

EFFICIENCY OF A NUTRITION EDUCATION PROGRAM IN THE PREDIABETIC POPULATION: IS IT NECESSARY?

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Rezumat

Introducere și obiective. Conform Raportului Național de Statistică a Diabetului 2020 al Centrului pentru Controlul și Prevenirea Bolilor (CDCP), 13% dintre adulții americani au diabet și 34,5% îndeplinesc criteriile pentru prediabet. Prevalența prediabetului crește odată cu vârsta. Scopul acestui studiu a fost de a sublinia importanța implementării programelor de educație nutrițională pentru prevenirea diabetului zaharat la populația prediabetică.

Material și metodă. Studiul a fost intervențional, prospectiv și randomizat, incluzând 218 pacienți cu prediabet, un eșantion reprezentativ pentru o populație cu risc de a dezvolta diabet, urmăriți și tratați într-un centru specializat. Am inclus pacienți diagnosticați cu prediabet, cărora li s-au aplicat principiile educației nutriționale. După 6 luni au fost reevaluați prin dozarea hemoglobinei glicozilate.

Rezultate. Au fost incluși 218 pacienți, cu o vârstă medie de 64,6 ani, dintre care 56,9% au fost femei. Indicele de masă corporală mediu a fost de 31,8 kg/m², cu o prevalență a obezității de 61,5% din populația studiată (obezitatea a fost diagnosticată și stadializată conform OMS). La șase luni de la implementarea programului de educație nutrițională s-a observat o scădere semnificativă statistic ($p=0,005$) a hemoglobinei glicozilate, cu -0,12%. Această diferență a fost menținută la 12 luni de la înscriere ($p=0,009$).

Concluzii. Educația nutrițională are o importanță majoră în prevenirea diabetului, fapt care poate reduce incidența la nivel mondial a acestei patologii împreună cu complicațiile care pot apărea prin expunerea prelungită la hiperglicemie.

Cuvinte cheie: prediabet, nutriție, educație, prevenire, studiu.



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Abstract

Background and aims. According to the Centers for Disease Control and Prevention (CDCP) 2020 National Diabetes Statistics Report, 13% of American adults have diabetes and 34.5% meet the criteria for prediabetes. The prevalence of prediabetes increases with age. The purpose of this study was to emphasize the importance of implementing nutritional education programs for the prevention of diabetes on prediabetic population.

Material and method. The study was interventional, prospective and randomized, including 218 patients with prediabetes, a representative sample for a population at risk of developing diabetes, followed and treated in a specialized center. We included patients diagnosed with prediabetes, to whom principles of nutritional education were applied. After 6 months they were reevaluated by dosing glycosylated hemoglobin.

Results. 218 patients were included, with an average age of 64.6 years, of which 56.9% were female. The average body mass index was 31.8 kg/m², with a prevalence of obesity of 61.5% of the studied population (obesity was diagnosed and staged according to WHO). Six months after the implementation of the nutritional education program, a statistically significant decrease ($p=0.005$) of glycosylated hemoglobin was observed, by -0.12%. This difference was maintained 12 months after enrollment ($p=0.009$).

Conclusions: Nutritional education has a major importance in the prevention of diabetes, a fact that can reduce the worldwide incidence of this pathology together with the complications that can appear related to prolonged exposure to hyperglycemia.

Keywords: prediabetes, nutrition, education, prevention, study.

Background and aims

Diabetes mellitus (DM) is a chronic pathological condition of great importance for public health, representing one of the four most problematic non-communicable diseases globally, along with cardiovascular diseases, chronic respiratory diseases and neoplasias⁽¹⁾.

In 2017, the global incidence of DM was 22.9 million cases, the prevalence of diabetes was 476 million cases and the mortality was 1.37 million⁽¹⁾. It is estimated that in the year 2025 these parameters will increase to 26.6 million cases, 570.9 million cases, respectively 1.59 million. Regarding the global annual costs (for prevention, treatment of the disease itself and complications), in 2016 they were higher than 827 billion dollars. The International Diabetes Federation estimated that between 2003 and 2013 they have tripled⁽¹⁾.

