nutrition knowledge may lead to increase motivation to adherence to a healthy diet. Therefore, we evaluated the effects of nutrition education of individuals plus a weight reducer diet on glycemic and lipidemic control in Iranian patients with T2DM.

Methods

Participants

Patients were recruited from Aliebneabitaleb Hospital in Ghom. By convenience sampling, 494 patients with T2DM, aged 14-87 years from both genders participated in this randomized controlled trial. T2DM was verified by patients' medical records. We assumed several categories of age in which each category was 5 years older than previous category. So, we assumed 15 age groups. The first referred participant of each age group assigned to an intervention group while the second referred participant of each age group was assigned to a control group and so on. All participants were outpatients and they had been referred to the hospital's nutrition unit to receive an appropriate diet. A trained dietitian visited them and described them about the method of the study in Persian language. Diabetic patients who were lactating or alcoholic or who were on insulin therapy or taking contraceptive drugs, glucocorticoids or weight reducer drugs were not allowed to enter the study. All participants gave written, informed consent to participate in the study. The study was approved by the Medical Center Institutional Review Board (Shahid Beheshti University of Medical Sciences).

General information assessment

The participants completed a general information form that included questions on age, marital status, pregnancy, lactation and taking oral contraceptive drugs (for women), any neuroendocrine or metabolic disorders, taking any hormonal drugs, neuroendocrine drugs, appetite effective drugs, supplements or weight loss medications, following any diet, smoking, drinking alcohols and education level.

Anthropometric measurements

Trained certified dietitians conducted all anthropometric measurements. Body weight was measured to the nearest 500 g using digital scales (Beurer, Germany) with participants in minimal clothing and without shoes. Height was measured in a standing position without shoes with the shoulders in a normal position using a non-stretch tape meter fixed to a wall. Height was recorded to the nearest 0.5 cm. The Body Mass Index (BMI) was calculated by dividing weight (kg) by height squared (m^2). Waist Circumference (WC) was measured at the end of normal exhalation. For some subjects whose minimal WC was not easily determined owing to obesity or wasting, we measured the circumference at the last vertebra, since the minimal WC is located in this area for the most people [20]. We measured the greatest circumference of the hip as the hip circumference. Waist to Hip Ratio (WHR) was calculated by dividing waist circumference by hip circumference.

Food intake assessment

To collect dietary data, a 168-item semi-quantitative FFQ validated for Iranian population was used [21]. The questionnaire included 168 food items with the standard serving size for each item. It was designed according to Willet method [22] and it was used in previous studies by Esmailzadeh and Azadbakht to determine dietary patterns [23]. Participations indicated their food intake amount and frequency on a daily, weekly, monthly and yearly basis during the past year. The dietary intake data were then converted to daily grams of food intake using household measures [24]. Then we calculated daily total energy intake for each person.

Assessment of Physical Activity (PA)

A validated, self-reported-based inventory was used for data collection and was expressed as Metabolic (MET) equivalents hour/day (METs-h/d) in which nine different MET levels and questions on level of physical activity at work were ranged on a scale from sleep/rest (0.9 METs) to high intensity physical activities (≥6 METs) [25]. The MET-time was calculated by multiplying time spent during each activity level by the MET value of each level.

Biochemical measurements

Peripheral venous citrate blood samples were taken after 12 hours fasting and centrifuged at 1,000 ×g for 10 min at 4°C. Plasma fasting glucose was measured by the glucose oxidase method using commercial kits (Pars Azmoon; Inter assay CV 2.2, Intra assay CV 2.2). Chromatography was used to measure HbA1c. Total cholesterol and triglyceride concentrations were measured by the auto analyzer using commercial kits (Pars Azmoon; Inter assay CV 2, 1.6 and Intra assay CV 0.5, 0.6, respectively).

Psychological assessments

The Depression Anxiety Stress Scale (DASS-42) was used to assess the negative emotional symptoms among participants. Afzali et al. [26]., have translated the DASS scale into Persian and reported that the DASS has reliable and valid scales for assessing client changes in stress [26]. Cronbach's alpha was 0.9 for the stress subscale of DASS-42, indicating internal consistency reliability of this instrument in measuring stress.

