



**“CAROL DAVILA” UNIVERSITY OF MEDICINE AND PHARMACY
BUCHAREST**



**DOCTORAL STUDY
MEDICINE FIELD**

DOCTORAL THESIS SUMMARY

Doctoral supervisor:

UNIV. PROF. DR. GABRIELA RADULIAN

PhD student:

ALEXANDRA (CRIȘAN) ALEXESCU

2024

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**DOCTORAL STUDY
MEDICINE FIELD**

**THE IMPACT OF LIFESTYLE CHANGES
THROUGH NUTRITIONAL INTERVENTION
IN OVERWEIGHT AND OBESE PEOPLE
ON ANTHROPOMETRIC, METABOLIC AND
BIOLOGICAL PARAMETERS**

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INTRODUCTION

Obesity is a chronic, relapsing condition that affects an increasing number of the population worldwide.[1] It is estimated that in the year of 2025 the globally prevalence of obesity will reach 18% for men and 21% for women.[2] Of these, approximately 257 million adults (6% of men and 9% of women) will struggle with severe forms of obesity (BMI over 35 kg/m²).[2]

Such a high incidence of extreme obesity is an extremely serious alarm signal to adopt a nutritional medical intervention as effective as possible, aimed at minimizing the serious consequences of these pathologies.

Through the scientific research topic addressed, I aimed to highlight the effects of the implementation of a healthy eating program, called DIACLASS, which is easy to apply and understandable to the patient.

Currently, the medical literature does not provide many details about what a balanced, nutritionally optimal diet means. Clear limits of the daily requirement of macronutrients and micronutrients are published, as well as recommendations for the care restrictions needed by the obese patient.

In 2020, the WHO claims that, in order to combat obesity, action must be taken from two directions: **on** the individual level, it recommends decreasing the intake of lipids and sugars, increasing the intake of fruits, vegetables, cereals, oleaginous fruits and increasing the level of physical activity, and **on** industrial level, **it** advocates reducing the use of fat, sugar and salt in processed foods, as well as ensuring the population has as many healthy food options as possible.[3]

Thus, obesity becomes a condition of very high severity, worrisome, which can be prevented through a good collaboration between the doctor, society and the individual. The more attention is directed to the real problems caused by obesity, the more nutritional intervention options and clinical trials appear that confirm or not certain eating patterns.

I also proposed that, through the scientific research carried out, to evaluate the clinical, biological and anthropometric relevance of educating the patient with obesity, at the expense of a standardized diet, based on fixed portions, food weighing and certain food restrictions.

We included two groups of patients: one composed of patients with a body mass index over 25 kg/m² and the other of patients with prediabetes. The goal was to find a

common denominator for these categories of patients who, through reassessment and nutritional intervention, lose weight and improve their glycemic control to preserve pancreatic beta cell function and, in this way, achieve the prevention of type 2 diabetes.

Also, an important factor was the simplicity of this process, so that the implementation of these notions is staged and does not last more than 20 minutes, so that the patient can maintain his focus and obtain as much compliance as possible with the process of nutritional intervention.

The first study, "Evaluation of the effectiveness of a nutrition education program among patients with prediabetes", was interventional, prospective and aimed at adapting a lifestyle to prevent diabetes. As a secondary hypothesis, I proposed a decrease in HbA1c, in all follow up visits.

The usual biological parameters were determined for the patients (full blood count, lipid profile, renal profile, liver profile, blood glucose, ESR, TSH), and for those who presented a fasting blood glucose value that exceeded the value of 100 mg/dL, their HbA1c was collected, a parameter we used to diagnose prediabetes.

The diagnosis of prediabetes was made according to the diagnostic criteria recommended by the American Diabetes Association, HbA1c between 5.7% and 6.4%.

The patients were subsequently re-evaluated every six months in four visits, and the results revealed the absence of diabetes for most patients, so the main objective of the research was achieved. The results were favorable due to the implementation of a healthy lifestyle with daily physical activity, regular meals, adequate water intake and decreasing the amount of foods rich in refined sugars.

A small number of patients presented at the 18-month assessment (less than 10% of the included group), on the one hand because the group is still recently formed and not enough time has passed for them to present themselves for re-evaluation, as a result of the lack of compliance with the lifestyle program, and on the other hand because of the epidemiological situation that appeared during the study.

Starting from this lack of compliance in adapting to a healthy lifestyle, without severe restrictions, we continued with study 2, designed to evaluate, on a population with excess weight or obesity, in the first place what is the evolution of weight only through nutritional intervention, using the same nutritional principles mentioned previously, as well as assessing the quality of life of these patients.

I thus, set a goal of 10% weight loss and improved quality of life after enlistment. Biologically, patients had all the usual blood parameters collected both at enrollment and at the 10% threshold.

There is an extremely important association between obesity and mental health conditions, which affects the obese patient in all aspects related to the quality of life.[4] The pathophysiological mechanism that links these two very serious conditions is still not known, but it is already extremely clear that the factors that affects the patient's emotional state precede the onset of obesity, along with society's attitude towards these patients.[4]

Obesity, unfortunately, is very often associated with a negative attitude from society. Weight stigma is defined as negative attitudes and direct discriminatory behavior.[5] But not only society contributes to the decrease in the quality of life of these patients, but also, themselves, through internalized self-stigmatization. These types of behaviors affect the individual in the social sphere, the couple's relationship, self-respect, and can even lead to self-hatred.[6]

In this direction, a bidirectional association between weight loss intervention and quality of life has been demonstrated, by substantially improving it, which indicates a major importance of psychological assessment of the patient at the beginning and during a weight loss program. [7]

The quality-of-life questionnaire used was WHOQOL-BREF, and patients weight was determined using the TANITA bioimpedance body analyzer.

