



## RESEARCH ARTICLE

## Low or Adequate Carbohydrate Diet and Aerobic Exercise Decrease Cardiometabolic Risk in Overweight Women: A Randomized Controlled Clinical Trial

Raquel Simões Mendes-Netto<sup>1,2</sup>, Ana Carolina Santos Barbosa Machado<sup>1</sup>, Bárbara Lúcia Fonseca Chagas<sup>1</sup>, Marina de Macedo Rodrigues Leite<sup>1</sup>, Alan Bruno Silva Vasconcelos<sup>3</sup>, Danielle Góes da Silva<sup>2</sup> and Marzo Edir da Silva Grigoletto<sup>1,3\*</sup>

<sup>1</sup>Department of Physical Education, Federal University of Sergipe, Brazil

<sup>2</sup>Department of Nutrition, Federal University of Sergipe, Brazil

<sup>3</sup>Department of Physiology, Federal University of Sergipe, Brazil



\*Corresponding author: Marzo Edir da Silva Grigoletto, M.E., Center of Biological and Health Sciences, Department of Physical Education, Federal University of Sergipe, Cidade Universitária Prof. José Aloísio de Campos, Av. Marechal Rondon, s/n Jardim Rosa Elze, 49100-000, São Cristóvão, Sergipe, Brazil

### Abstract

**Aims:** To evaluate the efficacy of a low carbohydrate diet on body composition and cardiometabolic markers in overweight women undergoing endurance physical training.

**Subjects/Methods:** A randomized, controlled clinical trial included 24 overweight women, 8 of whom consumed low-calorie diets containing an adequate carbohydrate content, while 16 consumed a low carbohydrate diet. The women regularly performed semi-supervised physical exercise (walking/running) for 12 weeks. Body composition (weight, abdominal and hip circumferences) and cardiometabolic parameters were analyzed. Data were analyzed using a two-way analysis of variance with the Bonferroni post-hoc test. A  $p$  value  $< 0.05$  indicated statistical significance.

**Results:** After 12 weeks, both groups exhibited significant reductions ( $p < 0.05$ ) in body mass (A-CHO: - 9.86%; L-CHO: - 8.48%), abdominal (A-CHO: - 7.48%; L-CHO: - 8.05%) and hip circumferences, fat percentage (A-CHO: - 7.32%; L-CHO: - 9.15%), and liver function marker levels (AST: A-CHO: - 12.24%; L-CHO: - 11.26%; ALT: A-CHO: - 6.48%; L-CHO: - 11.93%), as well as improved lipid profiles. However, no differences were observed in the anthropometric and biochemical variables regarding to the carbohydrate content ( $p > 0.05$ ).

**Conclusion:** The combination of a hypocaloric diets with jogging effectively promoted weight loss and improved

cardiometabolic risk parameters, regardless of the carbohydrate content of the diet.

Brazilian Clinical Trials Registry (Registration No. RBR-5n9g5f).

### Introduction

Overweight, which has led to increases in morbidity and mortality consequent to cardiometabolic changes, is among the most significant public health issues worldwide. Among food-related factors, a higher energy intake and associated lower caloric expenditure contribute to a positive energy balance and subsequent weight gain [1-4].

Current research indicates that hypocaloric diets involving manipulations of the carbohydrate content contribute uniquely to weight loss and cardiometabolic profile improvements and have been shown to be more efficient than fat-restricted diets [3,5-13]. It is considered as a low carbohydrate diet, those in which this nutrient contribution is  $\leq 45\%$  of the total energy intake [11,14].

However, in the presence of severe carbohydrate



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restriction (carbohydrate intake < 20 g/day or < 5% of the daily intake), unsatisfactory effects such as a lack of enthusiasm for physical activity, subsequent weight gain, and low adherence to dietary follow-up, have been observed [6,15-19]. Other studies have shown that compared with other types of diets, a reduction in dietary carbohydrate intake and corresponding increase in saturated fat intake could damage the cardiometabolic profile, leading to increases in the levels of markers such as low-density lipoprotein cholesterol [20]. In contrast, other studies have demonstrated improvements in the cardiometabolic condition, as indicated increased high-density lipoprotein cholesterol levels, decreased C-reactive protein levels, and increased adiponectin levels [12,13].

