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Artigo Original

Nutritional and Clinical Intervention in Patients with Uncontrolled Type 2 Diabetes Mellitus and Overweight or Obesity

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INFORMAÇÃO SOBRE O ARTIGO

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A B S T R A C T

Introduction: To evaluate the extent to which nutritional counselling and intensified clinical follow-up improve metabolic control in a sample of patients with uncontrolled type 2 diabetes mellitus and overweight or obesity.
Materials and Methods: Randomised controlled trial of three months' duration, with 49 participants with type 2 diabetes mellitus, glycated haemoglobin (HbA_{1c}) of more than 7% (53 mmol/mol) and overweight or obesity. The experimental group received individual nutritional recommendations and a clinical surveillance monthly during the three months of intervention. The control group continued their routine clinical monitoring. Anthropometric measurements, laboratory parameters and blood pressure values were the main outcome measures.
Results: At three months, there was a 0.6% reduction in glycated haemoglobin in the experimental group ($p = 0.001$), which was significantly different when compared with the control group ($p = 0.037$). The difference in waist ($p = 0.003$), hip ($p = 0.014$), brachial ($p = 0.011$) and crural ($p = 0.000$) circumferences; biceps ($p = 0.011$), triceps ($p = 0.000$), subscapular ($p = 0.002$) and crural ($p = 0.043$) skinfolds thickness; waist-height index ($p = 0.004$); body density ($p = 0.000$); and body fat percentage ($p = 0.000$) was statistically highly significant between experimental and control group.
Conclusions: A short-term nutritional and clinical intervention improves the anthropometric, metabolic and glycaemic control in patients with uncontrolled type 2 diabetes mellitus and overweight or obesity.

Intervenção Nutricional e Clínica em Pacientes com Diabetes Mellitus Não Controlada e Excesso de Peso ou Obesidade

Palavras-chave:
Antropometria
Diabetes Mellitus Tipo 2
Excesso de Peso
Obesidade
Terapia Nutricional

R E S U M O

Introdução: Avaliar em que medida o aconselhamento alimentar e a intensificação do acompanhamento clínico melhoraram o controlo metabólico uma amostra de pacientes com diabetes *mellitus* tipo 2 não controlada e excesso de peso ou obesidade.
Material e Métodos: Ensaio clínico controlado e aleatorizado com uma duração de três meses, com 49 participantes com diabetes *mellitus* tipo 2, hemoglobina glicada (HbA1c) superior a 7% (53 mmol/mol) e excesso de peso ou obesidade. O grupo experimental recebeu recomendações nutricionais individuais e uma vigilância clínica mensal durante os três meses de intervenção. O grupo controle

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continuou a sua monitorização clínica de rotina. As medidas antropométricas, parâmetros laboratoriais e valores de pressão arterial foram os principais resultados.
Resultados: Aos três meses, houve uma redução de 0,6% na hemoglobina glicada no grupo experimental (p = 0,001), o que foi significativamente diferente quando comparado com o grupo controle (p = 0,037). A diferença nos perímetros abdominal (p = 0,003), da anca (p = 0,014), braquial (p = 0,011) e crural (p = 0,000); pregas cutâneas bicipital (p = 0,011), tricipital (p = 0,000), subescapular (p = 0,002) e crural (p = 0,043); índice cintura-altura (p = 0,004); densidade corporal (p = 0,000); e percentagem de gordura corporal (p = 0,000) foi estatisticamente significativa entre os grupos experimental e controlo.
Conclusões: As intervenções nutricional e clínica a curto prazo melhoram o controlo antropométrico, metabólico e glicêmico em pacientes com diabetes *mellitus* tipo 2 não controlada e sobrepeso ou obesidade.