Thus, we evaluated both the quality of life of overweight or obese patients, as well as the relationship between the quality-of-life score and the rate of weight loss.

62 patients were included in the study, with an average age of 47.13 years, of which 24.2% were male. Regarding the personal pathological medical history of the patients included in the study, hypertension was present in 19 patients, dyslipidemia in 39 patients and prediabetes in 18 patients. The patients continued the lipid-lowering treatment they had previously.

Most patients fell into the 1st and 2nd stage of obesity (32.26%). Stage 3 obesity was present for 27.42%. Only 6.452% of patients were in the overweight category.

The study was divided into three parts to assess both the quality of life of overweight or obese patients and the relationship between weight loss and domain scores of the WHOQOL-BREF questionnaire.

In the first part of the study, the group was analyzed from the point of view of anthropometric indices, biological parameters, the presence and distribution of cardiovascular risk elements.

The second part of the study was devoted to the evaluation of the internal consistency of the questionnaire applied to the enrolled patients, using the method of consistency of the questions in the questionnaire, described by Cronbach, and a confirmatory factor analysis, which showed a good consistency, the questionnaire being relevant to be used in the studied population.

In the third part of the study, a comparative analysis was carried out between the values of total weight, fat mass and muscle mass (both in absolute value and in percentage value) at the start of the nutritional education program, and after its conclusion. The statistical significance of the results confirmed the usefulness of a nutrition education program. Patients showed a significant decrease in total weight, fat mass weight, fat mass percentage, with maintenance of muscle mass weight and basal metabolic rate.

In the last part of the study, the influence of quality of life on the effects of the nutrition education program was analyzed. Thus, it could be observed that there is a close correlation between the level of body mass index and the degree of quality of life. The higher the degree of obesity, the lower the quality of life, and this is closely related to patient's compliance with a nutritional plan, weight loss or nutrition education.

So, the earlier the intervention on weight occurs, the faster and more relevant the patient's results are and, finally, the quality of life does not start to decrease considerably.

1. STUDY 1: EVALUATION OF THE EFFECTIVENESS OF A FOOD EDUCATION PROGRAM AMONG PATIENTS WITH PREDIABETES

Introduction

Diabetes mellitus 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 neoplasia.[8]

In the year of 2021, the prevalence of diabetes worldwide was 537 million cases, i.e. 1 in 10 people, and the mortality associated with this condition was 6.7 million cases. In the current trend, it is estimated that in 2030 there will be 643 million patients diagnosed with diabetes, and in 2045, 783 million. Healthcare costs related to diabetes reached \$966 million

in 2021, representing a 316% increase over the past 15 years. Regarding prediabetes, the worldwide prevalence is 541 million cases.[8]

Narrowing down the information to the continent we are on, in Europe there were 61 million patients diagnosed with diabetes in 2021, with the mention that only 1 in 3 patients is diagnosed, and the mortality caused by diabetes was 1.1 million. The costs borne by the health system were 186 million dollars.[8]

Working hypothesis and general objectives

The primary objective of this study was:

— demonstrating the importance of the prevention program for decreasing the rate of progression to type 2 diabetes or even normalizing the values of the studied biological parameters (HbA1c).

The secondary objectives of this study were:

— periodic evaluation of the metabolic control of patients with prediabetes by means of repeated HbA1c measurements at six-month intervals.

— comparing the initial HbA1c values (start) with the HbA1c values collected after the establishment of a prevention program that involves changing the current lifestyle (every six months);

— estimation of global compliance of patients with prediabetes to the prevention program by presenting to periodic consultations.

— estimating the adherence of patients with prediabetes to the plan of the prevention program, a fact objectified by the decrease in HbA1c.

Material and method

The study was interventional, prospective, randomized on a sample of 267 patients with prediabetes, a representative sample for a population of patients at risk of developing DM, followed and treated in a specialized center.

Inclusion criteria:

- adults with a minimum age of 18;
- carbohydrate metabolism disorder that does not meet the ADA criteria for diabetes: IFG, or IGT, HbA1c value in the range of 5.7-6.4%.

Exclusion criteria:

- patients with a positive diagnosis of DM 1, DM 2 or gestational DM;

- extreme HbA1c values (< 5.4% or > 6.5%);
- age under 18 years;
- pregnancy or lactation;
- refusal to complete the informed consent.

The patients presented themselves at CMI Dr. Alexescu Alexandra and at the Clinical Hospital "N. Malaxa" with fasting blood glucose values above normal limits, for the purpose of screening for diabetes. Patients who met the enrollment criteria were included. At study inclusion, participants were clinically, anthropometrically and biologically assessed. Sampling for the assessment of biological parameters was done after 12 hours of fasting. The biological parameters used were represented by:

- full blood count
- lipid profile (total cholesterol, LDL, HDL, triglycerides)
- renal profile (uric acid, urea, creatinine)
- liver profile (TGO, TGP)
- serum glucose
- glycosylated hemoglobin
- total calcium
- magnesium
- sideremia
- TSH
- ESR

Biological investigations were performed in accredited laboratories. If certain deviations from the reference interval were discovered, the patients underwent additional blood tests or were referred to a specialist doctor.

After enrolled patients completed the biological investigations, they were introduced to the DIACLASS nutritional education program. It consisted of:

- Regular 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 the sensation that occurs 4-5 hours after the last meal, felt as a "hole in the stomach" accompanied by "specific noise") and stopping eating when satiety occurs.[9]
- Breakfast – at most one hour after waking up
- Lunch – 4-5 hours after breakfast
- Dinner – 3-4 hours before bed, ideally by 8 p.m.