For adults, the Dietary Reference Intake for macronutrients suggests a minimum daily carbohydrate intake of 130 g per day and/or 45-65% of the total dietary energy intake [21]. Given this wide range, the minimum amount of carbohydrates required to confer positive

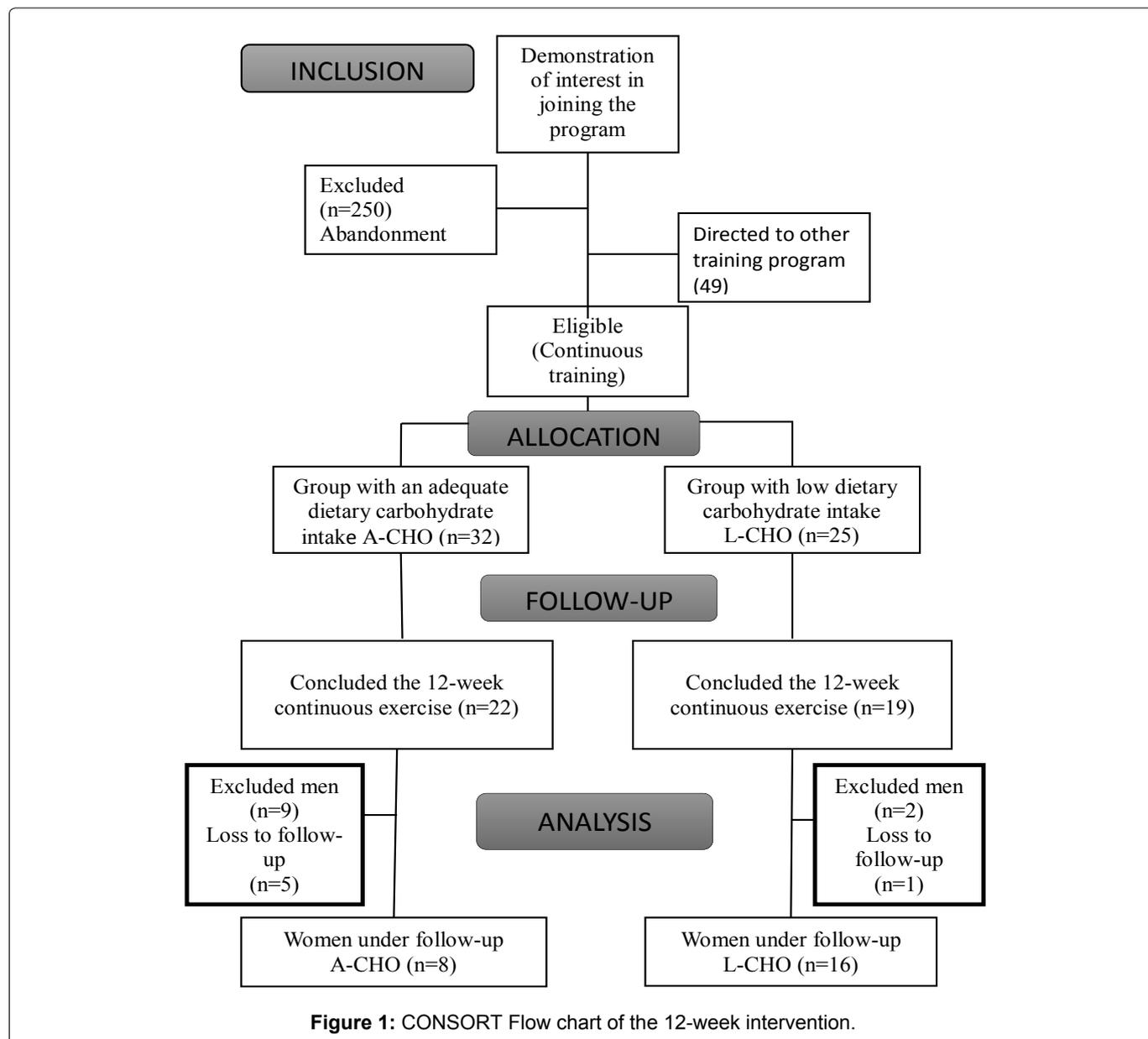
effects, such as an improved body composition and cardiometabolic parameters, remains controversial.

Therefore, we presumed that defining a dietary macronutrient distribution protocol would strengthen the nutrition strategies for overweight/obese patients, thus allowing greater control over their treatment and preventing deterioration of their conditions. This study aimed to evaluate the effects of dietary carbohydrate reduction on body composition and cardiometabolic markers in overweight women undergoing endurance physical training.