Introduction

Diabetes mellitus is becoming a worldwide epidemic.[1-3] Recent estimates indicate that, in 2000, the worldwide prevalence of diabetes mellitus was 171 million people and it is expected that this number will reach 366 million by 2030.[3] Type 2 diabetes mellitus (DM2) is the most common form of diabetes, comprising 90% - 95% of cases.[4] The increasing prevalence of this is associated with several factors, among which the obesity and/or central adiposity increase.[5-7] Several anthropometric measurements were positively associated with the risk of developing this and other metabolic and cardiovascular diseases, including waist circumference[5-7] and subscapular skinfold,[5] as well as estimates the body mass index,[5] waist-to-hip ratio,[5] waist-to-height ratio,[5] waist-to-thigh ratio[7] and body fat percentage.[5] The regional fat distribution, in particular its central distribution, may be a better predictor of the type 2 diabetes progression overall adiposity.[5-7] In contrast, peripheral anthropometric measurements are inversely associated with the type 2 diabetes risk.[6,7] Lifestyle modification is effective in improving these estimators of body composition and anthropometric measures by improving the metabolic profile of these patients and preventing the progression to the type 2 diabetes.[8] This also forms an integral part of the type 2 diabetes and obesity treatment,[4,9] focusing on the prevention or delaying the development of chronic complications of type 2 diabetes.[10] The reduction of multiple cardiovascular risk factors in order to achieve a close blood glucose control, dyslipidaemia improve and lower blood pressure is the main goal of these interventions.[4] The weight loss is the determining factor that delays the onset of complications of type 2 diabetes.[4,9,11] A moderate loss of weight (5-10% of initial body weight) has beneficial effects on metabolic DM2 and cardiovascular risk factors.[11] Studies have shown that an intensive nutritional intervention has the potential to improve glycaemic,[12-19] anthropometric,[12-17,19] the lipid profile,[12,14,15,17,19] and the values of blood pressure,[14,17] control in patients with type 2 diabetes. However, ideal nutritional approach for the treatment of type 2 diabetes and obesity has not been determined.[4,9] These studies, do not measure some anthropometric measurements, which are essential to describe the body composition and nutritional status of patients. These are related to energy intake, physical activity, energy metabolism and metabolic efficiency.[20] It is known that the incidence of type 2 diabetes increases with age[3] and that the change of lifestyle is effective in the prevention of type 2 diabetes in the elderly.[21] However, there is no concrete evidence about the association between age and type 2 diabetes duration with improved several metabolic risk factors and cardiovascular achieved in clinical trials whose intervention is based on lifestyle modification in patients with type 2 diabetes for the secondary complications prevention. This study investigated the intensive dietary and clinical advice extent able to influence anthropometric and glycaemic control in people with type 2 diabetes who had persistent hyperglycaemia.

Materials and Methods

This study, a randomised controlled trial of three months' duration, took place at the Hospital de Sousa Martins, Unidade Local de Saúde da Guarda, Guarda, Portugal, between July 2011 and March 2012, with this institution's Board approval, after a positive opinion of the Ethics Committee of the same.

Participants

We recruited potential participants through Hospital de Sousa Martins, Guarda. Eligibility criteria were to have been diagnosed with type 2 diabetes mellitus (International Classification of Diseases, 10th Revision [ICD-10] code E11.- and confirmed by physician) more than one year before study entry and, despite have been given standard dietary advice by dietitian, doctor or nurse and prescribed oral hypoglycaemic agents, insulin or both, have persistent unsatisfactory glycaemic control defined as HbA_{1c} more than 7% (53 mmol/mol)[4] determined by venous blood sample in the last three months and to have body mass index more than 24.9 kg/m2.[22] All participants gave written informed consent. Exclusion criteria were pregnancy, medical reasons precluding dietary modifications, refusal to participate in the study and any change in therapy or acute medical condition during the study (a posteriori exclusion criterion).

Randomisation

The participants assignment to each group (experimental and control) was performed using simple and unequal randomisation in a 2:1 ratio, with more patients in the experimental group, and to do this we resorted to the simple random sampling method.[23] To generating a random allocation sequence we used the software Microsoft Office Excel® 2007, which generate the random sequence. To implement this we considered the first 2/3 of the obtained values for the experimental group and the remaining for the control group. This was done by the professor of mathematics and statistics, which was not involved in field work. This study was not blinded.

Intervention

Each patient of experimental group received nutritional counseling individually or in the presence of family, through monthly nutrition sessions with a nutritionist experienced during three months of intervention, a total of four visits. In the first session, was produced the 24-hour dietary recall[24] for each patient and calculated its energy needs based on the World Health Organization (WHO) equation[25] for daily resting energy expenditure and the activity factor, establishing a meal plan

according to the recommendations of the European Association for the Study of Diabetes accepted internationally.[26] The recommended distribution of macronutrients was protein, 10% - 20% of total energy, lipids 20% - 35% of total energy and carbohydrates 45% - 60% of total energy.

