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Influence of education training in patients with type 2 diabetes in the improvement of lifestyle and biochemical characteristics: a randomized controlled trial

Original article

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Abstract: **Objective:** The objective of this randomized controlled trial study was to evaluate the education training in relation to lifestyle improvement in patients with type 2 diabetes through its influence in the levels of glycated hemoglobin (HbA1c), blood pressure, triglyceride, cholesterol levels, and body mass index (BMI).

Methods: The study included patients with type 2 diabetes randomly selected from 20 residential areas in Tirana, Albania where family physicians provide services. The sample size in total was 200 patients in both groups (control and intervention). The education training (four sessions) was conducted by trained nursing staff for 6 months. Patients were screened for the biochemical profile before and after the intervention. To compare the groups with respect to the interest outcomes, the *t*-test was used. The value of $P < 0.05$ was considered significant.

Results: There were 104 male patients and 96 female patients. The mean age was 54.9 ± 8.7. No significant differences were found between the study groups in relation to clinical and biochemical data before the education sessions. After the intervention, in the intervention group, the mean level of HbA1c was significantly lower than the value in the control group (6.2% vs 6.8%, $P = 0.001$) as well as for the mean values of BMI. The mean reduction (more than 15%) in HbA1c after the intervention was 43% in the intervention group and 2% in the control group (OR = 36.9, $P < 0.05$). Differences in BMI, HbA1c, triglycerides, and cholesterol were more significantly visible in the intervention group. However, the difference in systolic and diastolic blood pressure values was almost the same ($P > 0.05$).

Conclusions: The results of this study further support that the approach for education of patients with type 2 diabetes on changing lifestyle benefit the patient in controlling diabetes. It is believed that the establishment of diabetes education classes in health centers is an important investment in improving the management of type 2 diabetes.

Keywords: *type 2 diabetes • health education • management • randomized controlled trial • HbA1c • BMI*

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1. Introduction

Type 2 diabetes is a metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. About 85% of people suffer from type 2 diabetes, which is affecting younger individuals and is no longer unusual among adolescents.[1] The prevalence of diabetes was estimated to be at 12% in 2015 in Albania, but data on disease-determining factors and management are still limited.[2] In the last years, the prevalence of diabetes in Albania has increased, mainly due to population aging and lifestyle changes, and obesity and sedentary lifestyle are globally responsible for 80–85% of the overall risk for developing type 2 diabetes.[3] Patients with diabetes have 2–4 times higher risk to develop cardiovascular disease compared to people without diabetes.[4] Also, diabetes increases the risk of renal insufficiency[5] and visual impairment and is responsible for 5% of world blindness.[6] Common complications of diabetes include neuropathy, while about one-third of patients with diabetes experience sensory loss in the lower limbs, the appearance of the ulcers, significantly increasing the risk of amputation of lower limb.[7,8] Diagnosis of diabetes is often driven by the presence of characteristic symptoms, such as thirst, polyuria, weight loss, recurrent infections, and in more severe cases, coma. The final diagnosis can be made if the plasma glucose level is higher than 200 mg/dl.[1] In addition to known risk factors for diabetes (age, obesity, dietary factors, such as increased consumption of animal fats and carbonated beverages, sedentary lifestyle, family history of diabetes, history of gestational diabetes, polycystic ovarian syndrome, severe mental illness, hypertension, and hyperlipidemia).[1,2] It is increasingly acknowledged that some common medications may be related to metabolic side effects and increased risk of diabetes. High doses of thiazide diuretics exacerbate insulin resistance, whereas beta-blockers may impair its secretion.[9] It is proposed that glycated hemoglobin (HbA1c) can be used as a diagnostic test for diabetes because it does not require performing the sober and glucose test after the meal and is affected by fewer measurement errors. HbA1c is already being used to identify people at risk for diabetes.[10] Suggested diagnostic value of HbA1c for diabetes is 6.5% or higher, 6.0–6.4% indicates impaired glucose tolerance, and 5.7–6.4% indicates prediabetes.[11] Intensive multifactorial interventions for the reduction of cardiovascular risk factors and individual management have proven to be effective in reducing cardiovascular mortality from diabetes.[12] Evidence has shown that increasing individual knowledge in diabetes management lowers glucose hemoglobin values as it is associated with better control of the glucose hemoglobin level.[13,14] Randomized clinical trials have shown that improvement in glycemic control is associated with a reduction in cardiovascular complications,[15] while comprehensive intervention associated with cardiovascular risk factors can reduce mortality and morbidity in patients with diabetes.[16] The period after the diagnosis of diabetes is essential for its long-term management, as the patient has to assimilate an extremely large amount of information and skill.[17]

