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The Effect of Individualized Dietary Intervention in Anthropometric Profile Improvement and Metabolic Control of Sedentary Individuals with Type 2 Diabetes in Brazil

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Abstract

Objective: To evaluate the effect of individualized dietary intervention on nutritional diagnosis and metabolic control in sedentary subjects with type 2-diabetes.

Materials and Methods: This controlled clinical trial, investigated 80 adults, of both sexes, divided into intervention group (IG: 40 individuals with dietary intervention and hypoglycemic drug) and control group (CG: 40 individuals with hypoglycemic drug). Individualized dietary intervention was conducted, for 3 months, based on the *American Diabetes Association* (2002). We evaluated anthropometric variables: total body mass (TBM) and height to calculate body mass index (BMI), and waist circumference (WC); biochemical variables: blood glucose, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides (TG), and glycated hemoglobin (HbA1c); and dietary variables: energy, macronutrients, cholesterol and fibers. For inferential statistics two-way ANOVA was used with significant level of 95%.

Results: In the inter group analysis, the CG showed significant increase in TBM (Δ%=0.78), BMI (Δ%=0.76), WC (Δ%=0.75); whereas IG showed significant decrease in TBM (Δ%=-3.71), BMI (Δ%=-3.77), WC (Δ%=-3.98). In comparing the mean RI inter groups, there was significant difference in energy, lipids, saturated fats, cholesterol, fibers; blood glucose, total cholesterol, LDL-cholesterol and HbA1c.

Conclusions: The individualized dietary intervention was efficient in the improvement of anthropometric and biochemical variables of sedentary individuals with type 2 diabetes.

Keywords: Type 2 diabetes mellitus; Diet; Intervention studies; Glucose metabolism disorders; Nutrition therapy

Introduction

The diabetes mellitus worldwide prevalence in 2002 was of 150 million people and its projection for 2025 is around 300 million. Brazil stands out in South America as one of the main countries where the prevalence of type 2 diabetes [T2D] is high, corresponding to 25,000 deaths annually. This disease is ranked as the sixth leading cause of death in the country [1]. Furthermore, generally, it seems that individuals in urban population are more prone to developing T2D compared to their counterparts in rural communities [2].

In adults, the diabetes is associated with a high risk of cardiovascular disease, about 2 to 4 times higher than in individuals without diabetes. Moreover, cardiovascular disease is the leading cause of mortality and morbidity in patients with T2D [3]. Diagnosing and specially establishing an aggressive management of risk factors in patients with diabetes is one of the most central aspects of care for this population.

Lifestyle changes including nutritional therapy and aerobic physical activity may modify the lipid profile, reduce blood pressure levels, and are the key elements in managing blood glucose and weight control. Although much of the dietary approach has always been focused on weight control, greater emphasis has been given for adequate control of blood glucose and cardiovascular risk factors [4].

In Brazil, a randomized controlled trial conducted with adults aimed to assess the impact of nutritional counseling in the control of risk factors for T2D. This study was developed in a basic health unit in Sao Jose do Rio Preto, São Paulo. The volunteers were allocated between the control and the intervention by nutritional guidance group. After 6 months the group that had nutritional guidance showed significant weight loss, reduction of LDL-cholesterol and total cholesterol [5].

The Diabetes Prevention Program (DPP) evaluated 3234 obese patients with impaired glucose tolerance (IGT) and in the lifestyle intervention group, more than 50% of patients had achieved the goal of weight loss of 7 percent or more [6]. The Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastrich (SLIM) was a randomized controlled trial with 102 adults with IGT and overweight in the Netherlands. After the first 12 months of follow up, they found significant difference in post load glucose and insulin resistance by Homeostasis Model Assessment [HOMA] in the intervention group compared with the control group [7].

Therefore, the aim of this study was to evaluate the effect of individualized dietary intervention on the nutritional diagnosis and metabolic control in sedentary subjects with type 2 diabetes.