We translated recommended total energy intake and nutrient distribution for each participant into foods in grams based on the food composition table for the Instituto Nacional de Saúde Doutor Ricardo Jorge, Lisbon, Portugal.[27] It was taken into account personal preference, economic and sociocultural factors and chronic complications of diabetes mellitus. The emphasis was on appropriate food quantities, vegetables, fruit, legumes, grains and protein sources with low fat. Contacts were made via mail or electronic mail with patients in the following week to deliver the nutrition plan in the first visit. In follow-up visits was performed nutritional reassessment and evaluating compliance through a 24-hour dietary recall and the patients were weighed.

Additional contacts were made via telephone to answer any questions from patients.

Patients in the experimental group also received intensive clinical monitoring through consultation their doctor, monthly, for three months, without, however, changes occur in drug therapy. If necessary to do any change in medications, this was an exclusion criterion. In the first visit, they were also recommended to practice regular physical activity, defined as aerobic exercise for thirty minutes, five days per week. This adherence was not evaluated.

Control group patients were not subjected to any intensification of nutritional or clinical intervention. These patients had medical and laboratory evaluation at study entry and at three months. They were also recommended to practice regular physical activity. Only patients who had previous nutritional counseling remained the same. Control group was not submitted to 24-hour dietary recall or additional nutritional counseling.

Study Outcomes

The primary outcome measures were anthropometric measurements. Secondary outcome measures included HbA_{1c}, fasting plasma glucose, lipid profile and blood pressure.

At baseline, was administered a questionnaire on identification, demographic data, medical history, drugs and habits related to lifestyle.

Measurements were made at baseline and three months always by the same person, who was blinded to the treatment group. Resting blood pressure (triplicate) and anthropometric (duplicate) measurements was obtained under standardised conditions according to WHO guidelines.[28] Anthropometric measurements were weight; height; waist, hip, arm and thigh circumferences; triceps, biceps, subscapular, suprailiac and crural skinfold thickness. Weight was measured with a Jofre®'s balance mechanics, height with the Jofre®'s balance mechanics stadiometer, circumferences with flexible and inelastic tape measure and skinfold thickness with a Harpenden® caliper. We calculated some body composition estimators, namely body mass index, waist-to-hip ratio, waist-to-height ratio, waist-to-thigh ratio, arm muscle circumference, body density based on the Durnin and Womersley's equation[29,30] and body fat percentage based on Siri's equation.[31]

At baseline and three months, venous blood samples were collected after a 12 hour overnight fast. Blood samples were analysed at the Hospital de Sousa Martins, ULS da Guarda Laboratory. HbA1c was analysed using the ADAMS A1c HA-8160® analyser based on HPLC (high performance liquid chromatography). The fasting blood glucose, triglycerides, total cholesterol and HDL cholesterol were measured using the Roche/Hitachi cobas c® analyser, using a colorimetric enzymatic assay. LDL cholesterol was calculated according to the Friedewald's equation.[32] A nutritionist applied a 24-hour dietary recall only to the experimental group at baseline and three months. It was admitted that a 24-hour dietary recall translating a standard day diet. Nutritional composition of macronutrients consumed was analyzed based on the food composition table for the "Instituto Nacional de Saúde Doutor Ricardo Jorge, Lisbon, Portugal" using the software Microsoft Office Excel® 2007.[27]

Statistical analysis

To determine the appropriate sample size for the present study we considered the prevalence of diagnosed diabetes in 2010, which corresponds to 6.6%.[33] Considering only patients with body mass index (BMI) superior to 25 kg/m2 (88.8%), the prevalence is 5.86% and considering patients with HbA_{1c} superior to 7% this number falls to about 2.93%. Therefore, for an estimation error not bigger than 5%, considering a confidence level of 95%, we would take at least 44 patients.

We applied statistical inference techniques, including parametric and nonparametric, in order to validate the hypotheses under investigation. Parametric tests were used when their assumptions were found and alternatively were used non-parametric tests. To determine whether there were significant differences between the two groups for quantitative variables we used the independent samples T-test or the U Mann-Whitney test. To test the existence of commonality between the two groups for qualitative variables we applied the chi-square or Fisher's exact test. To verify the existence of significant differences in quantitative variables before and after the intervention within each