The major determining factors leading to the continuous upward evolution of these figures are represented by the metabolic risk (high BMI - body mass index) and the lifestyle characteristic of the modern world - imbalanced diet, smoking, lack of physical activity. Intervention on these factors, as a DM prevention strategy, is a powerful wish of WHO (World Health Organization)⁽¹⁾. The aim of this paper was to carry out a prospective experimental interventional study that evaluates the impact of a type 2 diabetes prevention program in a group of 218 patients at high risk of developing this pathology and with an inadequate lifestyle. The patients were known with prediabetes or were diagnosed at the time of enrollment.

The purpose of the paper was to highlight the importance of lifestyle changing of a population at risk, according to the standard recommendations of the diabetologist in reducing the progression to type 2 diabetes,

using the indications of the American Diabetes Association (ADA). The main objective of this study was to demonstrate the importance of a prevention program for decreasing the rate of progression to type 2 diabetes, or even normalizing the values of the studied biological parameters (HbA1c - glycosylated hemoglobin).

Material and method

Study design and patients

The study was interventional, prospective and randomized on a sample of 218 patients with prediabetes, a representative sample for a population of patients at risk of developing diabetes mellitus type 2, followed and treated in a specialized center. The inclusion criteria were:

- Adults with a minimum age of 18 years
- Carbohydrate metabolism disorder that does not meet the ADA criteria for diabetes: IFG (impaired fasting glucose), IGT (impaired glucose tolerance) within 75-g OGTT (oral glucose tolerance test) or HbA1c value in the range of 5.7 - 6.4%

Exclusion criteria were: Patients with a positive diagnosis of DM I, DM II or gestational DM, extreme HbA1c values (< 5.4% or > 6.5%), age under 18 years, pregnancy or lactation, refusal to complete the informed consent.

Patients presented themselves at Private Medical Practice - Alexandra Crișan and "Nicolae Malaxa" Clinical Hospital with fasting blood glucose values above normal limits, for the purpose of screening for diabetes. Patients who met the enrollment criteria were included in the study.



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Laboratory, anthropometric and clinical data collection

At study inclusion, participants were clinically, anthropometrically and biologically assessed. The sampling for the biological parameters evaluation was done after 12 hours of fasting.

The biological parameters used were: hemoleucogram, lipid profile (total cholesterol, LDL, HDL, triglycerides), renal profile (uric acid, urea, creatinine), liver profile (TGO, TGP), blood glucose, glycosylated hemoglobin, total calcium, magnesium, sideremia, TSH.

If certain deviations from the reference range were found, the patients underwent additional biological evaluation or were referred to the proper physician.

After finishing the investigations, the patients participated in a one-on-one consultation with the specialist doctor, in order to explain the food principles that are the basis of nutritional education. It consisted in:

- Regularity of meals. Disciplining the body, by keeping the food schedule, to consume food when the feeling of hunger appears (the feeling of hunger is defined as a sensation that occurs 4-5 hours after the last meal, felt as a "hole in the stomach" accompanied by a "specific noise") and stopping the meal when the state of satiety appears⁽²⁾.
 - ➔ Breakfast: maximum 1 hour after waking up

- ➔ Lunch: 4-5 hours after breakfast
- ➔ Dinner: 3-4 hours before going to bed, ideally until 8 p.m
- ➔ Snacks were optional and limited to approximately 100 kcal, from fresh fruits, oleaginous fruits or low-fat dairy products.

- Physical activity. The importance of physical activity was explained to the patients, so that during each consultation they committed to having a minimum movement target, such as 10,000 steps/day or 30 minutes of moderate-intense physical activity 5 times/week (bicycle, treadmill, jogging, alert walking, running or fitness and aerobic programs), within the limit of personal tolerance.
- Distribution of carbohydrates at breakfast and dinner. Starting from the idea of balance in terms of lifestyle, it was observed that both too high consumption of carbohydrates (>70%) and too little consumption (<40%), in the long term, are associated with an increased mortality rate.⁽³⁾
 - ➔ The main sources of carbohydrates were explained to the patients and they were directed to sources that were as unrefined as possible and as rich in dietary fiber as possible.
 - ➔ Starting from the idea of the distribution of carbohydrates in close connection with the rhythm of daily

activity, cereals, legumes, potatoes and fruits were recommended to be consumed until 6 p.m.