Materials and Methods

This non-randomized controlled clinical trial (experimental trial) investigated 80 sedentary adults, of both sexes, with T2D. The selection of participants was made after the first consultation with an endocrinologist and the subjects were asked if there was interest

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in participating in the study. Those who accepted to participate and to follow an individualized dietary counseling were assigned to the intervention group (IG) and those who did not, were assigned to the control group (CG). The sample was, therefore, divided into two groups: the IG with dietary intervention and hypoglycemic medication (n=40) and the CG only with hypoglycemic medication (n=40). The selected individuals did not practice physical activity regularly and were classified as sedentary according to the definition proposed by the American College of Sports Medicine [8].

The sample size calculation was based on the results obtained by Wing et al. [9]. They investigated the beneficial effect of dietary intervention for a six month period in the diabetes mellitus improvement. The sample size calculation was estimated by Pocock method [10]. Based on these data, the number of participants needed in each group was of 35 subjects. However, adding an estimated loss of 10%, it was required a minimum of 40 subjects in each group so that the sample had predictive power.

To include in the study, we selected sedentary subjects with clinical diagnosis of T2D, who had not been subjected to dietary treatment in the 6 months prior to the study and were already under therapy with simvastatin or metformin. We considered as exclusion criteria: subjects under 20 years old; insulin-dependent individuals; pregnant women; patients with kidney, heart, or liver failure; and / or people under continuous use of hyperglycemic drugs (corticoids). We also excluded subjects who had any drug treatment changes during the study.

This research is in accordance with the Ethical Guidelines for Biomedical Research Involving Human Beings as stated in the principles in the Declaration of Helsinki. The research project was approved by the Ethics Committee of Rio de Janeiro State University (SR2), and the protocol number is 009.3.2009. Participants received detailed information regarding the nature, purpose and types of evaluation of the study. Later, they were asked to sign an informed consent, prepared in accordance with Resolution 196/96 of the National Health Council of the Ministry of Health from Brazil.

This study was divided into four stages consisting of clinical evaluation, biochemical evaluation, anthropometric and dietary assessments, followed by intervention and re-evaluation.

Clinical evaluation

The clinical evaluation consisted of consultations with a doctor specialized in Endocrinology, regularly registered at the Medicine Regional Council, and who was responsible for diagnosing and prescribing medications such as oral hypoglycemic agents. This evaluation occurred in private endocrinology and nutrition office from July to December of 2009 in the city of Rio de Janeiro, Brazil.

Biochemical evaluation

Biochemical analyzes were performed after twelve hours of overnight fasting. Fasting plasma glucose was measured by enzymatic colorimetric method, with reference values from 70 to 99 mg / dL. For HbA1c, we used the high performance liquid chromatography method with reference values from 4% to 6% of glycated hemoglobin. The total cholesterol, HDL-cholesterol and triglycerides were determined by the enzymatic colorimetric method with the reference values according to the IV Brazilian Guidelines on Dyslipidemia and Atherosclerosis Prevention [11]. The LDL-cholesterol was calculated using the Friedewald formula and the reference values were less than or equal to 160 mg / dL. All tests were performed in a single clinical laboratory in Rio de Janeiro city.

Anthropometric and dietary assessments

For anthropometric assessment, we measured the total body mass (TBM) in the digital platform scale from Filizola® with a capacity up to 150 kg and a precision of 100 g. Height was measured using portable anthropometric tape from Sanny Medical®. Then, we calculated the body mass index (BMI) and measured the waist circumference (WC) using the tape-measure from Sanny Medical®. The WC was measured at the midway between the lowest rib and iliac crest, at the maximal expiration moment [12,13].

For dietary assessment, we used 24-hour recalls. The energy, macronutrients (specifying the different fatty acids), cholesterol and dietary fiber intakes were calculated using the software Nut Win 1.5 UNIFESP – São Paulo (2002) [14].