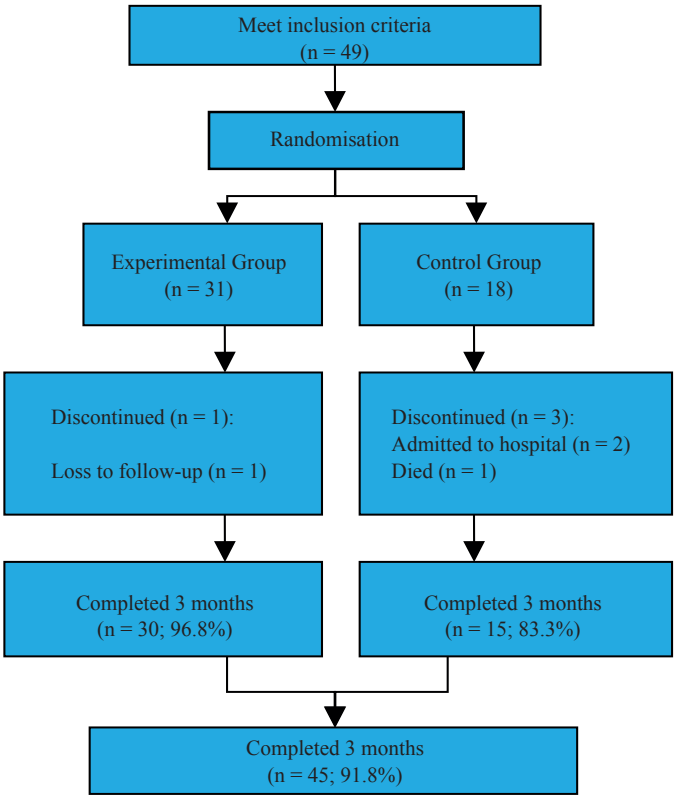

Figure 1. Flow chart of participants

group we used the paired samples Student's T-test or the Wilcoxon test. To analyse differences between groups we created variables "variation" (difference between the value of quantitative variables before the intervention and the value after the intervention). We used the Student's T-test for independent samples or U Mann-Whitney test. To verify that the macronutrient intake at the end of the intervention came from recommendations made during this and the difference in consumption of macronutrients from beginning to end in relation to these recommendations was significant we used the McNemar test.

We used the linear correlation coefficient of Pearson or the Spearman coefficients, to quantify the intensity and direction of association between quantitative variables. The level of significance was considered to be 0.05 (with 95% confidence intervals). Statistical analyses were performed using SPSS v19.0® statistical software.

Results

Initially, we recruited 49 patients who met the inclusion criteria of this study,[31] randomised to the experimental group and 18 for the control group. Forty-five from forty-nine patients completed the three-month study,[30] of which belong to experimental group and 15 patients to the control group (Fig.1).

Table 1 provides key characteristics of the two groups. Groups are homogeneous in all demographic and clinical characteristics, including anthropometric and analytical measures. A total of 51.1% of participants (53.3% in experimental group and 46.7%

Table 1. Baseline characteristics of study participants in experimental and control groups. Values are numbers (percentages) unless stated otherwise.

Characteristics	Experimental Group (n = 30)	Control Group (n = 15)	Statistical Test	*p*-value
Age (years)	61.10 ± 10.873[a]	65.4 ± 9.709[a]	t = -1.294#	0.203
Duration of diabetes (years)	15.00 ± 9.326[a]	14.80 ± 6.178[a]	t = 0.075#	0.941
Gender				
Women	21 (70.0)	12 (80.0)	$\chi^2 = 0.511$‖	0.368
Men	9 (30.0)	3 (20.0)		
Marital status				
Single	1 (3.3)	2 (13.3)		
Married	25 (83.3)	12 (80.0)	$\chi^2 = 2.193$‖	0.709
Widowed	3 (10.0)	1 (6.7)		
Divorced	1 (3.3)	0 (0.0)		
Level of schooling				
Illiteracy	1 (3.3)	2 (13.3)		
Primary education	24 (80.0)	11 (73.3)	$\chi^2 = 3.320$‖	0.364
Secondary education	3 (10.0)	0 (0.0)		
Higher education	2 (6.7)	2 (13.3)		
Professional status				
Employee	12 (40.0)	5 (33.3)		
Unemployed	2 (6.7)	1 (6.7)	$\chi^2 = 0.403$‖	0.884
Retired	16 (53.3)	9 (60)		
Therapeutic Agents				
Oral hypoglycaemic agents	7 (23.3)	7 (46.7)		
Insulin	9 (30.0)	2 (13.3)	$\chi^2 = 2.812$‖	0.283
Both	14 (46.7)	6 (40.0)		
Drug groups				
Sulfonylurea	11 (36.7)	7 (46.7)	$\chi^2 = 0.417$┼	0.371
Biguanides	20 (66.7)	9 (60.0)	$\chi^2 = 0.194$┼	0.452
Thiazolidinediones (glitazones)	3 (10.0)	5 (33.3)	$\chi^2 = 3.725$‖	0.068
Alpha glycosidase inhibitors	4 (13.3)	2 (13.3)	$\chi^2 = 0.000$‖	0.689
DPP 4 inhibitors (gliptines)	14 (46.7)	6 (40.0)	$\chi^2 = 0.180$┼	0.460
Meglitinides (glinides)	1 (3.3)	1 (6.7)	$\chi^2 = 0.262$‖	0.561
Chronic complications				
Retinopathy	20 (66.7)	4 (26.7)	$\chi^2 = 6.429$‖	0.013*
Nephropathy	3 (10.0)	3 (20.0)	$\chi^2 = 0.865$‖	0.311
Coronary	5 (16.7)	0 (0.0)	$\chi^2 = 2.813$‖	0.117
Cerebrovascular	1 (3.3)	0 (0.0)	$\chi^2 = 0.511$‖	0.667
Peripheral neuropathy	2 (6.7)	0 (0.0)	$\chi^2 = 1.047$‖	0.439
Autonomic neuropathy	0 (0.0)	0 (0.0)	-	-
Associated diseases				
Dyslipidaemia	25 (83.3)	14 (93.3)	$\chi^2 = 0.865$┼	0.335
Hypertension	26 (86.7)	14 (93.3)	$\chi^2 = 0.450$‖	0.453
Lifestyle				
Regular physical activity	16 (53.3)	7 (46.7)	$\chi^2 = 0.178$‖	0.458
Nutritional counseling	4 (13.3)	2 (13.3)	$\chi^2 = 0.000$‖	0.689