- Snacks were optional and limited to approximately 100 kcal – fresh fruit, oleaginous fruit or low-fat dairy.
- Physical activity. The importance of physical activity was explained to the patients, so that during each consultation they committed to a minimum movement goal, such as 10,000 steps/day or 30 minutes of moderate-intensity physical activity five times per week (bicycle, treadmill, jogging, brisk walking, running, or fitness and aerobics programs), within personal tolerance.
- Distribution of carbohydrates at breakfast and lunch. Based on the idea of lifestyle balance, both high carbohydrate intake (>70%) and low carbohydrate intake (<40%) have been found to be associated long-term with an increased mortality rate. [10]
- Patients were explained what the main sources of carbohydrates were and were directed to sources that were as whole as possible and as rich in dietary fiber as possible.
- Starting from the idea of the distribution of carbohydrates in close connection with the daily activity rhythm, it was recommended to consume flour, legumes, potatoes and fruits until 6 p.m.
- Lipid intake. The recommendation regarding lipid intake was to avoid saturated fats from high-fat animal products (fatty meat, very fatty dairy products, margarine, chips, snacks, puff pastry).
- Alcohol intake. Regarding alcohol intake, the recommendation was to exclude it from the daily diet if the target was weight loss, to eliminate a caloric surplus in the daily diet. Later, as a principle of healthy eating, alcohol was reduced to a maximum of two servings per day for men and a maximum of one serving per day for women.[11]
- Water intake: 30-40 ml/kg daily.
- Culinary techniques: the thermal preparation of food by boiling, steaming, baking, grilling.

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

More than nutrition education per se, patients were explained the term "mindful eating", the difference between physiological and emotional hunger, as well as notions of emotional eating in particular cases.

Results

1.4.1. Demographic and anthropometric data

267 patients were included in the study, of which 155 were women and 122 were men. The percentage frequency of women included in the research (58.05%) is statistically significantly higher ($p=0.010$) compared to that of men (41.95%).

The distribution of patients according to age group is significantly different from the point of view of gender ($p<0.001$), the frequency of women being higher in the age groups over 60 years, and of men in those under 60 years.

The current weight distribution among the patients in the study is not ideal ($p=0.010$), it's average being 87.40 ± 19.79 kg. The weight of the patients at the time of the study is statistically significantly different depending on their gender (Mann-Whitney test $U=4635.50$; $p<0.001$).

Among women, the average current weight was 82.13 ± 17.89 kg, with a minimum value of 36 kg and a maximum of 140 kg. The median was 80 kg, the 25th percentile 70 kg, and the 75th percentile 91.75 kg.

Among male patients, the mean current weight was 94.61 ± 20.06 kg, with a minimum value of 50 kg and a maximum of 180 kg. The median was 90 kg, the 25th percentile 82.50 kg, and the 75th percentile 102 kg.

The body mass index of the patients included in the study correlates statistically significantly negatively ($r=-0.306$; $p<0.001$) with the age of the patients; the older the patients, the lower the body mass index. And vice versa.

The study of the distribution of patients according to weight status reveals that only 10.7% are normal weight, and 28.4% are overweight. Obesity occurs in 60.5% of study participants. Among them, most (37.45%) have grade 1 obesity, followed by those with grade 2 obesity (13.17%) and those with grade 3 obesity (9.88%).

1.4.2. Identification of comorbidities of patients in the studied group

The prevalence of hypertension in the patients included in the study is 72.69%. The prevalence of hypertension among women participating in the study is 76%, and among men, 68.18%. There are no significant differences between the prevalence of hypertension according to gender ($p=0.162$).

The prevalence of hypertension in patients aged between 30 and 39 years is 0%, in those aged 40-49 61.54%, and in those aged 50-59 58.49%. In patients over 60 years of age, the prevalence of hypertension was around 80%. The prevalence of arterial hypertension is

significantly different according to the age group ($p=0.001$), the highest prevalences being in patients over 60 years of age.

The prevalence of dyslipidemia in the patients included in the study is 77.01%, so an increased prevalence of dyslipidemia was also found in the studied group. The prevalence of dyslipidemia among women in the study is 76.82%, and among men, 77.27%. There are no significant differences between the prevalence of dyslipidemia according to gender ($p=0.932$).

The prevalence of dyslipidemia in patients aged between 30 and 39 years is 75.00%, in those aged 40-49, 84.62%, in those aged 50-59, 66.04%. In patients aged 60-69, the prevalence of dyslipidemia was 86.40%, in those aged 70-79, 74.42%, and in those aged 80 and over, it was 44.44%. The prevalence of dyslipidemia is statistically significantly different depending on the age group ($p=0.001$), the highest prevalence being in patients aged 60-69 years.

The evolution of the lipid profile panel was an expected one, following the nutritional intervention. Statistical significance was reached for mean LDL cholesterol values ($p=0.018$), but not for the other components of the lipid profile.

It is important to note that during the study no changes were made in the treatment after patient inclusion. Initial treatment was continued, with the only improvement being inclusion in the DIACLASS program.

