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EFFECTIVENESS OF NON-SURGICAL WEIGHT LOSS TREATMENT FOR SEVERELY OBESE PATIENTS

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ABSTRACT

Purpose: Severe obesity is a worldwide public health problem. We aimed to evaluate the effectiveness of non-surgical treatment on weight, body mass index (BMI), food consumption, and physical activity practice of severely obese outpatients. Methods: Fifty-three severely obese adults were included in the study. Nutritional treatment with a tailored food plan was applied. Patients were followed through nine monthly visits. At statistical analysis, it was observed that some patients were using anti-obesity drugs, thus patients were stratified as follows: nutritional treatment (NT) group (n = 26), those who received only the nutritional intervention; and nutritional treatment plus medicine (NM) group (n = 27), those under NT and anti-obesity drugs. Results: Both groups presented linear reduction on weight and BMI means throughout the follow-up (P < 0.001). NT had lower mean weight values compared to NM in the last three visits (seventh: P = 0.036, eighth: P = 0.020, ninth: P = 0.025). Both interventions promoted clinically significant weight loss with no statistical difference between groups (weight loss %: NT = 7.2 ± 9.0%; NM = 5.9 ± 4.5%; P = 0.491). A qualitative improvement in overall food consumption was observed. NT showed a significant increase in vegetable consumption compared to NM in the sixth visit (P = 0.044). NM had greater adherence to physical activity practice (P < 0.001). Conclusions: The non-surgical treatment program was effective on weight and BMI reduction in severely obese patients with and without anti-obesity drugs, and the food consumption and physical activity practice improved.

Key words: Severe obesity. diet therapy. weight loss. food habit. physical activity.

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RESUMO

Eficácia do tratamento de perda de peso não-cirúrgico para pacientes obesos graves

Objetivo: A obesidade grave é um problema de saúde pública mundial. O objetivo do estudo foi avaliar a efetividade do tratamento não-cirúrgico com relação ao peso, Índice de Massa Corporal (IMC), consumo alimentar e prática de atividade física em pacientes obesos graves. Métodos: Cinquenta e três obesos graves foram incluídos no estudo. Foi realizado tratamento nutricional com plano alimentar personalizado. Os pacientes foram acompanhados por nove consultas mensais. Na análise estatística, observou-se que alguns pacientes usavam medicamentos anti-obesidade, sendo estratificados da seguinte forma: grupo tratamento nutricional (TN) (n = 26), pacientes apenas sob intervenção nutricional; e tratamento nutricional mais medicamento (TM) (n = 27), aqueles sob TN e medicamentos anti-obesidade. Resultados: Ambos grupos apresentaram redução linear de peso e IMC durante o seguimento (P <0,001). TN apresentou médias de peso menores que TM nas últimas três consultas (sétima: P = 0,036, oitava: P = 0,020, nona: P = 0,025). Ambas intervenções promoveram perda de peso clinicamente significativa sem diferença entre os grupos (% perda de peso: TN = 7,2 ± 9,0%; TM = 5,9 ± 4,5%; P = 0,491). Observou-se uma melhora qualitativa geral no consumo de alimentos. TN demostrou aumento significativo no consumo de vegetais comparado a NM na sexta consulta (P = 0,044). TM teve maior adesão à prática de atividade física (P <0,001). Conclusões: O tratamento não-cirúrgico foi efetivo na redução do peso e IMC de obesos graves com ou sem o uso de medicamentos anti-obesidade, e o consumo de alimentos e a prática de atividade física melhoraram.

Palavras-chave: Obesidade grave. terapia dietética. perda de peso. hábito alimentar. atividade física.

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INTRODUCTION

Obesity has been increasing alarmingly worldwide, especially severe obesity (body mass index [BMI] ≥35 kg/m2) (Di Cesare and colaborators, 2016; Sturm, 2013). In the United States, from 1975 to 2014, severe obesity increased 780% among men (from 1.5% to 13.2%) and 345% among women (from 4.0% to 17.8%) (Di Cesare and colaborators, 2016).