[a] Mean ± standard deviation; # t- test (independent samples); ┼ qui-square test; ‖ exact Fisher's test; * *p*-value < 0.05.

in control group) reported practicing physical activity on a regular basis and 13.3% of participants in both groups reported consulting a nutritionist at least twice in the last year (before entering the study).

Table 2 shows baseline and three months measurements of both groups and the differences between them. Improvements occurred in most clinical and laboratory measures in the experimental group, and minimal changes occurred in the control group. At three months, we obtained a significant reduction in weight (p = 0.010 and p = 0.011) and body mass index (p = 0.012 and p = 0.014) in the experimental and control group, respectively, without statistically significant differences between them. However, in the experimental group there are a significant reduction in waist, hip, arm and thigh circumferences; biceps, triceps, subscapular and crural skinfold thickness; waist-to-height ratio; body density; and body fat percentage with statistically significant differences between groups.

There was a 0.6% reduction in glycated haemoglobin in the experimental group (p = 0.001), which was significantly different when compared to the control group (p = 0.037). This study showed no significant improvements in blood pressure or lipid profile.

Table 3 shows the nutritional intakes of macronutrients calculated for the 30 participants of the experimental group from the 24-hour recall at both baseline and three months. The experimental group obtained an increase in the carbohydrates consumption (p = 0.038) and a reduction in the protein consumption (p = 0.026).

After the intervention, in the experimental group, it was found that a higher percentage of patients followed recommendations of the EASD in terms of proteins, lipids and carbohydrates. There was a statistically significant difference between the baseline and three months only in relation to protein intake (p = 0.001) (Table 4).

There was also a moderate negative correlation between age and weight reduction (r = -0,520; p = 0.003), age and body mass index reduction (r = -0.578; p = 0.001), age and arm circumference reduction (r = -0.496; p = 0.005) and duration of diabetes and weight reduction (r = -0.375; p = 0.041), duration of diabetes and body mass index reduction (r = -0.421; p = 0.021) and duration of diabetes and triceps skinfold thickness reduction (r = -0.398; p = 0.029). Also, in the same group, our results showed a moderate positive correlation between age and glycated haemoglobin reduction (r = 0.518; p = 0.003).

There were no harms or unintended effects of this type of intervention.

Discussion

In this study, the intensification of a clinical follow-up and a short-term nutritional intervention have led to improvement of anthropometric and glycaemic control in patients with type 2 diabetes and overweight/obesity whose glycaemic control was considered unsatisfactory.