2. Methods

2.1. Design and study sample

The purpose of this randomized controlled trial study was to evaluate the education training in patients with type 2 diabetes in relation to lifestyle improvement through the influence of education in the levels of HbA1c, arterial pressure, triglyceride, cholesterol levels, and in body mass index (BMI). The training (four sessions) was conducted by trained nursing staff for 6 months. The sample size in total was 200 patients in both groups (control and intervention). The study conducted in Albania included 20 residential areas in the Tirana region where family physicians provide services. These 20 physicians and diabetic patients were randomly selected from the Register of Compulsory Medical Insurance Funds (as the institution responsible for concluding work contracts with family practitioners) for the Tirana region. For each of the selected physicians, at least 10 patients who meet the inclusion criteria in the study were selected.

Inclusion criteria:

- Patients with type 2 diabetes who are treated with oral medications.
- Have a level of HbA1c >6.5%.
- Agree to participate in the study.

Exclusion criteria

- Presence of associated diseases such as dementia and psychiatric disorders.
- Disagree to participate in the study.

It is expected that participation in the training education groups may lower the HbA1c value by 15% of the baseline value after 6 months of the start of the training sessions, while this reduction will not occur in the control group.

The 15% value for HbA1c decrease was taken based on the practical guidelines on diabetes therapy.[18,19]

2.2. Study protocol

2.2.1. T1-The start time of the study

Patients who accept to take part in the study are screened for the biochemical profile (baseline); arterial blood pressure (mmHg), lipid profile (cholesterol and triglycerides in g/dl), HbA1c in %, and BMI [weight in kilograms-kg and height in metric units-m; BMI is calculated as the ratio of weight to square height]. In addition, patients' demographic data (gender and age) will be considered. The intervention group will be subjected to educational training sessions, while the control group will not take part in this training and will continue the lifestyle that it had before the study. The first training session will be within the first 2 weeks of the start of the study. The second training session will take place 1 month after the first and the last two training sessions will be offered within 1 month from each other (four training sessions in total).

2.2.2. T2-The second study time

After 6 months, all the selected patients from both the study groups will participate in the second check that will consist of evaluating their biochemical profile.

2.3. Data collection

To have a randomized trial, patients with diabetes who will be included in the study were randomly selected from the name list of family physicians (first and tenth in the list). Two family physicians for each health center of 10 administrative regions of Tirana were included for the data collection (a total of 20 physicians, 10 will be included in the control group and 10 in the intervention group). None of the physicians in the control group were aware of the education sessions that the patients will have with the intervention group and vice versa. Patients with type 2 diabetes and those with the latest HbA1c >6.1% levels (recorded in the medical file) were selected by each physician. Of these patients, 10 were randomly selected and their HbA1c level was measured again. If any of the selected patients had HbA1c <6.1%, then another patient was selected the same way until we had a number of 10 patients for each family physician in both groups. The laboratory staff who was analyzing the blood sample was not aware of which of the groups the patient belonged.

2.4. Data analysis

SPSS version 16 was used to analyze the data. Continuous data were presented by average and standard deviation, while categorical data were presented by relative frequencies in percentage. To compare the groups with respect to the interest outcomes, the *t*-test, Mann–Whitney *U* test, or Chi-squared test was used. To determine the factors associated with the reduction of HbA1c at 15%, logistic regression was used. Bivariate correlation was used to evaluate the influence of age on biochemical profile changes. The value of $P < 0.05$ was considered significant.

3. Results

The study included 200 subjects who met all criteria for inclusion in the study. The response rate was 100% as none of the subjects invited for the study refused attendance.

3.1. Participants' demographic characteristics

The demographic characteristics of participants are presented in Table 1. About half of the patients were under the age of 55.

No significant differences were found between the study groups in relation to clinical and biochemical data (Table 2). For the main variable in the study, the average value of HbA1c was found to be 7.02% in the intervention group and 6.9% in the control group, but with no significant differences ($P = 0.150$). HbA1c values were high and showed that individuals did not have good glycemic control over the last 3 months. Also,

Items	*n* (%)	M ± SD	95% Coefficient interval	Age range
Gender				
Male	104 (52)			
Female	96 (48)			
Age (years)		54.9 ± 8.7	53.7–56.2	36–80

Table 1. Demographic characteristics of participants ($n = 200$).