In the same period, Brazil had also worrisome increases in those prevalence for men (1450%, from 0.2% to 3.1%) and women (642%, from 1.2% to 8.9%) (Di Cesare and colaborators, 2016).

Despite this critical increase and the risk of morbidity and mortality, interventions capable of reducing the prevalence of obesity are unavailable (Laddu and colaborators, 2011; McTigue and colaborators, 2006)

Because of its high prevalence and the low resolution of conservative treatments, the number of bariatric surgeries performed increases daily (Chang and colaborators, 2014; Padwal and colaborators, 2011).

However, the recommended first line treatment for severe obesity lies on changes in lifestyle and surgery should be indicated only after several unsuccessful non-surgical interventions attempts (Apovian, Garvey and Ryan, 2015; Jensen and colaborators, 2014).

Some alternative treatments to bariatric surgery have promoted significant weight loss in non-surgical morbidly obese patients using a comprehensive approach and intensive lifestyle intervention (Burguera and colaborators, 2015; Dalle Grave, Calugi and El Ghoch, 2013; Ryan and colaborators, 2010).

Severely obese patients require tailored lifestyle interventions to achieve significant results (Blackburn, Wollner and Heymsfield, 2010; Dalle Grave, Calugi and El Ghoch, 2013).

Non-surgical treatments should be considered for those without the risk of death due to excess weight and comorbidities so developing effective programs is necessary since bariatric surgery is not feasible for the large majority of patients (Burguera and colaborators, 2015).

Given this problem, it is important to conduct studies on non-surgical interventions that contribute to the lack of knowledge regarding effective treatments on severe obesity.

Therefore, this study aimed to evaluate the effectiveness of non-surgical treatment on changes in weight, BMI, food consumption, and physical activity practice of severely obese outpatients.

MATERIALS AND METHODS

Design and location of the study

This is a non-randomized clinical trial with severely obese patients (classes II and III) from the Nutrition in Severe Obesity Outpatient Clinic (Ambulatório de Nutrição em Obesidade Grave [ANOG]) at Hospital das Clínicas (HC), Federal University of Goiás (Universidade Federal de Goiás [UFG]), Goiânia-Goiás, Brazil.

Subjects

We analyzed data from all patients who visited ANOG from October 2007 to October 2009. Data were collected from patients' medical records for the period of nine visits since admission at ANOG. Physicians from other clinics of the hospital referred patients who met the following criteria to our clinic: BMI ≥40.0 kg/m^2 or between 35.0 and 39.9 kg/m^2 with associated comorbidity, and adults over 18 years. Seventy-nine individuals received nutritional intervention at visits with a team of registered dietitians. The exclusion criteria were as follows: those who did not return to the second visit (n = 3) and patients who had an interval between visits longer than 65 days (n = 23).

This research was performed according with the standards laid down in the 1964 Declaration of Helsinki and its later amendments. It was approved by the Ethics Research Committee of HC/UFG (protocol nº 090/08). Informed consent was not necessary since the data collection was based on secondary data.

Non-surgical Treatment Program

An individualized and tailored nutritional treatment program was developed to offer a dietary and lifestyle intervention considering the specificities of the severely obese patients. At the first visit, the following

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procedures were performed: nutritional and socioeconomic interviews, anthropometric assessment, evaluation of existing laboratory exams, estimation of nutritional needs, and a food plan prescription considering the patients' morbidity status and respecting the socioeconomic condition of the patient regarding food obtainment.

The food plan consisted of a balanced hypocaloric diet (20-25 kcal/kg of adjusted weight), with a food substitution list (NHLBI and NIH, 1998; Seagle and colaborators, 2009).

Healthy eating habits were promoted, and changes and substitutions were proposed so that a habit shift could occur gradually (WHO, 2003). The objectives of the nutritional treatment were clarified, and the goals were set together with the patients.