Despite the small weight reduction in this study, we can consider that this is beneficial, because even small reductions in weight improve the cardiovascular risk factors and metabolic processes in patients with type 2 diabetes.[11,34] Like in others studies, we verified minor differences between the groups regarding the improvement of the weight, because the results have been minimized by the weight loss that occurred in both groups of comparison.[34] The decrease in weight in the control group could be explained by the called Hawthorne Effect.[35]

Others measures of adiposity improved in the experimental group and the differences between the two groups were significant. This can be explained by loss of fat mass observed in the experimental group. On the other hand, weight loss in the control group could be due to greater loss of lean body mass.

There was a 0.6% decrease in HbA_{1c} in the experimental group, without changes in glycaemic control of control group patients. In the UKPDS, each 1% reduction in mean HbA_{1c} was associated with reductions of 21% risk of developing complications of type 2 diabetes.[10] Failure to demonstrate significant improvements in blood pressure and lipid profile in experimental group may be due to the fact that values were close to target levels at the start of the study and that current antihypertensive and lipid modifying drugs are effective. In this study, patients with higher age have less weight reduction and more HbA_{1c} reduction and patients with long duration type 2 diabetes have a less weight reduction. Contrary to this study, Crandall and colleagues[21] found that the weight loss increased with increasing age. However, in their study, the main focus was on lifestyle change through increased exercise instead of nutritional change.[21] We thought that the lowest weight reduction in older individuals in our study was due to the fact that they had less weight initially than would be expected and nutritional counseling was less restrictive.

Nagrebetsky and colleagues found that glycaemic control was positively associated with advanced age,[36] like our study did. They found that relationships between older age and better glycaemic control are not explained by better medication adherence, but may partly relate to lower body mass index.[36] We did not study the influence of initial weight on glycaemic control.

Comparison with other studies

Nutritional intervention has repeatedly been shown to have the potential to improve glycaemic control and reduce cardiovascular risk in type 2 diabetes,[12-19] but no definitive data show its potential in improving all anthropometric measurements and the differences of the improvement according to the age and duration of diabetes mellitus. Like other studies, this could demonstrate a significant reduction in waist circumference,[12-14,36] waist-to-hip ratio[15] and biceps and triceps skinfold thickness[37] in the experimental group. About the glycaemic control, this study demonstrated a significant reduction in HbA_{1c} in the experimental group and statistically significant differences between groups. These data are supported by other studies,[12-19,34] some of which also showed a reduction of blood glucose.[14-19] Like this, ICAN study[12] and LOADD study[13] showed no improvement between the groups in relation to lipid profile and blood pressure values. Nevertheless, the Look AHEAD study[14] showed benefits from a lifestyle intervention among overweight and obese patients with type 2 diabetes in all aspects. However these studies have some differences between them and no studies to date have approached the clinical question considered here. Until now, no studies have demonstrated the extent to which lifestyle interventions has the potential to improve the anthropometric measures of adiposity in patients with uncontrolled diabetes and which patients groups benefit most from these interventions.

Strengths and limitations of study

The high retention rate throughout the study is a major strength, as is the fact that the dietary intervention was based on internationally accepted guidelines, those of the Diabetes and Nutrition Study Group of the European Association for the

Table 2. End points at baseline and three months and differences within and between experimental and control groups. Values are means ± standard deviations unless stated otherwise