## Materials and Methods

### Sample

This randomized controlled clinical trial included adult women enrolled from among the students, professors, and staff of the university. Although we identified 361 interested potential participants, only 106 met the inclusion criteria of an age between 18 and 59 years, sedentary status, body mass index between



25 kg/m<sup>2</sup> and 39.9 kg/m<sup>2</sup>, and no weight fluctuations exceeding  $\pm 3\%$  during the last 3 months. Participants who required medical or nutrition support, had nutritional disorders, and/or used anorectic drugs and/or hormonal medications were excluded. The participants were assigned to 2 different groups, randomized by age, sex and BMI, according to the level of carbohydrate included in their diet. During the 12 weeks of intervention, six volunteers left the program under personal reasons, also all men were excluded for analyses, since only 2 men remained in the low-carbohydrate group after the intervention (Figure 1).

The sample calculation was carried out and demonstrated that the minimum of 22 patients should enter the study for a power of 0.8 and an 82% of probability of detecting a treatment difference [11].

This study followed the recommendations of the Declaration of Helsinki and the National Health Council no. 466/2012, and was approved by the ethics committee of the research university at which the study was conducted (23421113.1.0000.5546). This study was also registered in the Rebec (Registry of Brazilian Clinical Trials) database under no. RBR-5n9g5f. All participants received an explanation of the study procedures and provided written informed consent.

## Experimental design

The individuals were evaluated at the baseline (M0) and after a 12-week intervention (M1). Anthropometric, dietary, and blood measurements were performed at both time points. Once a month during the 12-week period, the participants underwent individualized nutritional consultations with average durations of 30–40 minutes (Week 1 [W1], Week 5 [W5], Week 9 [W9]), during which the weight and hip circumference were measured and a 24-hour dietary recall was performed. Concurrently, attendance at thrice-weekly training sessions was recorded, and all participants' weights were recorded once weekly. Participants who did not attend the nutritional consultations and/or had more than 2 consecutive absences or 4 sporadic absences in the training program during the 12-week period were asked to withdraw from the study.

## Dietary protocol

The caloric restriction protocol was based on achieving a body weight reduction of 5–10% within 12 weeks, with a restriction of 500 or 1000 kcal/day for overweight and obese individual [22], respectively. The basal metabolic rate was individually calculated by the formula proposed by the Institute of Medicine [21].

The carbohydrate content varied between the two groups. For the adequate carbohydrate content (A-CHO) group, the caloric contributions of carbohydrates, protein, and lipids were set at 55%, 27%, and 19% of the total calorie intake, respectively. The Low Carbohydrate

Content (L-CHO) group received a dietary plan that allowed for caloric contributions of 25%, 48%, and 28% for carbohydrates, proteins, and lipids, respectively. The participants were encouraged to follow the assigned food plans, and intake was monitored via dietary records and food plan adherence questionnaires. During dietary follow-up, the groups were further divided based on the mean final carbohydrate intake of 130 g per day.

## Training protocol

A semi-supervised training program was proposed in this study. Three weekly sessions were performed for 12 weeks, with a duration of 60 minutes and a recovery time of 48 hours between sessions. The training sessions were conducted twice weekly under the supervision of technical staff and once weekly by the volunteers themselves in a place of their preference [23]. The intensity was controlled by the Borg scale [24] and the heart rate using the Polar Team2 system (Polar Electro®, Kempele, Finland).

Participants received individualized training sheets with guidance regarding the heart rate for each week of training. To control heart rate in training 3 (at home), participants received an individual polar (Polar Electro®, Kempele, Finland). The participants were required to practice continuous exercise, they began training at 65% of their maximum heart rate (MHR), with 5% increases over 4 weeks to 75% of their MHR at the completion of the 12-week program. The intensity was controlled individually using a heart rate monitor (watch) connected to a computer program, the data observed was used by the technical staff to alert the volunteer to increase or decrease the intensity of the exercise (Table 1).

## Anthropometric and cardiometabolic evaluation

At the initial (M0) and final (M1) evaluations, weight was measured using a digital scale (Lider®, P150C, Brazil) with a precision of 100 g. The abdominal and hip circumferences were evaluated using an inelastic tape (SANNY®, American Medical do Brasil Ltda) [25]. Body composition was measured via electrical bioimpedance (Biodynamics®310e, Corporation, EUA). In addition, 12-mL blood samples were collected via venipuncture from an antecubital vein after a 12-hour fast. The lipid profile (total cholesterol, very low-density lipoprotein cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and free triacylglycerols) and levels of hepatic profile markers (aspartate transaminase and alanine transaminase), blood glucose, uric acid, urea, and creatinine were measured. All blood tests were performed using an Immunoassay Analyzer (Abbott Architect i1000SR Analyzer, USA).