- Lipid intake. The recommendation regarding the intake of lipids was summed up in avoiding saturated fats from animal products rich in fats (fatty meat, very fatty dairy products, margarine, chips, snacks, pastry)
- Alcohol intake. Regarding alcohol intake, the recommendation was to exclude it from the daily diet as long as the goal was weight loss, in order to eliminate a caloric surplus in the daily diet. Later, as a principle of healthy eating, alcohol was reduced to a maximum of 2 portions per day for men and a maximum of 1 portion per day for women⁽⁴⁾
- Water intake: 30-40 ml/kg/day
- Gastrotechnics: thermic preparation of food by boiling, steaming, baking, grilling, and avoy frying.

All this information related to a healthier lifestyle, nutritional education, was synthesized in a brochure created for the purpose of this scientific research. The information was personalized, depending on the social, cultural and religious characteristics of the patient.

More than nutritional education per se, some terms were explained to the patients - the difference between physiological and emotional hunger, as well as notions about emotional eating, in particular cases.

Statistical analysis

The R program, version 4.0.2 Copyright (C) 2020 The R Foundation for Statistical Computing, R Core Team (2020) was used for the statistical analysis. A: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org> and

Excel program, "=COUNTIF", "=AVERAGE", "=COUNTIFS" functions.

In the first part, a descriptive analysis of the variables used in the study was made, for continuous variables, the mean, median, standard deviation (SD), minimum and maximum of the distribution were determined and histogram and normal probability plot (PPN) graphs were used. For the categorical variables the absolute frequencies (the number of each category, compared to the total number) and the relative frequencies (the percentages of each category) were calculated.

Results

218 patients were assessed, with an average age of 64.6 years with a standard deviation of 9.75 years, representing almost 30 years above the limit at which the American Diabetes Association recommends starting screening for diabetes. Regarding the gender of the enrolled patients, the majority was female (124 women), representing 56.9%, while males were 43.1% (94 patients).

As expected, patients with prediabetes also weighed more than normal, so the average weight of the studied population was 87.9 kg (standard deviation of 20.7 kg) (Figure 1).

The average level of the body mass index was 31.8 kg/m² (standard deviation of 6.39 kg/m²). The range in which the patients were located was between 17.1 kg/m² and 54.7 kg/m². (Figure 2) Thus, at the global level, the studied population falls within the sphere of obesity, which increases the risk of developing diabetes.

According to the DPP (Diabetes Prevention Program), nutritional intervention for an average weight loss of 7% can delay the onset of diabetes by 58% in the next 3 years⁽⁵⁾.



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From the non-obese population, but with diagnostic criteria for prediabetes, 23 patients were of normal weight since enrollment, meaning 12.29%, and 49 patients had a BMI between 25 kg/m² and 29.99 kg/m², i.e. overweight (26.2%).

Of the population with obesity, the staging was 60% grade 1, 21.7% grade 2 and 18.3% grade 3. Considering that grade 1 obesity is clearly the majority, it can be assumed that a larger number of patients can more easily reach a normal weight, and thus, the achievement of the primary objective will be fulfilled, by decreasing abdominal adiposity and improving insulin resistance.

Glycosylated hemoglobin was mandatorily collected, as a parameter for inclusion in the study. Patients with values between 5.7% and 6.49% were included. The mean value at inclusion was 6.05% (SD=0.231). Later, the patients were recommended to redose the glycosylated hemoglobin every 6 months. Glycosylated hemoglobin value was analyzed in this way, in stages, from 6 to 6 months, from enrollment to 12 months, in relation to the initial level.

But it is important to emphasize that the initiation of this program is recent and there are many patients among those enrolled who are not yet 18 months after enrollment, so that they have presented themselves for reevaluation. Thus, the hypothesis of the continuation of the study remains open, even

through the subsequent extension, from 6 to 6 months.

The inferential analysis assumed the comparison between the HbA1c values at enrollment and those from 6 months, with the following assumptions:

- The null hypothesis (H0) was that the average of the differences between HbA1c values at enrollment and HbA1c at 6 months is 0 (nutritional education does not lead to a decrease in HbA1c)
- The alternative hypothesis (H1) was that this average is greater than 0, which highlights that nutritional education leads to a decrease in HbA1c values at 6 months.