Power of Food Scale (PFS-21) was designed to measure appetite for palatable foods [27]. An English version of this questionnaire was translated into Persian based on consensus of experts and it was tested on 40 people. Again, the Persian version was translated into English by "back translation" method and was tested on 40 people. Validity of the questionnaire was confirmed based on the results of two tests, which had been done on two groups of 40 people, so that the correlation coefficient was 0.78-0.89. Cronbach's alpha was 0.78-0.93 which indicates the good reliability of this test.

Abnormal eating attitudes were identified through the Persian version of Eating Attitudes Test (EAT-26) which was validated by Babaei et al., [28]. The items were scored 0-3 (for items 1-25; never, rarely, and sometimes=0, often=1, usually=2, always=3 and for item 26; never=3, rarely=2, sometimes=1, and often, usually, always=0). Cronbach's alpha was 0.78 which indicates the good reliability of this test.

Dutch Eating Behavior Questionnaire (DEBQ) was completed to assess eating behavior. It consists of three subscales measuring emotional, external and restrained eating. It has been shown to have good internal consistency, validity and stability (Cronbach's alpha ≥ 0.9) [29]. The questionnaire was administered under the supervision of an academic and the researchers.

Psychometric properties was assessed thorough the Persian version of World Health Organization Quality of Life Questionnaire (WHOQOL-100) which was validated by Karimloo et al., on 1000 people [30]. This questionnaire consists of 25 different fields of quality of life. The more score of this questionnaire shows the better quality of

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life. The correlation coefficient is more than 0.7 which is acceptable. Cronbach's alpha was 0.9 which indicates the good reliability of this questionnaire.

Visual Analogue Scale (VAS) was assessed the maximum feeling of hungry using 100-mm visual analogue scales for ten time points including: before and after breakfast, morning snack, lunch, evening snack and dinner. Subjects were requested to make a vertical mark on each line that best matched how they were feeling at the time. Each score was determined by measuring the distance from the left side of the line to the mark [31].

Intervention

The participants were divided into two 247 person groups through stratified randomization. The two groups were matched on the basis of age. Intervention group were educated individually about the carbohydrate counting, sugar content in each food item, the importance of snacking, the effects of complex and simple carbohydrates on blood glucose, the differences between glycemic index and glycemic load, importance of vegetable and fruit consumption, disadvantages of high intake of cholesterol, saturated and trans fatty acid and the importance of the time for food consumption regarding the time for taking glucose reducer drugs by a trained certified dietitian within a 45 minute session. Duration of intervention was two months. Both groups received a weight reducer diet based on their adjusted ideal body weight, while the control group did not receive any nutrition education. Both groups were followed every two weeks via telephone contact to ensure good adherence to the recommendations and diet.

Statistical analysis

SPSS software version 11.5 was used for statistical analysis. We used the Kolmogorov-Smirnov test to determine if variables showed a normal distribution. Independent T-test and the Mann-Whitney test were used to compare the differences between the two groups (for variables with normal or abnormal distribution as appropriate). Chi-square test was used to compare the mean of categorical variables between the two groups. Wilcoxon tests were used to compare the changes before and after intervention. Logistic regression was used to determine the relation between intervention and patients' outcome. P-value < 0.05 was considered as significant.

Results

Age and weight had normal distribution and an Independent T-test was used for analysis, while the other variables had abnormal distribution and a Mann-Whitney test was used to compare data between two groups. The Chi-square test was used to compare qualitative variables between two groups. However all participants had BMI > 25 kg/m^2, the results showed that the two groups were different in terms of weight at baseline, significantly. Moreover, percentage of smokers was significantly higher within intervention group than control group. The other variables had similar distribution in both groups (Table 1).

To compare mean of weight and biochemical parameters before and after intervention, paired t-test and Wilcoxon test were used. The results showed that weight and all biochemical parameters decreased after intervention, significantly. Furthermore, the mean of fasting plasma glucose (FBS) and 2 hours after 75 g plasma glucose (2 Hpg) decreased significantly in the control group after two months (Table 2).

Table 3 showed the odds ratio of abnormal glycemic and lipidemic control according to nutrition education and diet therapy in patients. The results showed that intervention through nutrition education and diet therapy decrease the odds of abnormal glycemic and lipidemic control, significantly. However, the level of HbA1c did not change after intervention. All the results remained unchanged after adjusting for weight and smoking, except 2 hPG (Table 3).