## Statistical analysis

For all statistical analyses, a p value of < 0.05 (5%) indicated statistical significance. SPSS software, ver-

**Table 1:** Periodization for 12 weeks of endurance training.

Week	Intensity (% MHR)	Session 1 (min)	Session 2 (min)	Session 3* (at home) (min)
1	65	20	25	30
2	65	25	30	35
3	65	30	35	40
4	65	35	40	45
5	70	20	25	30
6	70	25	30	35
7	70	30	35	40
8	70	35	40	45
9	75	20	25	30
10	75	25	30	35
11	75	30	35	40
12	75	35	40	45

MHR = Maximum Heart Rate; min = minutes. \*in the at home training session the intensity was 5% lower than in the face-to-face sessions.

**Table 2:** Pre- and post-intervention anthropometric and body composition variables of overweight women according to diet type (A-CHO and L-CHO).

	(Mean (SE))		ANOVA		
	A-CHO n = 08	L-CHO n = 16	G F (p)	T F (p)	GxT F (p)
<b>Body Mass (kg)</b>					
Pre	77.77 ± 17.38	78.77 ± 11.47	0.06 (0.23)	99.72 (< 0.001)	0.10 (0.75)
Post	70.28 ± 17.44	72.18 ± 11.48			
Δ%	-9.86	-8.48			
ES	0.52	0.54			
<b>BMI (Kg/m<sup>2</sup>)</b>					
Pre	31.02 ± 6.25	32.41 ± 3.95	0.57 (0.45)	83.51 (< 0.001)	0.70 (0.41)
Post	27.97 ± 6.05	29.66 ± 3.88			
Δ%	-9.86	-8.48			
ES	0.54	0.72			
<b>Abdominal circumference (cm)</b>					
Pre	97.12 ± 16.72	101.4 ± 10.53	0.50 (0.48)	109.03 (< 0.001)	0.39 (0.53)
Post	89.85 ± 15.78	93.32 ± 11.04			
Δ%	-7.48	-8.05			
ES	0.61	0.74			
<b>Hip circumference</b>					
Pre	113.56 ± 11.88	109.88 ± 7.07	0.39 (0.53)	70.88 (< 0.001)	0.10 (0.75)
Post	105.91 ± 11.98	104.55 ± 8.62			
Δ%	-6.76	-4.91			
ES	0.60	0.67			
<b>% Fat (%)</b>					
Pre	36.46 ± 4.52	37.23 ± 4.24	0.03 (0.84)	46.59 (< 0.001)	0.00 (0.99)
Post	33.86 ± 5.13	33.84 ± 4.60			
Δ%	-7.32	-9.15			
ES	0.57	0.79			

<b>FM (Kg)</b>					
Pre	28.61 ± 9.94	29.51 ± 6.47	0.03 (0.85)	101.35 (< 0.001)	0.008 (0.93)
Post	24.42 ± 9.75	24.71 ± 6.34			
Δ%	-15.63	-16.64			
ES	0.61	0.79			
<b>LM (kg)</b>					
Pre	48.41 ± 8.42	49.26 ± 6.61	0.16 (0.69)	36.47 (< 0.001)	0.28 (0.60)
Post	45.86 ± 8.04	47.47 ± 6.43			
Δ%	-5.22	-3.62			
ES	0.18	0.22			

A-CHO: Adequate Carbohydrate Content; L-CHO: Low Carbohydrate content; ES: Effect Size; G: group; T: time; G×T: interaction effect of G and T; BMI: Body Mass Index; FM: Fat Mass; LM: Lean Mass; F: F value of the test.

**Table 3:** Pre- and post-intervention biochemical variables of overweight women according to diet type (A-CHO and L-CHO).