Measures	Experimental Group (n = 30)				Control Group (n = 15)				Difference between Groups
	Baseline	3 Months	*p*-value	Difference	Baseline	3 Months	*p*-value	Difference	*p*-value
Weight (kg)	82.69 ± 11.71	81.48 ± 10.78	0.010ǂ*	1.213 ± 2.399	78.19 ± 13.86	76.73 ± 13.36	0.011╪*	1.460 ± 2.002	0.698┼
Body mass índex (kg/m^2)	32.08 ± 4.27	31.66 ± 4.07	0.012╪*	0.416 ± 0.942	31.66 ± 4.07	30.69 ± 3.99	0.014ǂ*	0.574 ± 0.792	0.580#
Waist circumference (cm)	108.92 ± 10.92	107.67 ± 10.39	0.003ǂ*	1.247 ± 2.085	105.89 ± 10.99	106.07 ± 11.35	0.643ǂ	-0.180 ± 1.473	0.003┼*
Hip circumference (cm)	111.93 ± 11.37	110.30 ± 11.47	0.003ǂ*	1.630 ± 2.718	110.85 ± 8.71	110.77 ± 8.55	0.907╪	0.080 ± 2.218	0.014┼*
Arm circumference (cm)	33.29 ± 3.71	32.71 ± 3.81	0.001╪*	0.583 ± 0.813	33.57 ± 3.37	33.75 ± 2.93	0.480ǂ	-0.187 ± 0.997	0.011┼*
Thigh circumference (cm)	54.71 ± 5.46	53.56 ± 5.51	0.001ǂ*	1.150 ± 1.716	52.85 ± 4.56	53.07 ± 4.36	0.096╪	-0.220 ± 0.700	0.000┼*
Bicipital skinfold thickness (mm)	17.96 ± 7.77	18.67 ± 8.36	0.014ǂ*	1.400 ± 2.939	16.56 ± 7.18	19.28 ± 8.37	0.262ǂ	-0.613 ± 2.030	0.011┼*
Tricipital skinfold thickness (mm)	20.75 ± 8.52	19.94 ± 8.33	0.029ǂ*	0.806 ± 1.922	24.69 ± 10.37	25.75 ± 11.11	0.235ǂ	-0.613 ± 2.030	0.000┼*
Subescapular skinfold thickness (mm)	29.25 ± 8.20	28.00 ± 7.94	0.000ǂ*	1.243 ± 1.583	29.89 ± 6.54	30.75 ± 7.03	0.292ǂ	-1.053 ± 3.288	0.002┼*
Suprailiac skinfold thickness (mm)	20.73 ± 7.56	19.21 ± 7.08	0.002ǂ*	1.527 ± 2.499	24.27 ± 8.22	24.20 ± 7.50	0.930ǂ	-0.853 ± 3.018	0.073┼
Crural skinfold thickness (mm)	23.57 ± 12.11	22.55 ± 11.95	0.024ǂ*	1.027 ± 2.366	28.13 ± 11.54	28.40 ± 10.94	0.526ǂ	0.067 ± 2.886	0.043┼*
Waist-to-hip ratio	0.98 ± 0.06	0.95 ± 0.06	0.302ǂ	-0.004 ± 0.020	0.98 ± 0.06	0.96 ± 0.06	0.602ǂ	-0.267 ± 1.589	0.748┼
Waist-to-height ratio	0.68 ± 0.08	0.67 ± 0.07	0.007ǂ*	0.007 ± 0.014	0.67 ± 0.06	0.67 ± 0.06	0.643ǂ	-0.002 ± 0.015	0.004┼*
Waist-to-thigh	2.00 ± 0.200	2.02 ± 0.202	0.127ǂ	-0.021 ± 0.074	2.01 ± 0.199	2.00 ± 0.203	0.347ǂ	-0.001 ± 0.009	0.075#
Arm muscle circumference (cm)	26.77 ± 3.24	26.44 ± 3.34	0.087ǂ	0.330 ± 1.021	25.81 ± 2.55	25.66 ± 2.10	0.506╪	0.006 ± 0.023	0.590#
Body density (g/mL)	1.02 ± 0.02	1.03 ± 0.02	0.000*╪	-0.002 ± 0.002	1.02 ± 0.01	1.02 ± 0.01	0.129ǂ	0.144 ± 1.196	0.000#*
Body fat percentage (%)	33.90 ± 7.66	33.00 ± 7.91	0.000*╪	0.901 ± 0.884	36.73 ± 4.62	37.14 ± 4.48	0.130ǂ	0.001 ± 0.002	0.000#*
HbA_{1c} (%)	8.73 ± 0.92	8.11 ± 1.14	0.001ǂ*	0.627 ± 0.946	8.56 ± 1.26	8.49 ± 1.28	0.401╪	-0.408 ± 0.982	0.037┼*
Blood glucose (mg/dL)	188.47 ± 72.94	159.10 ± 56.53	0.070ǂ	29.367 ± 85.565	174.53 ± 75.28	183.87 ± 70.16	0.489╪	0.067 ± 0.362	0.136#
Triglycerides (mg/dL)	134.93 ± 51.76	130.37 ± 44.76	0.590ǂ	4.567 ± 45.943	162.40 ± 102.81	134.20 ± 49.58	0.122╪	-9.333 ± 69.264	0.400┼
Total cholesterol (mg/dL)	174.83 ± 42.27	168.80 ± 33.39	0.297ǂ	6.033 ± 31.107	183.40 ± 29.13	177.43 ± 36.38	0.193ǂ	28.200 ± 65.144	0.993#
HDL cholesterol (mg/dL)	46.97 ± 13.10	50.50 ± 15.04	0.064ǂ	-3.533 ± 10.044	46.53 ± 12.65	48.13 ± 11.11	0.249╪	5.969 ± 16.910	0.825┼
LDL cholesterol	100.88 ± 36.11	92.23 ± 29.78	0.066ǂ	8.653 ± 24.815	104.39 ± 31.13	102.46 ± 33.59	0.565ǂ	-1.600 ± 5.124	0.235#
Systolic blood pressure (mmHg)	150.83 ± 22.82	150.77 ± 18.84	0.982ǂ	0.067 ± 16.171	149.53 ± 23.81	151.27 ± 21.65	0.679ǂ	1.929 ± 12.671	0.725#
Diastolic blood pressure (mmHg)	75.80 ± 12.14	72.77 ± 11.56	0.199ǂ	3.033 ± 12.642	71.53 ± 7.78	74.93 ± 7.67	0.183╪	-3.400 ± 8.659	0.084#