At the follow-up visits, food consumption and change in eating habits, and physical activity practice were evaluated. A professional-to-patient link based on trust was nurtured at each follow-up visit, making the patients comfortable to report their difficulties and obstacles to adhere to the eating plan. The patient was asked to take a family member to the visits so that the family could be involved and motivated to support the patient during the treatment. The first visit with the nutritionist lasted approximately 1 h and 30 min, whereas the follow-up visits lasted approximately 40 min.

Variables

The following variables were collected: socio-demographic data (i.e., sex, age, years of study, and family income), anthropometric data (weight, height, and BMI data were collected at every visit), physical activity practice (evaluated at the first and ninth visits), and food consumption (evaluated at the first, third, sixth, and ninth visits).

Weight was assessed using a Welmy® platform scale (São Paulo, Brazil) with capacity for 300 kg and accuracy of 100 g; patients were barefoot and wore lightweight clothes. Height was assessed using a vertical scale attached to the platform within a scale of 0.1 cm.

Weight and height were measured according to the technique proposed by the World Health Organization (WHO, 1995). Weight was divided by the height (m) squared to calculate the BMI.

To assess physical activity practice, participants were asked to report the average amount of time spent per week in leisure-time physical activity during the previous month, as well as the type and intensity. The individual who practiced moderate to intense physical activity at least 150 min per week was regarded as a physical activity practitioner, according to the World Health Organization's recommendation (WHO, 2010).

Dietary intake was assessed by diet history data based on previous publications that were adapted to the present study (Garcia, Granado and Cardoso, 2011; Wharf and colaborators, 1997). An interview script was used to register the habitual consumption of foods and beverages.

The interview technique was similar to the 24-h recall, but instead of asking, "What did you consume the day before?" it asks, "What foods and beverages do you usually eat or drink from the moment you wake up until bedtime?" Food consumption during the night was also investigated (Garcia, Granado and Cardoso, 2011).

Food quantities were expressed in household measures that were converted into portions according to Annex C from the Food Guide for the Brazilian Population (Ministério da Saúde, 2005).

Quality Control

Data quality was assured using standardized forms to register the data. Besides offering nutritional treatment, ANOG conducts research, teaching, and extension activities; thus, data collection is performed carefully to facilitate future research.

Registered dietitians from ANOG were trained according to the treatment program to take anthropometric measures, assess diet history data and physical activity practice before starting patient care, and to ensure the quality of data collected. Moreover, the researchers in charge of this study supervised the team during the visits.

Statistical analysis

At the statistical analysis, we noticed that a greater number of patients received anti-obesity medicine prescription. This occurred

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because patients were followed by the multi-professional health team of the hospital, which performed clinical treatment according to the comorbidities, and health problems of patients. The patients' endocrinologist determined the use of anti-obesity medicine on an individual basis; sibutramine and fluoxetine were the most commonly prescribed medicines.

Thus, to evaluate the effectiveness of the nutritional intervention separately we divided the patients into two groups. Patients were divided as follow: those under nutritional treatment (NT, n = 26), and those that used anti-obesity medicines in addition to NT during the intervention period (NM, n = 27).

To compare means, paired and unpaired Student's t-tests were used. The chi-square test or its non-parametric equivalent (Fisher's exact test) was used for categorical variables, and for paired data, McNemar's test was used.

For weight, BMI, and food consumption means, variation along the series and between groups was tested using intention-to-treat (ITT) analysis. A mixed-effects model with a Toeplitz variance and covariance matrix was used for weight and BMI; for food consumption, we used a mixed-effects model of repeated measures variance analysis with an adjustment for consumption measures at baseline. For the sweetener and fried food consumption variables, generalized equations model for logistic regression were used. For the weight and BMI variables, the residuals did not present a Gaussian distribution; therefore, we employed logarithmic transformation to compare measures along the follow-ups and applied significance testing. Line graph analysis was adopted without the logarithmic transformation to preserve comprehension of the clinical aspects. The analysis was performed with SAS 9.4 software (SAS Institute Inc., Cary NC). The considered significance level was 5%.