Discussion

This study showed that a healthy eating behavior may improve glycemic and lipidemic control in patients with type 2 diabetes. Our finding also showed that the combination of diet therapy and nutrition education is more beneficial than diet therapy alone. On the other hand, most studies in this regard evaluated the effects of nutrition education on patients' knowledge, attitude and practice, while we evaluated the effect of education on weight and metabolic biomarkers.

For example, in Iran, Najimi et al., showed the beneficial effects of nutrition education according to BASNEF model on nutritional behavior of elderly diabetic patients [19]. Yazdanpanah et al. [32]., also suggested that participatory community-based care, including

Characteristics	Control group (n=247)	Intervention group (n=247)	P value
Sex, Women, n (%)	142 (49.7)	144 (50.3)	0.147
Pregnancy, No, n (%)	247 (100)	245 (99.1)	0.496
Smoking, No, n (%)	247 (100)	237 (95.9)	0.003**
Taking supplement, Yes, n (%)	52 (20.9)	45 (18.4)	0.277
Education			
Under diploma, n (%)	88 (35.3)	64 (26.1)	
Diploma, n (%)	136 (54.6)	149 (60.8)	0.150
Bachelor, n (%)	22 (8.8)	29 (11.8)	
Senior and higher, n (%)	3 (1.2)	3 (1.2)	
Age, mean (SD)	52.53 (11.24)	52.83 (11.32)	0.769
Weight, mean (SD)	78.42 (15.27)	75.88 (13.13)	0.048**
Height, median (IQR)	161 (16)	162.50 (15)	0.642
BMI, median (IQR)	29.46 (5.19)	29.31 (6.06)	0.270
Waist circumference, median (IQR)	109 (33)	107 (28.25)	0.116
Hip circumstance, median (IQR)	119 (62)	117.25 (20.50)	0.551
Waist/hip ratio, median (IQR)	0.91 (0.21)	0.89 (0.22)	0.109
Energy intake, median (IQR)	2109.28 (286.39)	2118.95 (277.82)	0.303
MET, median (IQR)	32.20 (10)	32 (8.05)	0.991
DEBQ, median (IQR)	31 (7)	31 (7)	0.974
DASS42 subscales			
Depression, median (IQR)	17 (7)	16 (7)	0.722
Anxiety, median (IQR)	15 (1)	15 (1)	0.460
Stress, median (IQR)	26 (8)	26 (9)	0.546
EAT 26, median (IQR)	3 (11)	3 (11)	0.970
PFS 21, median (IQR)	69 (38)	69 (38)	0.970
WHOQOL questionnaire, median (IQR)	78 (18)	77.50 (18)	0.896
VAS, median (IQR)	33.90 (20.25)	32.85 (20.12)	0.438
FBS, median (IQR)	210 (99)	202 (88)	0.194
2 hPG, median (IQR)	300 (140.50)	293 (110.50)	0.278
HbA1c, median (IQR)	10 (2.15)	10 (1.90)	0.610
Cholesterol, median (IQR)	205 (67.50)	202 (83)	0.336
TG, median (IQR)	225 (137.50)	206 (126.72)	0.077

*P value < 0.05 was considered as significant

SD: Standard Deviation; IQR: Inter Quartile Range; MET: Metabolic Equivalents; DEBQ: Dutch Eating Behavior Questionnaire; DASS42: The Depression Anxiety Stress Scale; EAT 26: Eating Attitude Test; PFS 21: Power of Food Scale; WHOQOL: World Health Organization Quality of Life Questionnaire; VAS: Visual Analogue Scale; FBS: Fasting Blood Sugar; 2hPG: 2 hours after 75 g Plasma Glucose; HbA1C: Glycosylated hemoglobin; Chol: Cholesterol; TG: Triglycerides

Table 1: Baseline characteristics of the study population

Biochemical tests	Baseline	After 2 months	Mean of changes	P value
Intervention Group				
Weight (SD)	75.88 (13.13)	74.28 (12.7)	- 1.6	<0.001*
FBS (IQR)	202 (88)	163 (80.50)	-12.11	<0.001*
2 hPG (IQR)	293 (110.50)	220 (87.50)	-11.460	<0.001*
HBA1c (IQR)	10 (1.90)	9.50 (1.90)	-12.11	<0.001*
Chol (IQR)	202 (83)	181 (66)	-9.87	<0.001*
TG (IQR)	206 (126.72)	180 (72)	-10.42	<0.001*
Control Group				
Weight (SD)	78.42 (15.27)	79.02 (15.6)	0.6	<0.07
FBS (IQR)	210 (99)	200 (110.50)	-3.22	<0.001*
2 hPG (IQR)	300 (140.50)	284 (160)	-3.89	<0.001*
HBA1c (IQR)	10 (2.15)	10 (2.1)	-1.95	0.050
Chol (IQR)	205 (67.50)	201 (52)	-1.82	0.068
TG (IQR)	225 (137.50)	230 (136)	-1.73	0.082