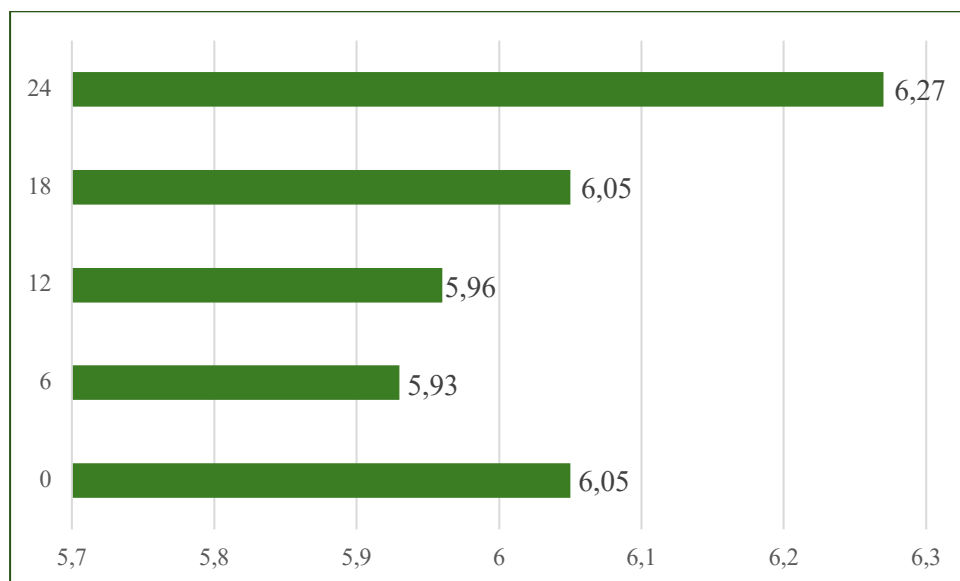
However, starting from the idea that LDL cholesterol is the most recommended marker to be used in the evaluation, diagnosis and treatment of dyslipidemia, it can be stated that the DIACLASS intervention on the lifestyle addressed in this paper, led to a decrease in LDL cholesterol and thus to a decrease in cardiovascular risk of enrolled patients, as all showed low values compared to baseline.

1.4.3. Patient adherence to the DIACLASS lifestyle intervention plan

The distribution of glycosylated hemoglobin at enrollment is Gaussian ($p=0.195$), at six months it is also Gaussian ($p=0.387$), also at 12 months ($p=0.423$), at 18 months ($p=0.838$) and at 24 months ($p=0.444$).

Taking into account all the patients included in the study, it was found that the average values of glycosylated hemoglobin differ statistically significantly ($p<0.001$) between the five moments evaluated, starting from an average value of $6.05\pm 0.22\%$ at the initial moment and having values of $5.93\pm 0.33\%$ at six months, $5.96\pm 0.39\%$ at 12 months, $6.05\pm 0.35\%$ at 18 months and $6.27\pm 0.51\%$ at 24 months.

The evolution of the mean values of glycosylated hemoglobin during the visits



The assessment of the prevalence of diabetes was made at one year and at two years, by performing HbA1c.

Of the 69 patients who were included in the one-year diabetes prevalence study, five patients had diabetes, so the 12-month diabetes prevalence is 7.25%.

Among the 47 patients in whom the presence of diabetes was assessed at 24 months, it was found that 13 patients (27.7%) had diabetes.

It is already known that the evolution from prediabetes to diabetes is almost certain, in a variable time. In this study, progression to diabetes was delayed for 92.75% of patients at 1 year and for 72.34% at 2 years.

1.4.4. Patient compliance to the diabetes prevention program

Among the 276 patients included in the study, 85 patients showed up at the 6-month visit, 67 patients at the 12-month visit, 24 patients at 18 months, and 47 patients at 24 months.

Patient compliance when it comes to prevention is an extremely important public health issue. However, prevention programs for chronic diseases are growing in Romania, so attention to the aspects that delay the patient to the medical consultation are extremely important to be able to implement an effective program.

In addition to social or medical education aspects, in this study patient compliance was hampered by the SARS-COV2 virus pandemic, which considerably limited patient visits to medical clinics in the middle of this study.

Conclusions

The present study followed the effects of a nutritional education program through the DIACLASS lifestyle change of 267 patients from Romania, diagnosed with prediabetes through the value of fasting blood glucose and glycosylated hemoglobin, as well as the level of compliance and adherence to the nutritional plan, in depending on age, gender or degree of obesity.

- The average age of the population was 64.1 ± 9.725 years, with a statistically significantly higher prevalence for the female group over 60 years old and the male group under 60 years old. ($p < 0.001$)
- The average weight of the population included in the study was 87.50 ± 19.79 kg, and the average body mass index was 31.58 ± 19.79 kg/m², with a statistically significantly different distribution according to age, thus that the older the patients included in the study were, the lower their weight and BMI were ($p < 0.001$).
- Hypertension had a prevalence of 72.69% in the studied group, with a statistically significantly increased prevalence in the over 60 age group ($p = 0.001$), but without statistical significance depending on weight status.
- Of the total number of patients with hypertension included in the study, 11.23% were diagnosed with this condition at the time of enrollment in the study.
- Dyslipidemia had a prevalence of 77.01% in the studied group; of all patients with dyslipidemia, 31.5% were diagnosed at the time of study enrollment.
- Dyslipidemia was encountered most frequently in the 60-69 age group ($p = 0.001$).
- HbA1c values showed a statistically significant decrease in the first year of follow-up, with no statistically significant differences between gender groups.
- The evolution of the lipid profile was favorable; LDL cholesterol showing a decrease of 10.25 mg/dl ($p = 0.010$).
- The prevalence of diabetes 12 months after inclusion in the study was 7.25%, and at 24 months, 27.7%.

- Compliance with the nutritional education program for patients with prediabetes was decreasing: 31.84% showed up at the second visit, 25.09% at the third and only 17.60% at the 24 months.
- The 30-39 age group showed the highest level of compliance.
- Patients with grade 2 obesity showed the highest level of compliance.
- No statistically significant differences were identified between genes in relation to the level of compliance.