The sample size used to determine differences with respect to the studied outcome was calculated a posteriori. Considering a significance level of 5%, the difference in the final weight between groups of 7.3 kg, and a standard deviation of 18.6, the study required 25.2 patients in each group to achieve a power of 80. Thus, the number of patients in this study was adequate for the proposed objectives.

RESULTS

At the end of follow-up, data from 53 patients were analyzed. Patients presented mean age of 39.9 ± 10.1 years, mean BMI of 48.8 ± 6.6 kg/m^2, and mean weight of 121.0 ± 16.6 kg; 90.6% (n = 48) were women (data not shown). Baseline sociodemographic and anthropometric characteristics were similar between both groups, except for initial BMI that was higher in NM (*P* = 0.023) (Table 1). Twenty-one (39.6%) patients completed all nine visits.

All variables of Table 1 were also analyzed for patients excluded from the study (n = 26), and no statistically significant differences were found between the groups, except age was higher for NM (data not presented).

Both groups had BMI reduction greater than 3 kg/m^2 and weight loss percentage greater than 5%, with no difference between them. BMI reduction, weight loss, weight loss percentage, and excess weight loss percentage were higher in NT, but not statistically different from NM. Both groups were followed for approximately 7 months and had similar number of visits (Table 2).

Table 1 - Baseline characteristics of participants according to sociodemographic and anthropometric variables.

Variable	NT (n = 26)	NM (n = 27)	P-value*
Age (years)	37.2 ± 8.6	42.5 ± 10.8	0.057
Education (years)	9.8 ± 3.2	7.1 ± 4.2	0.108
Per capita family income (R$)	241.96 ± 154.46	303.28 ± 226.38	0.269
Height (m)	1.59 ± 0.07	1.56 ± 0.08	0.177
Body weight (kg)	118.4 ± 16.0	123.6 ± 17.1	0.262
BMI (kg/m^2)	46.7 ± 5.9	50.8 ± 6.8	0.023

Legends: Values are given as mean ± standard deviation. NT, nutritional treatment; NM, nutritional treatment plus medicine; BMI, body mass index; R$, reais. * Unpaired Student's t-test.

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Table 2 - Anthropometrical changes and follow-up characteristics of participants in groups NT and NM at the end of follow-up.

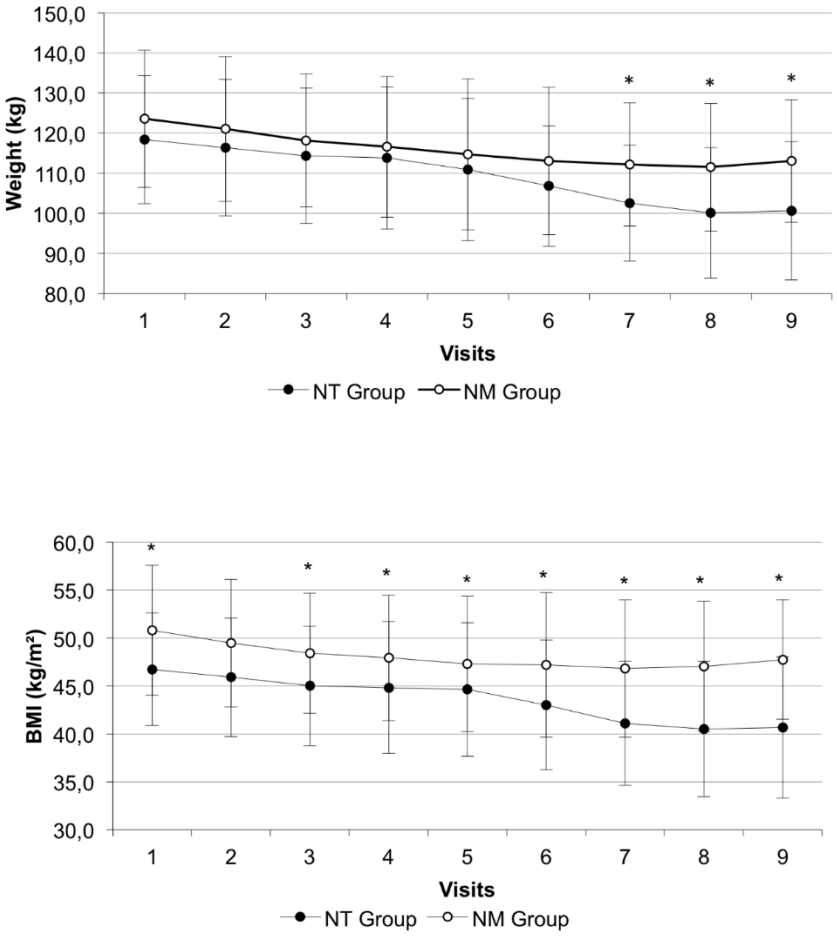
Variable	NT (n = 26)	NM (n = 27)	*P*-value*
BMI reduction (kg/m^2)	-3.4 ± 4.4	-3.0 ± 2.6	0.695
Weight loss (kg)	-8.7 ± 11.5	-7.0 ± 5.7	0.511
Weight loss (%)	7.2 ± 9.0	5.9 ± 4.5	0.491
Excess weight loss (%)	13.8 ± 16.7	10.1 ± 7.8	0.311
Follow-up time (months)	6.6 ± 3.8	7.0 ± 3.2	0.629
Number of visits	5.9 ± 2.6	6.9 ± 2.2	0.154
Use of anti-obesity drug (months)	-	4.3 ± 2.3	-