Clinical and biochemical characteristics	Groups (M ± SD)		*P*
	Intervention	Control	
Systolic arterial pressure (mmHg)	129.30 ± 11.80	131.50 ± 7.50	0.111*
Diastolic arterial pressure (mmHg)	74.50 ± 8.40	74.40 ± 7.10	0.678*
HbA1c (%)	7.03 ± 0.25	6.90 ± 0.34	0.118*
BMI (kg/m^2)	26.70 ± 1.80	26.90 ± 1.40	0.361*
Cholesterol (mg/dl)	218.37 ± 43.50	213.33 ± 43.20	0.412*
Triglycerides (mg/dl)	228.70 ± 99.20	211.12 ± 75.50	0.100*

Note: **t*-test; $P < 0.05$ is considered significant.

Table 2. Clinical and biochemical characteristics of the participants by groups at the time of inclusion in the study ($n = 100$).

other variables of the study did not show any statistical differences of mean values in the intervention and control groups.

Table 3 shows the differences in clinical and biochemical characteristics after the training educational sessions in both groups. When the mean values of HbA1c (at the end of the study) by study groups were compared, it results that in the intervention group the mean value of HbA1c is significantly lower than the mean value in the control group (6.2% vs 6.8%, $P = 0.001$).

The same situation is presented for the mean values of the BMI by study groups, while there are no statistically significant differences for other variables included in the study.

To better determine the differences in biochemical values before and after the intervention, the mean values by groups were compared (Table 4). After 6 months, there was a decrease in the mean values of clinical and biochemical characteristics in both groups. All changes were statistically significant when *t*-test was analyzed to compare the mean values of independent groups.

To assess in which of the groups the decrease in the values of the clinical and biochemical characteristics was more evident, the mean of the differences in values of the clinical and biochemical characteristics for each group was compared (Table 5). Differences in BMI, HbA1c, triglycerides, and cholesterol were visibly more significant in the intervention group than in the control group. However, the difference in systolic and diastolic blood pressure values was almost the same and statistically unchanged for both groups.

Clinical and biochemical characteristics	Intervention group	Control group	*P*
HbA1c (%)	6.20	6.80	0.001*
Systolic arterial pressure (mmHg)	128.50	130.53	0.199
Diastolic arterial pressure (mmHg)	74.60	74.50	0.860
Cholesterol (mg/dl)	207.18	210.20	0.188
Triglycerides (mg/dl)	197.07	208.60	0.187
BMI (kg/m^2)	25.30	26.90	0.001*

Note: **t*-test; $P < 0.05$ is considered significant.

Table 3. Clinical and biochemical characteristics of the participants by groups after intervention.

3.2. Results for the reduction of HbA1c more than 15%

At the end of the study in both groups, 45 patients (22.5%) with diabetes had a 15% reduction in the initial HbA1c value. Distributed by study groups, in the intervention group, this percentage was 43. In the control group, only two (2%) patients had a 15% reduction of the initial value of HbA1c (Table 6).

Table 7 shows the results of the logistic regression for the effect of education (controlled by gender and age) in lowering HbA1c by 15%. The table shows that education in diabetes management as a variable directly affects HbA1c decrease, and the odds ratio of education in lowering HbA1c by 15% is increased about 37 times. When analyzed by logistic regression in two models, this effect does not seem to be affected by gender (model 1) and the age of the participants in the study (model 2). Thus, the education of patients with diabetes is considered to be an independent determinant factor in glycemic control and diabetes management.

4. Discussion

In this study, we evaluated the education training in patients with type 2 diabetes in relation to lifestyle improvement through the influence of education in the levels of HbA1c, arterial pressure values, triglyceride and cholesterol levels, and BMI. In total, 200 patients were included, 100 patients respectively in the intervention and control groups. The mean age of patients 54.9 ± 8.7 (age range [36–80] years, Table 1).

Table 2 shows high values of HbA1c both in the intervention and control groups at the time of inclusion

Items	Intervention group			Control group		
	Baseline	After 6 months	*P*	Baseline	After 6 months	*P*
HbA1c (%)	7.02	6.23	0.001*	6.90	6.81	0.001*
Systolic arterial pressure (mmHg)	129.38	128.54	0.001*	131.50	130.50	0.020*
Diastolic arterial pressure (mmHg)	74.57	74.65	0.535	74.40	74.46	0.695
Cholesterol (mg/dl)	218.37	207.18	0.001*	213.30	210.20	0.001*
Triglycerides (mg/dl)	228.57	197.70	0.001*	210.70	208.60	0.170
BMI (kg/m^2)	26.65	25.32	0.001*	26.80	26.90	0.678

Note: **t*-test; $P < 0.05$ is considered significant.