2. STUDY 2: ASSESSMENT OF QUALITY OF LIFE AND EFFICACY OF A NUTRITION EDUCATION PROGRAM AMONG PATIENTS WITH OVERWEIGHT OR OBESITY

2.1.Introduction

Morbidity and mortality associated with obesity has been a well-known fact for more than 2,500 years, since the time of Hippocrates.[12]

Optimal management of overweight or obese patients should combine a calorie-restricted diet, physical activity, and cognitive-behavioral therapy. Associated with these, some patients may also require pharmacological therapy or bariatric surgery.[13]

2.2.Working hypothesis and general objectives

The aim of the second study was to evaluate the quality of life of overweight or obese patients, adherence to the DIACLASS nutrition education program and the relationship between body weight and its compartments with quality of life.

The main objectives of the study were:

- obtaining a decrease in body mass of 10% of the initial weight, through the DIACLASS nutritional education program.
- assessment of the quality of life of overweight or obese patients.
- the influence of the quality of life on the effects of the DIACLASS nutritional education process.
- investigating the existence of correlations between the outcome of the nutritional education process and the quality of life, as quantified by the patient questionnaire.

The secondary objectives of the study were:

- body analysis assessment during the DIACLASS nutritional education program.

— identification of possible demographic-clinical parameters that can influence the patient's response to the nutritional education process.

2.3. Material and method

The second study of this paper was a prospective, experimental, non-randomized study, on a sample of 62 patients with obesity and overweight, enrolled from the Individual Medical Practice Dr. Alexescu Alexandra and from the Clinical Hospital "N. Malaxa" Bucharest, who followed a medical-nutritional therapy program whose main goal was to educate the patient from a nutritional point of view and optimize the lifestyle.

In this group, the quality of life was quantified with the help of a specialized questionnaire (WHOQOL-BREF), the sample being representative of a population with obesity diagnosed and treated by a specialist in diabetes, nutrition and metabolic diseases.

Inclusion criteria in the study:

- age over 18 years;
- willingness to participate;
- overweight or obesity;
- balanced chronic conditions;
- patients who can perform physical activities;
- accepting and completing the informed consent;
- the possibility to complete the WHOQOL-BREF quality of life assessment questionnaire.

Exclusion criteria from the study:

- BMI below 25 kg/m²;
- the impossibility of understanding and completing the WHOQOL-BREF quality of life assessment questionnaire;
- chronic conditions that require specific medical-nutritional therapy;
- contraindication in using the body analyzer with bioimpedance;
- pregnancy;
- lactation.

The subjects were selected from both genders, aged over 18 years, with a body mass index of over 25 kg/m², who presented themselves to the doctor expressing their desire to lose weight, in the period 2019-2021. Patients who met all inclusion criteria were enrolled in the study.

The dependent variables discussed were:

- total weight values before and after implementation of the nutritional education program;
- the values of the weight of fat mass before and after the implementation of the nutritional education program;
- fat-free mass weight values before and after the implementation of the nutritional education program;
- BMI values before and after the implementation of the nutritional education program;
- the values of the total scores and by domains in the administered questionnaire;
- biological parameters.

The independent variables were:

- patient demographic data;
- data quantifying the patient's social status.

The sampling for the evaluation of the biological parameters was done, according to the recommendations, after 12 hours of fasting.

The biological parameters used were represented by:

- full blood count;
- lipid profile (total cholesterol, LDL, HDL, triglycerides);
- renal profile (uric acid, urea, creatinine);
- liver profile (TGO, TGP);
- blood sugar;
- glycosylated hemoglobin;
- total calcium;
- magnesium;
- sideremia;
- TSH;
- ESR.

The weight assessment was carried out with the help of a TANITA weight analyzer that uses the bioimpedance method as its operating principle. Quality of life was assessed using the WHOQOL-BREF questionnaire, the Romanian version, which was self-administered by the patient. The questionnaire includes 26 questions, grouped into 4 assessment areas - physical health, mental health, social relations and the environment.

The DIACLASS nutrition education program contained the same terms, addressed in chapter 1, subchapter 1.3.

The data were collected in Microsoft Excel 2013, then they were coded and constituted a database in SPSS 23.0 (Statistical Package in Social Sciences 23.0).

2.4. Results

2.4.1. Description of patient's profile

A number of 62 patients were included in the study, 15 of them (24.2%) were male, and the remaining 47 (75.8%) were female. The distribution of patients according to their gender is statistically significantly different ($p < 0.001$).

The 62 patients participating in the study are Gaussian distributed according to age ($p = 0.834$), with an average of 47.13 ± 13.46 years.

The mean age does not differ statistically significantly according to the gender of the patients ($p = 0.947$), being 47.33 ± 11.21 years in men and 47.06 ± 14.21 years in women.

The distribution of patients by age groups is made without statistically significant differences ($p = 0.052$) and without significant differences according to their gender by age groups ($p = 0.548$). However, most patients belong to the age groups 40-49 years (15 patients, six men and nine women) and 50-59 years (14 patients, four men and ten women).

The distribution according to the level of education of the patients participating in the study is significantly different ($p < 0.001$), with most patients having higher education (24 patients, 39.3%). The distribution according to educational level and gender does not show statistically significant differences ($p = 0.664$).

Also, the distribution of the entire group of patients according to marital status shows statistically significant differences ($p < 0.001$), with most patients being married (35 patients, 56.5%).

Regarding the distribution of patients according to marital status and gender, it does not show statistically significant differences ($p = 0.886$).

Regarding the comorbidities present in the studied group, the prevalence of arterial hypertension in the patient group is 30.6%, statistically insignificantly ($p = 0.304$) higher in women (34.0%) compared to men (20%).

The prevalence of prediabetes in women is 25.5%, statistically insignificant ($p = 0.282$) lower than the prevalence of prediabetes in men (40%). Across the entire cohort, the prevalence of prediabetes is 29%.