Legends: Values are given as mean ± standard deviation. NT, nutritional treatment; NM, nutritional treatment plus medicine; BMI, body mass index. * Unpaired Student's t-test.

Table 3 - Weight loss percentage ranges of participants in the NT and NM groups at the end of follow-up.

Weight loss (%)	NT (n = 26)	NM (n = 27)	*P*-value*
>10%	6 (23.1)	4 (14.8)	0.732
5–10%	6 (23.1)	13 (48.2)	0.282
<5%	14 (53.8)	10 (37.0)	0.473

Legends: All data are presented as n (%). * Fisher's exact test.



Legends: Abbreviations: NT, nutritional treatment; NM, nutritional treatment plus medicine; BMI, body mass index. *P < 0.05 mixed-effects model with Toeplitz variance and covariance matrix. Data are presented as mean ± standard deviation.

Figure 1 - Mean BMI and weight of participants in the NT and NM groups throughout the follow-up.

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The range of weight loss percentage did not differ between the groups. Weight reduction was ≥ 5% in 46.2% of NT patients and 63.0% of NM patients (Table 3).

Both groups presented similar weight loss throughout the follow-up period. The weight means reduced linearly and were different at each visit ($P < 0.001$).

When comparing weight means between groups throughout the period, NT presented statistically lower values than NM in the last three visits (Figure 1).

The weight change did not differ significantly between groups at the end of the study ($P = 0.094$).

The BMI results were similar to the ones for weight, except when the BMI means were compared at each visit. NT had statistically lower BMI means than NM throughout the study period, except at the second visit ($P = 0.051$) (Figure 1).

Considering the food consumption analysis (Table 4), only fruit consumption presented significant variation along the series with increasing means in NT ($P = 0.044$).

Other variables had no significant change; however, some improvement was noticed, as there was higher number of mean meals for both groups, and higher vegetable consumption and reduction of sweets in NT.

When comparing groups, no variable presented significant interaction between time and group (numbers of meal: $P = 0.585$, fruits: $P = 0.255$, sweets: $P = 0.158$, milk: $P = 0.308$, meat: $P = 0.787$, cereals: $P = 0.314$, legumes: $P = 0.778$), except for a higher vegetable consumption ($P = 0.044$) in NT at the sixth visit compared to NM (Table 4).

Physical activity practice increased in both groups. Physically active individuals increased from 23.1% to 42.3% in NT, whereas for NM, it increased from 22.2% to 66.7%. Only in NM this difference was statistically significant ($P < 0.001$).

Table 4 - Mean number of meals and food portions consumed from baseline to the ninth visit by treatment group.