Intervention and re-evaluation

The participants in the IG were subjected to 12 weeks dietary intervention. The intervention consisted of individualized diet plans prescribed according to the recommendations from American Diabetes Association [15]. After receiving the diet plans, the subjects in the IG were rescheduled to return to the nutritionist's office after 15 days to evaluate the diet adherence. During the dietary treatment, all questions about the diet plan were answered by the nutritionist through telephone or e-mail contact. Altogether, four individualized appointments with the nutritionist were conducted. The participants in the CG were not subjected to dietary intervention and received monthly medical follow-up. They returned only after 12 weeks to perform anthropometric, dietary and biochemical re-evaluation.

Statistical analysis

For data analysis, we used descriptive statistics by mean, standard deviation, maximum and minimum values and frequency distribution in absolute and relative values. Shapiro Wilk test verified data normality. For inferential statistics ANOVA two-way was used. It was used 95% confidence level for all variables. The statistical package used was SPSS version 17.0.

Results

The mean age of subjects in the CG (47.5% men and 52.5% women) was of 66.1 ± 11.4 years old, while in the IG (45% men and 55% women), it was of 60.5 ± 10.5 years old. The subjects in the CG and in the IG had the diabetes diagnose for a mean of 10.2 ± 6.3 years and 7.36 ± 5.0 years, respectively.

Table 1 compares the CG and the IG, at baseline moment (M0) and after 12 weeks intervention (M1) (Table 1). In this intra group

		CG (n=40)			IG (n=40)		
		Mean ± SD	Δ%	*p*-value	Mean ± SD	Δ%	*p*-value
TBM (kg)	M0	75.8 ± 12.8	0.78	0.014*	82.8 ± 16.9	-3.71	0.000*
	M1	76.4 ± 13.1			79.8 ± 15.7		
BMI (kg/m²)	M0	27.8 ± 3.6	0.76	0.012*	31.1 ± 5.2	-3.77	0.000*
	M1	28.0 ± 3.7			29.9 ± 4.7		
WC (cm)	M0	97.0 ± 11.6	0.75	0.019*	103.1 ± 14.8	-3.98	0.000*
	M1	97.7 ± 12.1			99.1 ± 13.0		

Legends: CG: Control group; IG: Intervention group; M0: Baseline moment; M1: After 12 weeks intervention; SD: Standard deviation; TBM: Total body mass; BMI: Body mass index; WC: Waist circumference; Δ%: percentage delta; *p-value < 0.05.

Table 1: Anthropometric parameters of individuals with diabetes from control group and intervention groups at baseline moment (M0) and after 12 weeks intervention (M1).

analysis, the CG presented significant increase in all anthropometric variables: TBM (Δ%=0.78; p=0.014), BMI (Δ%=0.76; p=0.012), WC (Δ%=0.75;p=0.019), while the IG showed a significant decrease in all anthropometric variables: TBM (Δ%=-3.71; p= 0.000), BMI (Δ%=-3.77; p=0.000), WC (Δ%=-3.98; p=0.000).

Regarding the dietary variables (Table 2), by analyzing the dietary variables in the CG, there was no significant difference between the M0 and after 12 weeks intervention (M1). In the IG, there was significant reduction, between the M0 and the M1, in the variables: energy (%Δ=-20.57; p=0.000), saturated fats (Δ=-36.36%; p=0.000), cholesterol (%Δ=-28.27; p=0.006) and significant increase in fiber intake (Δ = 32.61; p=0.000).

Dietary Intake		CG	IG
Variables		(n=40)	(n=40)
		Mean ± SD	Mean ± SD
Energy/ day (kcal)	M0	1774.0 ± 317.3	1894.0 ± 470.0
	M1	1843.0 ± 324.7	1504.0 ± 273.0§*
PTN (g/kg /day)	M0	1.4 ± 0.4	1.4 ± 0.5
	M1	1.4 ± 0.4	1.3 ± 0.4
CHO (% TEI)	M0	48.6 ± 9.4	49.3 ± 11.6
	M1	48.2 ± 11.1	51.7 ± 8.9
LIP (%TEI)	M0	24.2 ± 7.6	25.4 ± 8.6
	M1	25.9 ± 9.2	20.8 ± 7.2*
Saturated fats (%TEI)	M0	7.6 ± 3.3	8.1 ± 3.6
	M1	8.5 ± 3.7	5.1 ± 1.3§*
MONO fats (%TEI)	M0	8.7 ± 2.9	9.5 ± 3.5
	M1	9.1 ± 2.9	8.4 ± 2.0
POLY fats (%TEI)	M0	7.6 ± 2.6	7.6 ± 2.9
	M1	7.21 ± 2.64	7.1 ± 3.0
CHOL (mg/day)	M0	230.1 ± 101.2	221.6 ± 94.6
	M1	238.6 ± 87.9	159.0 ± 42.5§*
Dietary fibers (g/day)	M0	20.7 ± 7.3	23.0 ± 9.1§
	M1	19.9 ± 5.6	30.5 ± 5.0§*