Dyslipidemia registered a prevalence of 62.9% in the entire group of patients who were included in the study, not being statistically significantly ($p = 0.378$) different in women (66%) compared to men (53.3%).

2.4.2. Evaluation of biological parameters following the DIACLASS nutritional education program

From the point of view of biological parameters, we analyzed the group of patients from two perspectives. We evaluated at baseline the difference between the biological parameters evaluated in the group of patients who later reached the weight loss target of 10%, compared to those who did not reach this goal. It was found that there were differences between the two groups, but without statistical significance.

The evolution of the biological parameters evaluated at baseline and post-intervention, in the group that reached the target weight, showed changes, but also in this case without statistical significance.

2.4.3. Identifying the effects of the DIACLASS nutrition education program on body weight and body composition

The mean of the body mass index within the group that reached the proposed target is statistically significantly ($p < 0.001$) lower post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean body mass index is also statistically significantly ($p < 0.001$) lower after the intervention compared to when the study started.

The average total weight within the group that reached the proposed target is statistically significantly ($p < 0.001$) lower post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean total weight is also statistically significantly ($p < 0.001$) lower after the intervention compared to when the study started.

The average fat weight in the group that reached the proposed target is statistically significantly ($p = 0.014$) lower post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean fat weight is also statistically significantly ($p = 0.001$) lower after the intervention compared to when the study started.

The mean percentage of fat in the group that reached the proposed target is statistically significantly ($p < 0.001$) lower post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean body fat percentage is also statistically significantly ($p = 0.018$) lower after the intervention compared to when the study started.

The average of the percentage of muscles within the group that reached the proposed target is statistically insignificant ($p = 0.670$) higher post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean percentage of muscle is also statistically insignificant ($p = 0.138$) higher after the intervention compared to when the study started.

The average percentage of water within the batch that reached the proposed target is statistically insignificant ($p = 0.797$) higher post-intervention compared to the time of inclusion in the study.

Within the group that did not reach their proposed target, the mean percentage of water is also statistically insignificant ($p = 0.292$) higher after the intervention compared to when the study started.

The average of the basal metabolic rate within the group that reached the proposed target is statistically significantly ($p < 0.001$) lower post-intervention compared to the time of inclusion in the study.

In the group that did not reach its proposed target, the average basal metabolic rate is statistically insignificantly ($p = 0.739$) higher after the intervention compared to when the study started.

Evolution of weight, body mass index and body composition before and after the DIACLASS program for patients who reached the weight goal

Parameter	Baseline	Post-interventional	p
BMI	30,54±4,83	25,88±2,78	<0,001
Weight	99,7±15,12	86,07±11,68	<0,001
Body fat (%)	33,95±8,05	29,16±5,41	0,014
Lean mass (%)	58,55±9,16	59,89±2,68	0,670
Water (%)	43,81±13,39	43,02±2,01	0,797
BMR	1707,28±248,31	154,14±137,21	<0,001

Evolution of weight, body mass index and body composition before and after the DIACLASS program for patients who did not reach the weight goal

Parameter	Baseline	Post-interventional	p
BMI	36,52±6,49	35,51±6,23	0,001
Weight	102,48±21,43	100,01±20,66	0,001
Body fat (%)	42,66±5,77	41,65±6,39	0,018
Lean mass (%)	54,65±6,39	55,36±6,15	0,138
Water (%)	41,54±3,91	39,75±10,67	0,292
BMR	1781,17±467,70	1799,03±371,53	0,739

2.4.4. Evaluation of the results of the DIACLASS nutritional education program on patient's quality of life

The reliability analysis of the questionnaire was carried out, both for each of the four domains of the questionnaire and for the entire questionnaire, by studying the reliability of the questionnaire by domains and in total, before and after the nutrition education program. The evaluation of the reliability of the questionnaire was carried out using two techniques for calculating the internal consistency: the correlation of the scale of the items and the Cronbach α coefficient.

The pre-intervention Cronbach α coefficient was 0.830 (95% CI 0.759-0.888), indicating good reliability of the entire questionnaire before the start of the nutrition education program.

The post-intervention Cronbach α coefficient was 0.807 (95% CI 0.581-0.943), indicating good reliability of the entire questionnaire after participating in the nutrition education program.

The evolution of the quality of life, based on the total score of the evaluation questionnaire, showed a statistically significant increase ($p=0.040$), after the application of the nutritional education program by 5.60 ± 8.61 .

The mean score of the Physical Health domain increased statistically significantly ($p=0.017$) after applying the nutritional education program by 3.60 ± 3.89 .

The mean score of the Mental Health domain increased statistically insignificantly ($p=0.052$) after applying the nutritional education program by 2.50 ± 4.19 .

The mean score of the Social Relations domain increased statistically significantly ($p=0.049$) after applying the nutritional education program by 1.30 ± 2.16 .

The mean score of the Environment domain increased statistically insignificantly ($p=0.819$) after the application of the nutritional education program by 0.30 ± 4.03 .

2.4.5. Identifying factors influencing quality of life outcomes of the DIACLASS nutrition education program

Quality of life scores correlate with some of the sociodemographic and morbidity characteristics of the patients included in the study.

The differences obtained in terms of the D1 Physical Health score are statistically significantly negatively correlated with the patient's age ($p=0.018$), i.e. the older the patient's age, the smaller the increase in the Physical Health score was, and statistically significantly with their gender ($p=0.036$), i.e. the increase recorded in the Physical Health score was greater in women.