Variable	Group	Baseline NT: n = 22 NM: n = 26	Third visit NT: n = 21 NM: n = 24	Sixth visit NT: n = 15 NM: n = 17	Ninth visit NT: n = 10 NM: n = 13	*P*-value*
Number of meals	NT	4.3 ± 1.0	4.2 ± 1.4	4.7 ± 0.9	4.8 ± 1.0	0.227
	NM	4.3 ± 1.0	4.5 ± 1.1	4.5 ± 1.3	4.6 ± 1.2	0.537
Fruit	NT	1.3 ± 1.6	1.7 ± 1.5	1.8 ± 1.4	2.3 ± 2.3	0.044
	NM	1.4 ± 1.1	2.1 ± 1.5	1.6 ± 1.6	1.4 ± 1.0	0.893
Vegetables	NT	1.5 ± 1.1	1.2 ± 1.0	2.0 ± 1.1†	1.8 ± 0.9	0.477
	NM	1.9 ± 1.2	1.5 ± 0.7	1.3 ± 0.8†	1.9 ± 1.1	0.853
Sweets	NT	0.3 ± 0.5	0.2 ± 0.3	0.6 ± 1.0	0.1 ± 0.3	0.216
	NM	0.2 ± 0.4	0.4 ± 0.6	0.3 ± 0.5	0.2 ± 0.3	0.877
Milk and dairy	NT	0.8 ± 0.7	0.6 ± 0.6	1.4 ± 1.2	0.7 ± 0.7	0.869
	NM	0.8 ± 0.8	0.8 ± 0.8	1.0 ± 0.9	0.8 ± 0.4	0.781
Meat and eggs	NT	1.6 ± 0.9	1.7 ± 1.1	1.6 ± 1.0	1.7 ± 0.7	0.839
	NM	1.3 ± 0.7	1.3 ± 0.7	1.3 ± 0.6	1.7 ± 0.6	0.122
Cereals and tubers	NT	2.5 ± 1.4	2.2 ± 0.9	2.7 ± 1.8	2.5 ± 1.2	0.847
	NM	2.3 ± 0.9	2.6 ± 1.0	2.2 ± 0.8	2.0 ± 0.9	0.390
Legume	NT	0.9 ± 0.8	0.8 ± 0.9	1.0 ± 0.8	0.8 ± 0.6	0.641
	NM	1.2 ± 0.8	1.0 ± 0.8	1.0 ± 0.8	1.1 ± 1.3	0.816
Sweetener	NT	0.2 ± 0.5	0.4 ± 0.5	0.3 ± 0.6	0.4 ± 0.7	0.301
	NM	0.2 ± 0.5	0.5 ± 0.4	0.4 ± 0.5	0.4 ± 0.6	0.328
Fried food	NT	0.4 ± 0.4	0.2 ± 0.5	0.1 ± 0.7	0.4 ± 0.6	0.891
	NM	0.3 ± 0.4	0.1 ± 0.6	0.2 ± 0.6	0.2 ± 0.8	0.522

Legends: Data are presented as mean ± standard deviation. NT, nutritional treatment; NM, nutritional treatment plus medicine. * Mixed-effects model of repeated measures variance analysis, comparison of the first to ninth visits. † Mixed-effects model repeated measures variance, comparison between NT and NM groups ($P = 0.044$).

DISCUSSION

This study demonstrated that the non-surgical treatment program with and without anti-obesity drugs was effective on promoting a significant clinical weight loss (> 5% of body weight).

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This result is important since body weight reduction percentages between 5% and 10% can improve obese patients' metabolic profiles (Powell, Calvin and Calvin, 2007; Wing and colaborators, 2011).

Also, lifestyle changes were achieved with some improvement in food pattern consumption and increased physical activity practice.

Approximately 46% of patients in NT and 63% in NM had weight loss above 5%. For both groups, the weight and BMI decreased linearly each visit, demonstrating the effectiveness of the nutritional treatment program. Meta-analyses provided evidence that the association of pharmacological agents to a nutritional and lifestyle intervention can promote greater weight reduction (Douketis and colaborators, 2005; Franz and colaborators, 2007).