Legends: CG: Control group; IG: Intervention group; M0: Baseline moment; M1: After 12 weeks intervention; SD: Standard deviation; RI: Ratio index; g: Grams; kg: Kilograms; mg: Milligrams; %: Percentage; PTN: Proteins; CHO: Carbohydrates; LIP: Lipids; MONO: Monounsaturated fats; POLY: Polyunsaturated fats; CHOL: Cholesterol; TEI: Total energy intake; *inter group (CG x IG) significant difference (p < 0.05); § intra-groups (M0 x M1) significant difference (p < 0.05).

Table 2: Analysis of the dietary intake of the participants from the control and intervention groups at baseline moment (M0) and after 12 weeks intervention (M1).

Biochemical variables		CG	IG
		(n=40)	(n=40)
		Mean ± SD	Mean ± SD
Blood glucose (mg/dL)	M0	129,0 ± 42,6	159,3 ± 69,9*
	M1	150,6 ± 52,1	111,4 ± 29,3§*
Total cholesterol (mg/dL)	M0	182,4 ± 42,0	191,4 ± 45,0
	M1	184,9 ± 40,9	164,7 ± 38,1§
LDL-cholesterol (mg/dL)	M0	103,0 ± 36,8	109,5 ± 39,7
	M1	108,2 ± 37,6	89,3 ± 34,5
HDL-cholesterol (mg/dL)	M0	47,7 ± 13,9	48,1 ± 15,0
	M1	47,8 ± 13,9	45,6 ± 14,2
TG (mg/dL)	M0	163,8 ± 98,0	151,0 ± 70,9
	M1	147,7 ± 87,0	111,8 ± 42,3
HbA1c (%)	M0	7,2 ± 1,5	7,8 ± 1,9
	M1	7,4 ± 1,2	7,0 ± 1,6

Legends: CG: Control group; IG: Intervention group; M0: Baseline moment; M1: After 12 weeks intervention; SD: Standard deviation; RI: Ratio index; LDL: Low density lipoprotein; HDL: High density lipoprotein; TG: Triglycerides; HbA1c: Glycated hemoglobin; *inter group (CG x IG) significant difference (p<0.05); § intra-groups (M0 x M1) significant difference (p < 0.05).

Table 3: Biochemical variables of the participants from the control and intervention groups at baseline moment (M0) and after 12 weeks intervention (M1).

Comparing CG and IG, the same variables presented a significant difference at M1: energy (p=0.000), saturated fats (p=0.000), cholesterol (p=0.006) and significant increase in fiber intake (p=0.000).

With respect to biochemical variables (Table 3), we observed at intra-groups analysis that only blood glucose (Δ=-30.05; p=0.000) and total cholesterol levels (Δ= -13.97; p=0.024) presented a significant decrease. Comparing CG and IG, only blood glucose presented a significant difference at M0 (p=0.042) and M1 (p=0.004).

Discussion

In this study, the subjects in the IG showed reduction in the variables: body mass, WC and BMI. The reduction of 5% in body weight improve insulin action, decrease fasting blood glucose levels and reduce the need for medications for diabetes mellitus control [16].

In the present research, the subjects in the CG showed increase in the TBM, WC and BMI. The risk for developing diabetes, glucose intolerance, increased rate of HbA1c and other chronic diseases seems to be associated with overweight, especially in the abdominal region. The weight that is gained in adulthood, around 5%, in comparison with the reported weight at age 20, is related to increased occurrence of hypertension, dyslipidemia, and especially hyperinsulinemia [17,18].