The test used was a one-way Paired T test and is shown in the following table (the average value of HbA1c at enrollment is different from the one in the descriptive statistics, only patients for whom data were available at 6 months were taken into account).

The test allows the rejection of H0 ($T=2.66$, $gl=50$, $p<0.01$). H1 can be considered plausible, namely that there is an effect of the nutritional education process, the average HbA1c decrease at 6 months being 0.12%, with the lower limit of the 95% CI of 0.04, as can be seen in the following figure (Figure 3).

For the comparison at 12 months, a procedure similar to the previous one was used (with the

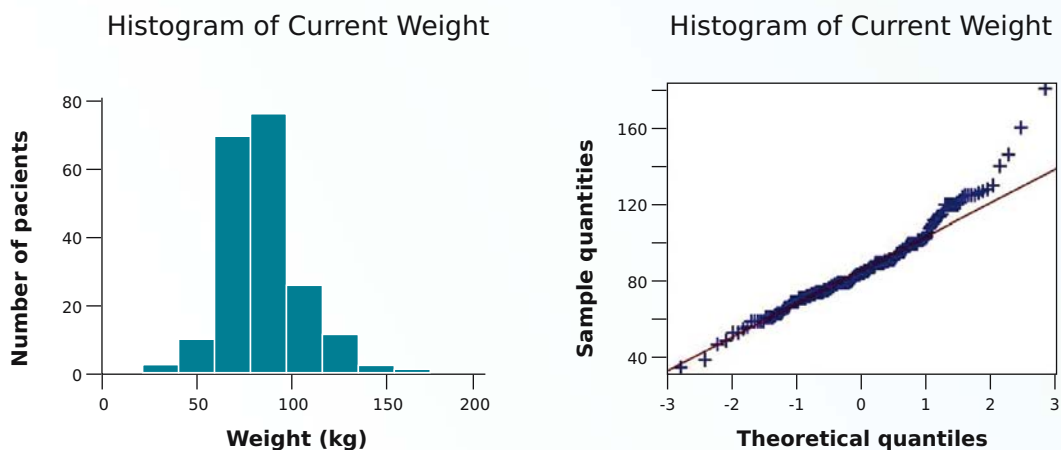


Figure 1. Histogram and normal probability plot in terms of enrollment weight

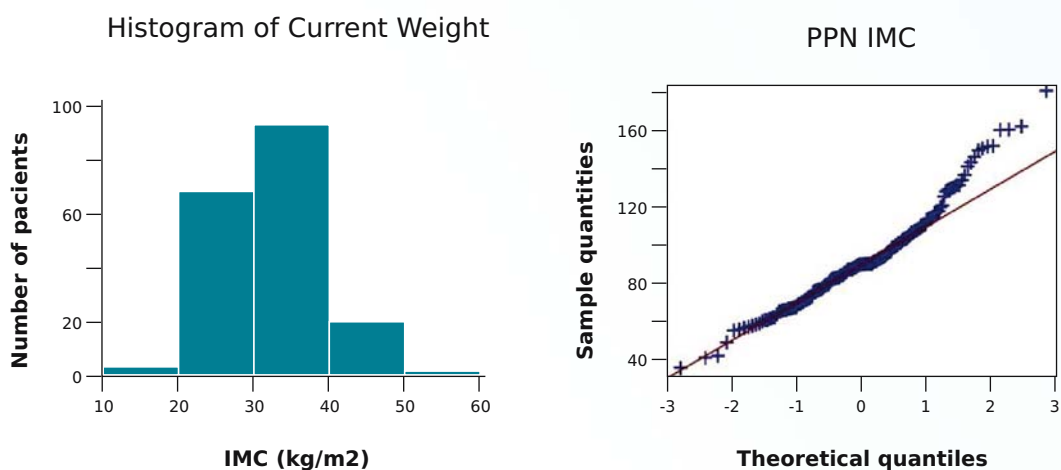


Figure 2. Histogram and normal probability plot regarding BMI

Average HbA1c enrollment	Average HbA1c Months	6	T statistic	p	Mean differences (IC95%)
6.02	5.93		2.662,50	0.0052	0.12 (0.04 Inf)

Table 1. Inferential analysis of HbA1c at 6 months



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same hypotheses H0 and H1), but it should be mentioned that there were only 18 HbA1c values at 12 months, the power and accuracy of the test being diminished.