The difference in D2 Mental Health score was statistically significantly negatively correlated with pre-intervention body mass index ($p=0.032$), i.e. the lower the pre-intervention body mass index, the more the Mental Health score improved after the intervention program. nutritional education.

The difference in the Ambient D4 score was statistically significantly negatively correlated with the number of kilograms lost ($p=0.047$) and with the age of the patients ($p=0.020$), i.e. the lower the number of kilograms lost and the lower the age of the patients, the lower the D4 score improved more. Also, the D4 score was significantly correlated with the existence of prediabetes, that is, the D4 score improved more in patients with prediabetes following the intervention.

The total WHOQoL score correlated statistically significantly negatively with the patient's age ($p=0.011$) and with their gender ($p=0.044$), in other words, the improvement in the WHOQoL score was greater the lower the patient's age and increased more at female patients.

2.5. Conclusions

- Regarding body compartments, the nutritional intervention had beneficial effects, achieving statistical significance for the decrease in body mass index, total weight and fat mass.
- Muscle mass showed a statistically insignificant decrease following the nutritional intervention.
- Basal metabolic rate showed a slight decrease, without statistical significance.

- Weight loss of 10% brings with it an increase in the quality of life, by evaluating the total score by applying the WHOQOL-BREF questionnaire.
- The field of physical health and social relations shows significant statistical improvements following the 10% weight loss.

3. GENERAL CONCLUSIONS

The implementation of a phased DIACLASS nutritional education program brought significant benefits both for patients with prediabetes and for those with various degrees of obesity or overweight.

The concepts provided are common to various pathologies and are geared towards educating patients about a healthy lifestyle, not just a healthy diet.

The originality of this research consists in the elaboration of a synthesis of the general recommendations of food education, the DIACLASS program, with the introduction of the restriction of carbohydrates at dinner and its application to two groups of patients: one with patients with prediabetes, another with patients with obesity or overweight.

The use of the quality-of-life assessment tool (WHOQOL-BREF) was helpful for a more complex and multi-perspective analysis (all four domains of quality of life), through the perception of patients and their quality of life.

The results emphasize that obesity management not only leads to a decrease in morbidity and mortality, but also to an increase in the quality of life for the overweight population in Romania.

Following this scientific research, in 2022 we created a digital platform that makes available to patients, in a virtual environment, the information provided to the patients included in the present study. Up to the present moment, the DIACLASS.RO platform has 1200 subscribers, and the online courses have been followed in their entirety by 210 people. The creation of this platform supports the present work, to make the information provided in the office available to as many people as possible, in order to achieve the greatest possible effect on the Romanian population.

The online social environment is an important part of patient's lives, and a digital platform that provides patients with prediabetes or obesity with valid information with scientific results can be a public health solution to intervene in stopping the progression from prediabetes to diabetes and reducing obesity.

The present study was conducted in a large population and during the pandemic years following the SARS-COV2 virus, so it could be observed how the addressability of the

patients included in the study decreased. In this light, DIACLASS.RO comes to the support of patients through the digital interface.

4. PERSONAL CONTRIBUTIONS

The personal contributions in this research paper consist in the development of a type 2 diabetes prevention program (appendix 1), for the Romanian population, which offers flexible indications, as easy as possible to follow, based on the recommendations present in the specialized literature, at to which we added limiting carbohydrate intake to the last meal of the day.

In addition to summarizing the nutritional recommendations of the DIACLASS program, we have built a digital platform with the same name (www.diaiclass.ro – Your Diabetes Academy) that provides all the information related to the prevention of diabetes in the online environment.

We found this method of delivering information to patients opportune due to the low attendance at preventive consultations, especially during the SARS-Cov2 pandemic when the online environment proved to be a more accessible communication channel for patients.

BIBLIOGRAPHY

1. Bray BA, Kim KK, Wilding JPH. Obesity is a chronic relapsing progressive disease process: A position statement of World Obesity Federation. *Obesity Reviews*. 2017;18:715-723 (7).
2. NCD Risk Factor Collaboration. Worldwide trends in bodymass index, underweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128,9 million children, adolescents, and adults. *Lancet*. 2017;390:2627-2642.
3. World Health Organization. Obesity and overweight. [online] Available at: <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>.
4. Taylor VH, Forham M, Vigod SN, et al. The impac of obesity on quality of life. *Best Practice & Research Clinical Endocrinology & Metabolism*. 27 (2013) 139 – 146.
5. Puhl RM, Heuer CA. The stigma of obesity§ A review and update. *Obesity (Silver Spring)*. 2009;17(5):941 – 964.

6. Durso LE, Latner JD. Understanding self-directed stigma: development of the weight bias internalization scale. *Obesity (Silver Spring)*.2009;16(suppl. 2): S80 – S86.
7. Payne ME, Porter Starr KN, Orenduff M, et al. Quality of life and mental health in older adults with obesity and frailty: association with a weight loss intervention. *J Nutr Health Aging*. 2018;22(10):1259 – 1265.
8. IDF diabetes atlas - 2021.
9. Fred Brouns. Overweight and diabetes prevention: is a low-carbohydrate-high-fat diet recomandable?. *European Journal of Nutrition*, 57:1301-1312, 2018.
10. Sidelmann SB, Claggett B, Cheng S, et al. Dietary carbohydrate intake and mortality: a prospective cohort study and meta-analysis. *Lancet Public Health*. 2018;3:e419-e428.
11. US Department of Agriculture and US Department of Health and Human Services. *Dietary Guidelines for Americans, 2020 – 2025*. 9th edition. December 2020. Available at DietaryGuidelines.gov.
12. Mota M, Popa SG, Mota E, et al. Prevalence of diabetes mellitus and prediabetes in the adult Romanian population: PREDATORR study. *Journal of Diabetes*. 2015.
13. Wannamethee SG, Shaper AG. Weight change and duration of overweight and obesity in the incidence of type 2 diabetes. *Diabetes Care* 1999; 22: 1266-72.