Against this evidence, the present study showed that the NT program was effective regardless the use of anti-obesity drugs, and furthermore, NT presented lower mean weight values compared to NM from the seventh visit onwards. It is duly stressed that there is no possibility of bias because the study investigators were blinded to the medication therapy, as this was only known at the time of statistical analysis.

Despite the linear reduction of BMI and weight means in both groups, NM presented a certain plateau from the sixth visit onward, corresponding approximately to the sixth month of intervention. This has also been observed in other studies, including systematic reviews and meta-analyses (Franz and colaborators, 2007; Glenny and colaborators, 1997; Haddock and colaborators, 2002).

The continued use of medication seems to favor the maintenance of weight loss; however, it is unlikely that a higher weight reduction than that reached in the plateau may occur (Glenny and colaborators, 1997; Haddock and colaborators, 2002). NT presented a plateau only after the eighth visit. This finding agrees with another study that also observed a plateau with interventions that included a food plan (Franz and colaborators, 2007).

A significant increased in consumption of fruit for NT throughout the follow-up and a greater vegetable consumption for NT in the sixth visit compared with NM were observed, among other changes in food consumption despite no significance. Therefore, a trend in improvement seemed to occur regarding food consumption with the adoption of healthier eating habits. Obese individuals tend to under-report the consumption of foods rich in fat and simple sugars that are socially regarded as unfavorable (Lissner, 2002). Studies have observed higher under-reporting in obese than in eutrophic individuals when using a 24-h food record and food registers (Gemming and colaborators, 2014; Scagliusi and colaborators, 2008). However, in another study this did not occur using a food frequency questionnaire (Scagliusi and colaborators, 2008). Thus, changes in food consumption may have been missed due to the evaluation method. Another difficulty to detect these differences relates to the consumption means analysis, as they may not truly represent what happens in clinical practice.

Both groups increased physical activity practice, which was significantly higher in NM. Exercise produces greater body weight reduction when associated with a nutritional intervention (Anderson and colaborators, 2001; Curioni and Lourenço, 2005).

In our study, registered dietitians encouraged patients to practice physical activities; however, there was no physical education professional on the multi-disciplinary team. Perhaps if professional counseling and prescriptions for exercise practice were available regarding the physical limitations of the severely obese patients, it would be possible to achieve even better results.

We consider the method for evaluation of physical activity practice a limitation of this study. We opted to use a simpler and more direct method than the longer questionnaires available because of difficulties with the length of the visit. Furthermore, the dietary assessment was also a limitation, as high accuracy evaluation methods are unavailable because most of them have deficiencies. It is recommended that future researchers apply different food consumption evaluation methods to identify bigger nuances in severely obese individuals' eating patterns and determine beneficial modifications throughout the treatment (Buzzard, 1998).

Considering the use of anti-obesity medication, it must be considered that most patients in the NM group did not use the drug continuously during the follow-up period. This issue, however, does not limit the

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comprehension of the findings, and the objective of the present research that was to analyze the effect of nutritional treatment without medication, since from the ethical viewpoint it is not possible to limit the prescription and use of medication as the patient performs routine health follow-ups with other health professionals. A statistical approach was the chosen manner to control the use of medication without losing the study's objective and aggregate knowledge to our findings.

CONCLUSION

This study demonstrated that the non-surgical program, independently of anti-obesity drug use, with emphasis on a nutritional and lifestyle intervention for severely obese individuals effectively reduced weight and BMI in the medium-term, promoted changes in patients' food consumption, and promoted a higher frequency of physical activity practice. This should be the first treatment choice for severely obese individuals, except in imminent life-risk situations.

Future research should focus on extending the follow-up to evaluate whether the success of weight loss and lifestyle change can be enhanced, and determine strategies to maintain weight loss. The development of effective low cost and low risk treatment options to severely obese patients and performing more studies on this issue are important to broaden the knowledge on this subject.

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Conflict of interest

The authors declare that there is no conflict of interest.

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