The result of this test also allows rejecting H0 ($T = 2.58$, $gl = 17$, $p < 0.01$) thus making H1 plausible. It can be considered that there is an effect of nutritional education even 12 months after its implementation.

The influence of age on the evolution of the HbA1c value was analyzed, the evolution of this parameter being quantified using the difference between the HbA1c values before the start of the nutritional education program and the HbA1c values after 6 months of inclusion. The model used was that of simple univariate linear regression, with the dependent variable being the difference between the HbA1c values before therapy and 6 months after therapy, while the independent variable was the patient's age.

The analysis reveals that there is a significant influence for the age variable ($p < 0.01$), with older patients having a less favorable evolution, with a smaller decrease in HbA1c values at 6 months.

Later, a more precise analysis was made, dividing the patients into age groups; considering that there were 51 patients for whom data were available for both measurement moments of HbA1c (pre-therapy and 6 months post-therapy), it was decided to divide the patients into two groups,

using the cut-off value (for homogeneity) the median value of the age distribution, its value being 65 years: patients under 65 years and patients older than or equal to 65 years. On these two created subgroups, a two-way Welch T test was used for two independent samples, the result being the following:

- average difference in HbA1c for patients under 65: -0.28
- average difference in HbA1c for patients over 65: -0.03

The test indicates that the differences are statistically significant ($p < 0.05$) meaning that the decrease in HbA1c was much more pronounced in patients younger than 65 years old.

Discussion

In literature, a significant amount of information is published regarding the diagnosis and prevention of diabetes, in parallel with the updates of the continuously increasing prevalence data of diabetes.

The present study, still in progress, brings to light statistically significant evidence arguing the urgent need for implementing nutritional education programs in the population with prediabetes, as soon as possible.

Body mass index, weight gain and obesity are very closely related to the development of