*P value < 0.05 was considered as significant

IQR: Inter Quartile Range; FBS: Fasting Blood Sugar; 2hPG: 2 hours after 75 g Plasma Glucose; HbA1C : Glycosylated hemoglobin; Chol: Cholesterol; TG: Triglycerides

Table 2: Changes in weight and biochemical parameters between intervention and control groups

Biochemical parameters	Crude Model			Adjusted model**		
	OR	95% CI	P value	OR	95% CI	P value
FBS	0.278	(0.175-0.440)	0.000*	0.274	(0.172-0.435)	0.000*
2 hPG	0.464	(0.259-0.833)	0.010*	0.463	(0.257-0.832)	0.060
HbA1C	0.592	(0.241-1.456)	0.254	0.592	(0.240-1.458)	0.254
Chol	0.438	(0.303-0.632)	0.000*	0.437	(0.300-0.636)	0.000*
TG	0.277	(0.173-0.444)	0.000*	0.287	(0.178-0.462)	0.000*

*P value < 0.05 was considered as significant

** OR adjusted for weight and smoking

FBS: Fasting Blood Sugar; 2hPG: 2 hours after 75 g Plasma Glucose; HbA1C: Glycosylated hemoglobin; Chol: Cholesterol; TG: Triglycerides

Table 3: Odds ratio and confidence interval of abnormal glycemic and lipidemic control according to nutrition education and diet therapy in participants

nutrition education and physical exercise intervention, could be a feasible model for control of diabetes and its risk factors [32]. In Saudi Arabia and Britannia, the positive effects of nutrition education on knowledge, attitude and practice of diabetic patients has been shown [33,34]. In recent years, patient counseling programs for American usage to educate patients about self management became a process that improved their ability to adapt themselves to their disease and its management [35-36]. These educational programs help patients to change their unsuitable dietary and lifestyle habits [37].

Generally, a dietary pattern including carbohydrate from sources such as fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged for good health. Although many diabetic patients believed that a high carbohydrate diet is the most harmful factor for control of diabetes, studies show that a low-carbohydrate diet, restricting total carbohydrate below 130 g/day, is not recommended in the management of diabetes. Low-carbohydrate diets which restricted carbohydrate to 130 g/day are not recommended in the treatment of overweight/obesity patients, because the long-term effects of these diets are still unknown [38]. On the other hand, diabetic patients should know that carbohydrate can be an important source of energy, fiber, vitamins and minerals. Furthermore, carbohydrates are important in diet palatability [38]. So, helping diabetics to understand how to carbohydrate count and use the food exchange system, will allow them to better control the portion size of carbohydrate-rich foods served and assist in managing their total daily carbohydrate intake. It might be a key strategy in achieving glycemic control.

Our findings about the effect of nutritional intervention on glycemic and lipidemic control are consistent with several clinical trials which have shown decrease in HbA1c of 1–2% in type 2 diabetes through medical and nutritional therapy [39,40]. Furthermore, in the UK prospective diabetes study, which recruited a newly diagnosed cohort, after three months of dietary treatment, HbA1c levels decreased from 9.1% to 7.2% [41]. The level of HbA1c did not change in our study after the intervention. It may be because the half life of HbA1c is more than duration of our follow up.

Elevation of plasma cholesterol and triglycerides in type 2 diabetic patients are predictors of the need for renal replacement therapy [42]. Some observational studies suggest that dyslipidemia increases albumin excretion and the rate of progression of diabetic nephropathy [43]. Because many diabetic patients have dyslipidemia, we also educate them about the effects of cholesterol, trans and saturated fatty acids on lipid profile. Following the recommendations and diet therapy, cholesterol and TG showed a significant decrease after two months.