Table 4. Values of clinical and biochemical characteristics of the participants at the end of the study.

in the study. This is an indication of poor management of diabetes.[15,20]

Also, in most cases, patients were obese or overweight (mean BMI > 25 kg/m^2), and this finding was consistent with the study conducted by Weinger and colleagues, indicating the fact that the majority of individuals who were diabetic were obese or overweight.[21]

This profile of patients with diabetes is supplemented by other data as the average of cholesterol and triglyceride levels are above the normal value (200 mg/dl and 150 mg/dl). A study found that HbA1c was positively correlated with high triglyceride in patients with type 2 diabetes. In addition, HbA1c can be an indicator of lipid profile and in patients with type 2 diabetes, and it can be one of the predictors of cardiovascular risk factors.[22]

The systolic blood pressure values had an average of 130 mmHg, which may be an indication of good arterial blood pressure management by the study population. Increased blood pressure is considered as one of the leading risk factors for death and disability in people with type 2 diabetes.[23]

Study shows that after 6 months of training education for lifestyle modification, there are significant changes in the biochemical and clinical profile of the patients involved in the study (Tables 3 and 4). In addition, the mean differences in values of the clinical and biochemical characteristics of the participants before and after the intervention show that BMI, HbA1c, triglycerides, and cholesterol were visibly more significant (P = 0.001) in the intervention group than in the control group (Table 5). However, the difference in systolic and diastolic blood pressure values was almost the same and statistically unchanged for both groups. This finding of our study is consistent with the conclusions of numerous studies in this area that evaluate the education of patients with diabetes as very important in reducing the values of HbA1c and thus in the management of effective control of diabetes.[24]

At the end of the study in both groups, 45 patients (22.5%) with diabetes had a 15% reduction in the initial HbA1c value. Distributed by study groups, in the intervention vs control groups, the percentage was 43 vs 2, respectively (Table 6). Our findings about the effect of training education in lifestyle improvement, including changes in nutrition, are consistent with other studies that have shown a decrease in HbA1c values after the intervention.[20]

In addition to glycemic control, the HbA1c can be used for predicting dyslipidemia in patients with type 2 diabetes.[25]

The odds ratio of education in lowering HbA1c by 15% is increased about 37 times, OR = 36.9; CI [8, 7–162] in the intervention group. A pilot study conducted in patients with type 2 diabetes found that the awareness about the disease was low, and it was reflected in the biophysical profile of the study participants (blood pressure values and random blood sugar levels). The results emphasize the impact of education on type 2 diabetes management.[26]

The mean differences in values of the clinical and biochemical characteristics	Group (mean)		P
	Intervention	Control	
BMI (kg/m^2)	–1.3203	0.0090	0.001*
HbA1c (%)	–0.7906	–0.0854	0.001*
Triglycerides (mg/dl)	–31.5025	–2.1054	0.001*
Cholesterol (mg/dl)	–11.1878	–3.0894	0.001*
Systolic arterial pressure (mmHg)	0.0800	0.0600	0.715
Diastolic arterial pressure (mmHg)	–0.8400	–1.0200	0.914

Note: **t*-test; $P < 0.05$ is considered significant.

Table 5. Comparison of the mean differences in values of the clinical and biochemical characteristics of the participants before and after the intervention.

Group	Reduction of HbA1c <15%	Reduction of HbA1c = 15%
Intervention	57%	43%
Control	98%	2%

Table 6. The distribution of participants by level of reduction of HbA1c value and study groups.

5. Conclusions

This study further supported the approach of placing the patient in the center of care in diabetes management and filled a gap in terms of the efficiency of patient education in the Albanian context. In addition, patient education on changing lifestyle and perception of the illness involves the patient in controlling diabetes. In the current conditions in Albania as a developing country, the role of educating patients with diabetes in

Group	OR*	95% Coefficient interval	OR**	95% Coefficient interval	OR***	95% Coefficient interval
Intervention	36.9†	8.7–161.9	37.6†	8.7–162	37.9†	8.7–162
Control ^	1		1		1	

Note: *Odds ratio raw; **Odds ratio controlled for gender; ***Odds ratio controlled for gender and age; ^ Reference; †Significant in 0.05.

Table 7. Effects of education in lowering HbA1c by 15%.

educational sessions provided by nursing staff trained in controlling and preventing diabetes complications is considered to be important. Based on this conclusion, it is believed that the establishment of diabetes education classes near health care centers is an important investment in improving the management of type 2 diabetes.

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Ethical approval

The study was approved by the University of Medicine of Tirana Research Ethics Committee, M.E.C., in March 2016. Patients participated voluntarily in the study after being informed in advance for the purpose of study. Patients were assured anonymity and each of them gave verbal consent for participation in the study.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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