	<b>(Mean (SE))</b>		<b>ANOVA</b>		
	A-CHO n = 08	L-CHO n = 16	G F (p)	T F (p)	G×T F (p)
<b>TC (mg/dL)</b>					
Pre	198.62 ± 41.00	195.81 ± 19.84	0.005 (0.94)	23.33 (< 0.001)	0.11 (0.73)
Post	169.00 ± 32.05	173.62 ± 30.87			
Δ%	-14.41	-10.67			
ES	0.70	0.68			
<b>VLDL-c (mg/dL)</b>					
Pre	23.00 ± 17.75	24.25 ± 9.01	0.21 (0.65)	13.34 (0.001)	0.61 (0.44)
Post	15.37 ± 7.38	17.75 ± 6.80			
Δ%	-20.38	-21.60			
ES	0.76	0.82			
<b>LDL-c (mg/dL)</b>					
Pre	117.75 ± 25.95	113.06 ± 28.33	0.035 (0.85)	28.68 (< 0.001)	0.003 (0.95)
Post	91.87 ± 24.48	92.50 ± 27.07			
Δ%	-21.81	-17.47			
ES	0.76	0.68			
<b>HDL-c (mg/dL)</b>					
Pre	57.87 ± 9.26	58.50 ± 12.00	0.06 (0.79)	8.11 (0.009)	0.14 (0.71)
Post	61.75 ± 10.19	63.37 ± 9.87			
Δ%	6.96	9.28			
ES	0.55	0.47			
<b>TG (mg/dL)<sup>b</sup></b>					
Pre	84.28 ± 28.22	120.50 ± 45.29	4.22 (0.05)	10.66 (0.004)	2.88 (0.10)
Post	65.71 ± 20.43	89.19 ± 33.69			
Δ%	-19.50	-20.37			
ES	0.76	0.79			
<b>Glycemia (mg/dL)</b>					
Pre	87.75 ± 11.90	91.25 ± 8.69	0.76 (0.39)	5.38 (0.03)	0.46 (0.50)
Post	84.25 ± 6.36	86.18 ± 6.64			
Δ%	-3.00	-5.15			
ES	0.25	0.56			
<b>AST (U/L)<sup>a</sup></b>					
Pre	26.50 ± 4.40	22.46 ± 4.58	3.13 (0.09)	12.72 (0.002)	1.41 (0.24)

Post	22.87 ± 3.87	20.60 ± 4.59			
Δ%	-12.24	-11.26			
ES	0.79	0.39			
<b>ALT (U/L)<sup>a</sup></b>					
Pre	23.00 ± 8.07	16.60 ± 7.05	5.27 (0.03)	1.84 (0.18)	3.46 (0.07)
Post	20.50 ± 8.45	14.06 ± 7.60			
Δ%	-6.48	-11.93			
ES	0.69	0.40			
<b>Uric acid (mg/dL)</b>					
Pre	3.68 ± 0.65	3.84 ± 0.93	0.12 (0.72)	1.28 (0.26)	0.07 (0.79)
Post	3.55 ± 0.61	3.68 ± 1.27			
Δ%	-2.78	-4.85			
ES	0.07	0.12			
<b>Urea (mg/dL)</b>					
Pre	21.00 ± 4.03	22.06 ± 5.76	0.03 (0.84)	0.41 (0.52)	0.02 (0.88)
Post	22.37 ± 3.96	22.06 ± 5.19			
Δ%	8.55	2.73			
ES	0.23	0.10			
<b>Creatinine (mg/dL)</b>					
Pre	0.70 ± 0.11	0.69 ± 0.09	0.78 (0.38)	9.50 (0.005)	2.38 (0.13)
Post	0.67 ± 0.10	0.61 ± 0.08			
Δ%	-2.46	-11.32			
ES	0.35	0.78			

A-CHO: Adequate Carbohydrate Content; R-CHO: low carbohydrate content; ES: Effect Size; G: group; T: time; G×T: interaction F, F test; p, significance; TC: Total Cholesterol; VLDL-c: Very Low-Density Lipoprotein cholesterol; LDL-c: Low-Density Lipoprotein cholesterol; HDL-c: High-Density Lipoprotein cholesterol; TG: free triacylglycerols; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; <sup>a</sup>R-CHO, n = 15; <sup>b</sup>A-CHO, n = 7.

sion 20 for Windows (Armonk, NY: IBM Corp) was used for the data analysis. Descriptive statistics, delta variations, and standard errors were used to compare data between groups and as a function of time. The Shapiro-Wilk test was used to determine data normality. A two-way analysis of variance and Bonferroni post-hoc test were used to compare the anthropometric and physical fitness data between groups (G×T), over time (T), and within groups (G).