Unfortunately, weight gain may be a consequence of some anti-diabetic medications [44]. So, weight loss is an important therapeutic objective for diabetic patients [45]. All participants in the current study were categorized as overweight at baseline. The intervention group showed a significant weight loss (approximately 2%) after adherence to weight reducer diet and nutritional recommendation for two months. Several studies have shown the direct effect of weight loss on significant reduction of fasting triglyceride and total cholesterol [46,47]. They suggest that modest weight reductions (as little as 5%) lead to reductions in fasting plasma glucose and triglyceride and long term benefits in patients with type 2 diabetes [48]. Some short term studies also have found that moderate weight loss in diabetic patients can lead to decreased insulin resistance and improved glycemic and lipidemic factors [49]. On the other hand, some studies showed that energy restriction independent of weight loss can have considerable affects on glycemic control [50]. There are also several studies that have shown that improved glycemic control could be achieved within 10 days of imposing energy restriction even before any significant weight loss [48]. However the amount of weight loss in our participants was not as much of 5% that observed in previous studies, the intervention group showed a significant weight loss after two months. Furthermore, the mean of weight differences within intervention group was significantly more than within control group. One of the interesting points of this current study is use of two different kinds of intervention between two groups. According to our knowledge, there is not any study to compare the combination of diet therapy and nutrition education with diet therapy alone, at least in Iran. Our finding showed that when nutrition education is added to energy restricted diets; it may have more beneficial outcomes than restriction of energy intake without any education. On the other hand, FBS and 2 hours after 75 g plasma glucose decreased in control group, too. Although the control group did not show any weight reduction, the beneficial effects of a healthy diet might improve some patients' outcome in this group, independently of the weight loss. Since both groups had received a weight reducer diet, we may conclude that nutrition education has positive effect on adherence to a healthy diet, maybe through increase of patients' motivation or their responsibility for adherence to a healthy diet. It is also possible that nutrition awareness makes patients stricter to follow the healthy dietary programs. All together, we could not neglect the beneficial effects of weight loss on diabetes outcomes, but we emphasis on the role of patients' nutrition knowledge on their responsibility and adaptation to weight reducer diets. On the other hand, we found that the education level of the majority of participants in both groups was diploma and under diploma. It shows the necessity of nutrition education for patients who live in Ghom. We should note that the hospital in which sampling was done, is a reference center for diabetes and so, we can extend our results to all patients from Ghom.

Several studies have found that depression is prevalent among diabetic patients and it may worsen diabetes outcomes, particularly glycemic and functional status [51]. Although the score of DASS-42 questionnaire did not show a normal status (moderate for depression and severe for anxiety and stress) in both groups at baseline [52], there were not any significant differences in these scores between the two groups. The score of EAT-26 was below the 20 and it shows that both groups were normal in term of eating attitude [27]. Two groups also did not show any significant difference in term of PFS-21, WHOQOL, DEBQ and VAS scores. So, the effect of nutritional intervention on glycemic and lipidemic control was independent of psychological parameters in our participants.

Several researchers have found that smokers have a less healthy diet than non-smokers, leading to higher risk of chronic disease due to both dietary and smoking habits [53-55]. So, smoking is a confounder factor in study of diet-diabetes complication relationships. In our study, however, the number of smoker patients in the intervention group was significantly higher than in the control group, both crude and adjusted odds ratio (adjusted for smoking) of glycemic and lipidemic abnormality decreased after intervention, significantly. This finding shows that the effect of nutrition education plus diet therapy on glycemic and lipidemic control is independent of smoking status. It is also possible that the patients in the intervention group reduced or quitted smoking after participation in this study. To assess this point, we need to collect information about smoking status at the end of study, again.

In conclusion, the first nutrition priority should be encouraging patients with type 2 diabetes to alter eating behavior to achieve glycemic and lipidemic control [38]. It is suggested that T2DM patients refer to dietetics to receive the most important points, educations and an appropriate diet, at first. Policy makers should note that the main patients' reason for avoiding attention to diet therapy clinics may be the high cost of personal counseling in Iran. They should provide a suitable condition for patients by decreasing the cost of counseling or by presentation of education program via public media according to Iranian culture. Nutrition education programs plus weight reducer diet is more effective than weight reduction without any education. It is not only cost saving but also generates more health benefits compared with conventional treatment [2]. Adherence to nutritional programs and awareness of healthy food choices can lead to considerable decrease in diabetes complications and may also lead to saving economic resources.

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Conflict of Interest

Authors have no conflict of interest.

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