HDL = high density lipoprotein; LDL= low density lipoprotein; ╪ Wilcoxon test; ┼ U Mann Whitney test; ǂ t- test (paired samples); # t -test (independent samples); * *p*-value < 0.05.

Table 3. Nutritional intakes at baseline and three months in experimental group.

Nutritional Intakes	Experimental Group (n = 30)			
	Baseline	3 Months	95% IC	*p*-value
Protein (% TE)	18.62 ± 2.75	17.13 ± 2.07	0.197 to 2.791	0.026ǂ*
Lipids (% TE)	29.71 ± 5.19	29.81 ± 4.34	-1.985 to 1.774	0.910ǂ
Carbohydrates (% TE)	48.81 ± 8.66	52.14 ± 5.28	-6.464 to -0.191	0.038ǂ*
Energy (Kcal)	1539.72 ± 220.31	1481.58 ± 184.72	-2.497 to 118.764	0.060ǂ

TE = total energy; ǂ t -test (paired samples); * *p*-value < 0.05.

Table 4. Nutritional intakes according to the recommendations of the easd in experimental group.

Nutritional Intakes	Experimental group (n = 30)		
	Baseline	3 Months	*p*-value
Protein (10 - 20% TE)	17 (56.7)	29 (96.7)	0.001Ŧ*
Lipids (< 35% TE)	27 (90.0)	28 (93.3)	0.500Ŧ
Carbohydrates (45 - 60% TE)	20 (66.7)	25 (83.3)	0.063Ŧ

Values are presented as numbers and (percentages); TE = total energy; * *p*-value < 0.05; Ŧ McNemar test.

Study of Diabetes.[26] The non-prescriptive dietary approach, consideration of participants background and socioeconomic circumstances may have contributes to the high retention rate. We also proved that there was homogeneity between the groups regarding demographic and baseline clinical characteristics, which contributes to minimize the confounding factors. Randomisation helped to reduce the selection bias, as well as the willingness to participate and the fact that participants were volunteers not prejudices the results.[23] The bias of intervention and measurement were present but were minimized by the fact that outcome measures were obtained in a standardised manner in both groups and by the same observer, who was blinded to the study. One way to overcome this would be to get an estimate of body fat via DXA.

This study also had more limitations, such as the sample size. We are aware that a fundamental step in this kind of research is the sample size. Let us note however that in this case we are restricted to consider a dimension of 49 patients, which corresponds to the entire population who meet the inclusion criteria.

Implications

Although there is no optimal nutritional approach to the treatment of type 2 diabetes or obesity and many dietary patterns can be adopted as treatment for type 2 diabetes. The Diabetes and Nutrition Study Group guidelines are less prescriptive and emphasize that appropriate intakes of total energy and a dietary pattern in which fruits, vegetables, wholegrain cereals and low fat protein sources predominate are more important than the precise proportions of total energy provided by the major macronutrients. This clinical trial showed that participants adhered to these nutritional recommendations. The results seen in this trial should encourage patients to modify their eating habits. It is necessary that any nutritional intervention is supported with the involvement of family and the environment.

Conclusions

We conclude that the intensification of a clinical follow-up and a short-term nutritional intervention have led to improvement of anthropometric and glycaemic control in patients with type 2 diabetes and overweight/obesity whose glycaemic control was considered unsatisfactory.

This study was designed so that it can be applied in clinical practice. A monthly monitoring seems to be easily workable in ambulatory practice and would allow better control of these patients if was extended in time and not just a short-term intervention. However, studies would be needed to see if there is maintenance of this improvement over time and studies to measure cost-effectiveness of implementation of this strategy in clinical practice.

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