The Effect Size (ES) was calculated as the mean of the difference divided by the mean of the standard deviations of the pre- and post-intervention timings. Absolute ES values (modulus) of 0.20-0.49, 0.50-0.79, and > 0.80 were considered small, moderate, and large, respectively [26].

## Results

Twenty-four overweight women participated in this study. The mean age were 32.19 ± 9.55 years in the A-CHO group and 29.37 ± 12.28 years in the L-CHO group. The anthropometric data analysis (Table 1) showed significant reductions across the parameters as a function of time, with no significant differences between A-CHO and L-CHO groups.

Although participants from both groups exhibited significant decreases in lean mass over time, this re-

duction had a low clinical effect (ES < 0.2). By contrast, changes in the abdominal circumference and body fat had higher effect sizes (ES: 0.5-0.79).

The participants also exhibited improved lipid profiles, with a decrease in total cholesterol, very low-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and free triacylglycerol levels that were accompanied by a significant increase in high-density lipoprotein cholesterol over time (T). However, the difference between the groups was not statistically significant (G×T; Table 2, Table 3).

Although a decrease in aspartate aminotransferase levels was observed in both groups over time, no G×T difference was observed. The alanine aminotransferase levels, however, differed between the L-CHO and A-CHO groups (p = 0.03). The uric acid and urea levels did not change over time or with respect to dietary intervention outcomes. However, both groups exhibited decreases in creatinine levels over the 12-week period.

## Discussion

The main finding of the present study was that the combination of caloric restriction with an endurance physical training program yielded changes in body weight and body composition and improved

the cardiometabolic profile, regardless of the dietary carbohydrate content. This finding agrees with those of previous studies indicating that moderate caloric restriction (300-500 kcal) appears to facilitate adherence to weight loss programs, regardless of the dietary carbohydrate content, and contribute to improvements in body composition and inflammation levels over a 12-week period [27-30].

Despite the different carbohydrate contents of the diets administered in the present study, the carbohydrate reduction proposed to the L-CHO group was not intense when compared with ketogenic diets [12]. Therefore, the anthropometric and cardiometabolic profile parameters may have not been drastically affected, as the minimum limits recommended by the Dietary Reference Intake criteria (110 g/day or 45% of the total energy intake) were observed [21].

The participants exhibited changes in blood lipid profiles throughout the intervention period that did not interact with the dietary carbohydrate composition. Diets with moderate carbohydrate contents and those with severe restrictions seem to have similar short-term effects [31-33]. Over the long term, however, intense carbohydrate restriction appears to have a reduced effect on triacylglycerol levels [34,35].

In the present study, the hypocaloric diet designed to control carbohydrate intake may have led to a slower insulin release, thus promoting increased hepatic glucose degradation and the use of free fatty acids as an energy source by inhibiting the action of lipoprotein lipase [36]. The reduced release of insulin, in conjunction with a reduced dietary supply of energy and fats, may have also contributed to the reduced synthesis and release of blood lipids, such as cholesterol and triacylglycerol, in the form of lipoproteins [37].

Despite the importance of the dietary follow-up, the inclusion of regular physical exercise is well known to reduce the risk of chronic noncommunicable diseases by 6-10% while increasing the quality of life and life expectancy [21]. Adherence to dietary interventions ( $\geq 80\%$ ) in association with physical activity potentiates a reduction in cardiometabolic risk [38,39].

The strengths of this study included the randomized design, carbohydrate reduction in compliance with dietary reference guidelines, dietary planning based on regional and financial aspects, and follow-ups conducted by health professionals to facilitate program adherence. However, this study was also limited by our inability to establish an experimental group with a very low carbohydrate intake ( $< 20$  g/d) for comparison. Moreover, this condition would have required more intense monitoring of patients, which was not possible within the framework of our study.

In summary, changes in the carbohydrate compositions of diets need not be severe to affect body weight reduction. Furthermore, consumption of a hypocaloric diet within the recommended carbohydrate intake range over a 12-week period, when accompanied by regular physical exercise, could promote improvements in the lipid profiles of overweight women.

## Author Contributions

RSMN and MESH designed research; ACSBM, BLFC and ABSV performed experiments; AGRN and MESH analyzed data; AGRN and JCAS interpreted results of experiments; RSMN, MMRL, ABSV and DGS drafted manuscript; ABSV and MESH edited and revised manuscript; RSMN and MESH approved final version of manuscript.

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## Conflict of Interest

The authors declare that there is no conflict of interest.

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