LISTA LUCRĂRILOR PUBLICATE

1. „Boala arterială periferică și sindromul metabolic în rândul pacienților cu diabet zaharat tip 2”. **A. Ilinca**, E. Rusu, R. Drăguț, C. Parpală, A. Coșniță, O. Crăciun, G. Radulian – prezentare poster la al 40-lea Congres al SRDNBM, Sibiu, 2014.
2. „Evaluarea statusului nutrițional într-o comunitate rromă” **A. Ilinca**, E. Rusu, G. Enache, F. Rusu, M. Jinga, R. Drăguț, R. Nan, H. Popescu-Vâlceanu, C. Parpală, I. Teodoru, G. Radulian – prezentare poster la al 12-lea Congres al FRDNBM, Cluj-Napoca, 2014.
3. „Evaluarea statusului nutrițional într-o comunitate din județul Călărași” – **A. Ilinca**, E. Rusu, G. Enache, G. Radulian – prezentare poster la al 41-lea Congres al SRDNBM, Sibiu, 2015.

4. „Evaluarea afecțiunilor metabolice într-o populație rromă” – **A. Ilinca**, R. Radu, E. Rusu, G. Enache, C. Cristofor, F. Rusu, R. Drăguț, R. Nan, G. Radulian, prezentare poster la al 13-lea Congres al FRDNBM, Timișoara, 2015.
5. „Terapia cu pompă de insulină la un pacient cu diabet zaharat tip 1” – **A. Ilinca**, C. Novac, E. Rusu, C. Cristofor, R. Radu, G. Radulian – prezentare poster la al 42-lea Congres al SRDNBM, Brașov, 2016.
6. „Terapia medical nutrițională în afecțiunile bronhopulmonare” – „Managementul nutrițional în diabetul zaharat, boli metabolice și alte patologii”, Coordonator Prof. Dr. Gabriela Radulian, Editura Universitară „Carol Davila”, volumul 2, București, 2015.
7. Relația dintre indicele de masă corporală și echilibrul glicemic în rândul pacientelor cu diabet gestațional / Relationship between body mass index and glycemic balance in patients with gestational diabetes – **Alexescu A.**, Popa D., Mihalache D., Șoldea L., Mihai A., Radu F., Rusu E., Radulian G., Acta Diabetologica Romana, 2017; 43: 97-98. Al 43-lea Congres Național al SRDNBM, 24-27 mai 2017, Brașov, România.
8. Inițierea terapiei cu infuzie subcutanată continuă cu insulină. **Alexescu A.**, Cavalioti-Enache T., Rusu E., Radulian G., Practica tânărului diabetolog, 2017. Editura Universitară de Medicină și Farmacie „Iuliu Hațieganu” Cluj-Napoca, nr.7.
9. Impactul implementării unui program de educație asupra pacienților cu diabet zaharat tip 1 sub tratament cu infuzie subcutanată continuă cu insulină. **Alexescu A.**, Young Diab. 6-8 iulie 2017, Cluj-Napoca, România.
10. Complicațiile microvasculare ale diabetului zaharat și afecțiunile oftalmologice. **Alexescu A.**, Alexescu M., Cavalioti-Enache T., Radulian G., Oftalmologie. 2018-2019; 18.
11. The Effects of weight loss in body composition of obese and overweight patients. **Alexescu A.**, Rusu E., Dragomir A., Pietriși N., Radulian G., Romanian Journal of Diabetes, Nutrition and Metabolic Diseases. 27 (2):9-13, 2020.
<https://rjdnmd.org/index.php/RJDNMD/article/view/767>
12. Patterns used in weight loss in patients with obesity: a literature review – **Alexescu A.**, Rusu E., Radulian G., Romanian Journal of Diabetes, Nutrition and Metabolic Diseases. 28 (1):88-92, 2021. <https://www.rjdnmd.org/index.php/RJDNMD/article/view/912>

ANEXA

Principii pentru un Stil de Viață Sănătos



Nume Prenume

Greutatekg, IMCkg/mp

1. Mese regulate:

- Mic Dejun:
- Gustare 1:
- Prânz:
- Gustare2:
- Cină:

2. Evită la cină carbohidrații din:

- Dulciuri
- Cartofi
- Fructe
- Făinoase (pâine, orez, paste, cereale, mămăligă, griș, cous-cous)
- Leguminoase (fasole boabe, linte, năut, mazăre)

3. Activitate fizică:

4. Aport hidric:

- 30-40 ml/kgc/zi

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CÂTEVA SFATURI...



Legume/fructe:

- Ai grijă să ai câte o porție de legume proaspete la fiecare masă
- Evită fructele la masa de seară

Produse animale

- Pește: minim de 2 ori pe săptămână
- Carne albă nu mai mult de 1 masă/zi
- Carne roșie (de preferat slabă: muschiuleț de porc, mușchi de vită) - maxim 1 dată/săptămână
- Lactate: 1 masă/zi Ouă: 4 bucăți /săptămână

Gastrotehnie:

- Evită să prepari termic uleiul
- Folosește cât mai mult grătarul/cuptorul (cu condimente din belșug - pentru a păstra gustul cât mai plăcut al alimentelor).

Și încă ceva!

- Păstrează 1 masă pe zi, fără produse animale.
- Evită foietajele, dulciurile sau orice alt aliment care conține zahăr adăugat.
- Încearcă să nu folosești mai mult de 1 lingură de ulei la 1 kg de mâncare atunci când gătești.

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