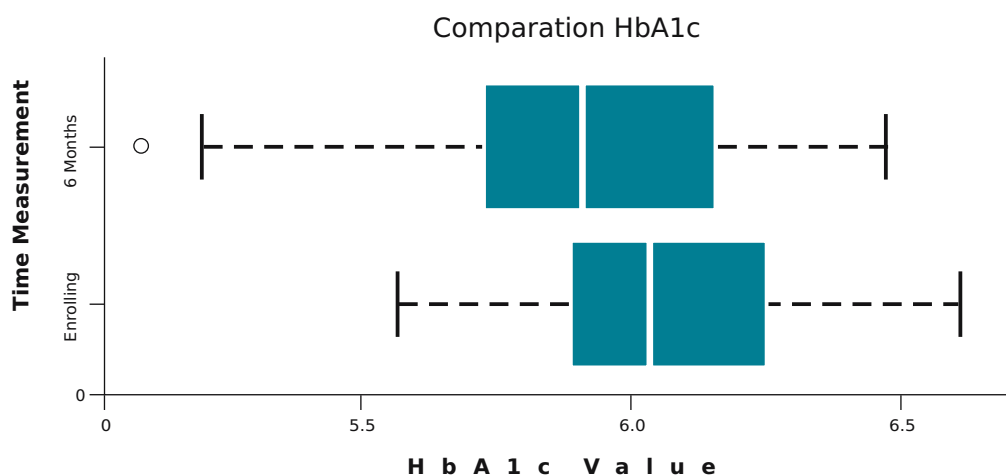


Figure 3. Comparison of Hba1c from enrollment to 6 months

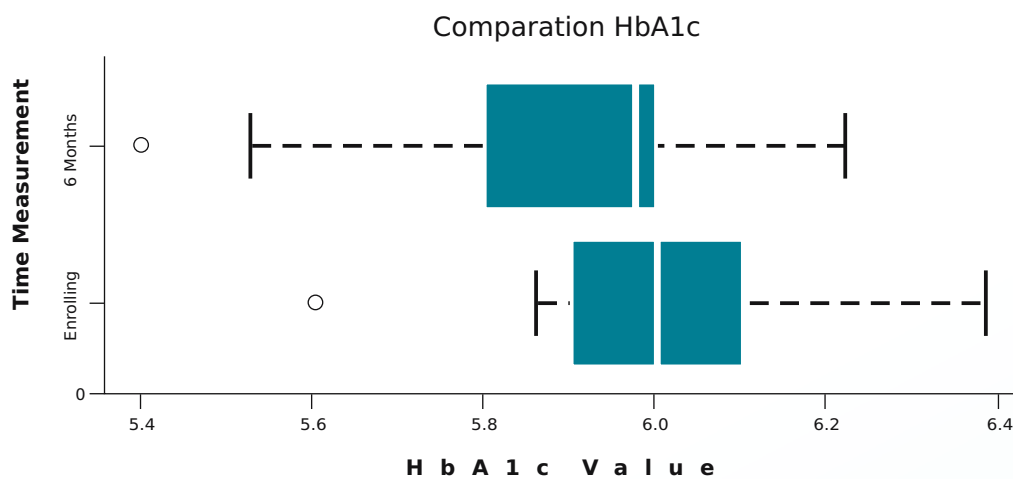


Figure 4. Hba1c comparison from enrollment to 12 months

Average HbA1c enrollment	Average HbA1c 12 Months	T statistic	p	Mean differences (IC95%)
6.02	5.93	2.585, 17	0.0096	0.11 (0.03 Inf)

Table 2. Inferential analysis of HbA1c at 12 months



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type 2 diabetes⁽⁶⁻⁸⁾. Therefore, improving the energy balance, either by increasing caloric intake or by decreasing caloric consumption, plays an extremely important role in the occurrence of type 2 diabetes⁽⁹⁾.

Epidemiological evidence points out that multiple dietary patterns are favorably associated with the prevention of type 2 diabetes; and more, the intake of whole grains, fibers, fruits, vegetables, oleaginous fruits, monounsaturated fatty acids, magnesium and the low intake of alcohol delay the onset of diabetes, while the consumption of red and processed meat and saturated fats can increase the risk of developing diabetes type 2⁽¹⁰⁻¹¹⁾.

Additionally, a diet rich in red and processed meat, sweets, fried potatoes, refined grains, was associated with a higher risk of developing disorders of carbohydrate metabolism in women⁽¹²⁾. A major diabetes prevention study is The Finnish Diabetes Prevention Study (DPS), which included 522 patients aged between 40 and 64, with a body mass index over 25 kg/m² and impaired glucose tolerance, highlighted by the average of 2 blood glucose values at 2 h from the oral glucose tolerance test with 75 g of glucose⁽¹³⁾.

The study was conducted on 2 arms, one interventional and one control. It is important to mention that the intervention was stopped prematurely, in the year 2000, due to the fact that a significant decrease in the incidence of

diabetes was obtained in the intervention group⁽¹³⁾. IG (Interventional Group) involved an initial consultation of 30 minutes to 1 hour, and then other individual consultations in weeks 1, 2, 5 and 6 and subsequently from 3 to 3 months. The goal was to provide patients with the necessary information to acquire the knowledge and means by which they can achieve a lifestyle change aimed at preventing type 2 diabetes⁽¹⁴⁾.

CG (Control Group) assumed an initial consultation of 30 minutes to 1 hour in which general knowledge for weight loss was synthesized through printed materials, video, outside the consultation individualization according to the needs of each patient, thus all receiving the same information^(13,15).

In both groups, TTGO with 75 g of oral glucose, physical examination and measurements of anthropometric indices were performed annually. The food survey is constant in keeping a food diary for 3 days before each consultation, including the one for inclusion in the study⁽¹³⁾. The results pointed out that 55% of the enrolled patients had a body mass index of over 30 kg/m². The IG group obtained an average decrease in weight of 3.5 kg (SD 5.1), a decrease in BMI of 1.3 kg/m² and in HbA1c by 0.2%⁽¹³⁾. Similar to the decrease in Hb1c, through an intensive intervention program, was also observed in the present study, even with a much greater laxity of the implemented measures.

Conclusions

Following the nutritional education program, the patients obtained a statistically significant decrease in glycosylated hemoglobin both at the 2nd visit and at the 3rd visit after enrollment.

The evolution of a nutritional education program has low efficiency in the case of population over 65 years old.

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