Weight loss improves glucose tolerance, lipid profile, blood pressure and symptoms associated with degenerative joint disease, especially when associated with lifestyle changes (regular physical activity for 30 minutes / day) compared with the individuals using only metformin [19].

When analyzing the dietary variables of the IG, in the present study we observed a significant reduction in variables: energy, saturated fats percentage and cholesterol. There is a positive correlation between the consumption of saturated fats with increased blood glucose and consequently the onset of diabetes mellitus [20].

In this study, we observed a significant increase in dietary fiber intake after dietary intervention in the IG. In another study, the high dietary fiber intake (25 g of soluble fiber and 25 g of insoluble fiber) improved glycemic control, reduced hyperinsulinemia and serum lipid levels in individuals with T2D [21]. A low glycemic load diet associated with high dietary fiber intake, particularly of whole grains, can reduce the risk of developing diabetes mellitus [22,23].

In the present investigation, the CG showed no significant difference in dietary variables and there is evidence in the literature that intervention with adequate diet can prevent the diabetes mellitus. This demonstrates the importance of nutrition that can effectively contribute to the prevention of glucose intolerance (24).

In the Nurses' Health Study, conducted with 84,941 American women, it was observed that the absence of smoking, daily physical activity practice of 30 minutes, weight maintenance and habitual eating pattern rich in fiber and polyunsaturated fatty acids, poor in saturated fats and trans fatty acids decreased by 91% the risk for developing T2D after a 16 years follow-up period [25].

The change in the regular dietary carbohydrates quality, seen in many countries, has been identified as one of the determinants of the diabetes mellitus increased frequency. An ecological analysis of the association between the carbohydrates quality consumed in the American diet on the disease prevalence observed in the United States over the past 20 years, found that the trend of increased refined carbohydrates consumption, highly concentrated in fructose and sucrose rather than the consumption of foods naturally rich in fiber, was strongly related to increased risk for diabetes mellitus type 2 development [26].

In Brazil, the population aging associated with overweight, sedentary lifestyle, and changes in dietary patterns [such as increased consumption of sugars and soda instead of fruits and vegetables] has been suggested as possible factors involved in increased risk for the development of diabetes, in recent years [24].

In this study we observed a significant difference for the blood glucose variable in both groups at M0, being higher in the individuals from the IG, probably because of the non-randomized design. After dietary intervention, only the IG showed a significant difference for blood glucose and cholesterol levels. In the Diabetes Education Program, implemented and tested in different countries of Latin America, they evaluated 446 individuals with T2D. After 12 months, they observed a significant decrease of fasting blood glucose, glycated hemoglobin, total cholesterol and triglycerides levels [27].

Study with 78 patients with T2D before and after a one-year of multidisciplinary monitoring period, found a significant reduction in postprandial glucose and glycated hemoglobin [28].

In another study, subjects with type 2 diabetes who had elevated HbA1c, at M0, were able to reduce this rate and reach normal values, after one year of treatment with a multidisciplinary team involving medical treatment, balanced diet and regular physical activity [3]. Individuals with T2D who had high initial levels of glycated hemoglobin showed reduction in biochemical parameter values reaching the normal range. This happened after one year of treatment with a multidisciplinary team involving medication, diet and regular physical activity [27]. In a study conducted in Costa Rica, they found that the community educational intervention, with the participation of patients with T2D, their families and health professionals, significantly reduced blood glucose, glycated hemoglobin and triglycerides [29].

This research presents the limitation of not being a randomized study, but a comparison of the anthropometric and biochemical parameters at baseline between groups was not significantly different, showing the homogeneity of the sample. The only variable that showed significant difference at baseline was the blood glucose which value was greater in the IG.

The results of this study clearly demonstrated the effectiveness of individualized dietary intervention in improving anthropometric profile and metabolic control in sedentary individuals with T2D in a short term, which can prevent the onset of co-morbidities.

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