

## Alimentary Habits, Physical Activity, and Framingham Global Risk Score in Metabolic Syndrome

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### Abstract

**Background:** Metabolic syndrome is a complex disorder represented by a set of cardiovascular risk factors. A healthy lifestyle is strongly related to improve Quality of Life and interfere positively in the control of risk factors presented in this condition.

**Objective:** To evaluate the effect of a program of lifestyle modification on the Framingham General Cardiovascular Risk Profile in subjects diagnosed with metabolic syndrome.

**Methods:** A sub-analysis study of a randomized clinical trial controlled blind that lasted three months. Participants were randomized into four groups: dietary intervention + placebo (DIP), dietary intervention + supplementation of omega 3 (fish oil 3 g/day) (DIS3), dietary intervention + placebo + physical activity (DIPE) and dietary intervention + physical activity + supplementation of omega 3 (DIS3PE). The general cardiovascular risk profile of each individual was calculated before and after the intervention.

**Results:** The study included 70 subjects. Evaluating the score between the pre and post intervention yielded a significant value (p < 0.001). We obtained a reduction for intermediate risk in 25.7% of subjects. After intervention, there was a significant reduction (p < 0.01) on cardiovascular age, this being more significant in groups DIP (5.2%) and DIPE (5.3%).

**Conclusion:** Proposed interventions produced beneficial effects for reducing cardiovascular risk score. This study emphasizes the importance of lifestyle modification in the prevention and treatment of cardiovascular diseases. (Arq Bras Cardiol. 2014; 102(4):374-382)

Keywords: Food habits; Cardiovascular diseases; Lifestyle; Exercise; Probability; Risk factors; Metabolic x Syndrome.

### Introduction

Metabolic syndrome (MS) is a clinical condition described as a group of metabolic disorders and cardiovascular risk factors, which are generally associated with central fat deposition and insulin resistance, present in the same individual<sup>1</sup>. According to the World Health Organization (WHO), cardiovascular diseases accounted for 33% deaths in Brazil in 2011<sup>2</sup>, a relevant fact when associated with the estimate that MS is responsible for a 2.5-times increase in cardiovascular mortality<sup>1</sup>.

Structured lifestyle modification programs, including dietary education and supervised physical exercise, are effective for the treatment of MS. The use of fish oil, which is rich in omega

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3 fatty acids, helps in decreasing plasma triglycerides, very low-density lipoprotein (VLDL), and arterial pressure, and it is recommended for the treatment of MS in association with lifestyle intervention  $^{3-6}$ .

Scores that allow the stratification of the risk for cardiovascular disease, such as the Framinghan score, have been used to identify individuals at a higher risk for cardiovascular events and are indicators of the potential benefits of lifestyle changes and pharmacological treatment<sup>7-9</sup>.

In Brazil, the Ministry of Health recommends the use of Framingham scores as a strategy to estimate cardiovascular risk. The use of scores that allow the stratification of risk is important in the primary prevention of cardiovascular disease, in view of the multiplicity of risk factors that an individual may present<sup>10</sup>.

The overall cardiovascular risk score, which was recently published by the Framingham study group, now includes the risk for future overall cardiovascular events, i.e., stroke, transient ischemic attack, and heart failure. In addition, this new score includes the concept of vascular age (VA), which aims to adjust the age of patients according to their atherosclerotic state<sup>11,12</sup>.

This study aimed to determine the effects of a lifestyle modification program on the Framingham risk score in individuals with MS.

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### Methods

This was a blinded, randomized, controlled clinical trial that aimed to study the effects of distinct lifestyle change interventions on the Framingham risk score and cardiovascular risk factors for MS.

The study sample was extracted from a secondary database of a primary study in which the participants were selected from a group of volunteers who enrolled after the study was announced in the press or promoted by the cardiology outpatient clinic of the Hospital São Lucas at the Pontifícia Universidade Católica of Rio Grande do Sul (PUC-RS). The participants included men and women aged between 30 and 60 years who exhibited three or more of the findings indicated by the National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP III)8,13: an abdominal circumference (AC) of > 88 cm for women and > 102 cm for men, a systolic arterial pressure (SAP) of  $\geq$  130 mmHg and a diastolic arterial pressure of  $\geq 85$  mmHg, a fasting glucose level of  $\geq$  100 mg/dL, a triglyceride level of  $\geq$ 150 mg/dL, and a high-density lipoprotein cholesterol (HDL-C) level of < 40 mg/dL for men and < 50 mg/dL for women. Patients with absolute contraindications for physical activity because of musculoskeletal, neurological, vascular, pulmonary, and cardiac problems; those on lipid-lowering medication; those on anticoagulant medication; those who exercised regularly (30 min twice a week or more); those with a psychiatric disorder; those on antidepressant medication; those diagnosed hypothyroidism; pregnant patients; those consuming omega 3 supplements or any other food or vitamin supplements; and those who were difficult to contact and/or were lost to follow-up were excluded.

A total of 87 individuals were eligible for the study. All patients were provided with information about the study through the informed consent document.

After the initial evaluation, the patients were randomized into 4 groups that received one of the following interventions over 3 months: (1) dietary intervention (DI) and placebo administration (1 g/day of mineral oil; DIP), (2) DI combined with omega 3 fatty acid (1 g/day) supplementation (DIS3), (3) DI and placebo administration (1 g/day of mineral oil) combined with a physical exercise program (3 times per week) (DIPE), and (4) DI and omega 3 supplementation (1 g/day) combined with a physical exercise program (3 times per week; DIS3PE). The scheme of the study is shown in Figure 1.

DI was supervised by the nutrition team, while the physical exercise sessions were supervised by the physiotherapy team; both teams comprised fully trained professionals. The biochemical tests were performed using blood samples collected via venipuncture after 12 h of fasting. Plasma glucose, total cholesterol (TC), serum triglyceride, and serum HDL-C levels were determined through enzymatic methods performed in a fully automated analyzer (VITROS 950 dry-chemistry system, Johnson & Johnson, Rochester, NY, USA). Low-density lipoprotein cholesterol (LDL-C) levels were estimated using the Friedewald equation<sup>14</sup>.

The dietary follow-up included two assessments, one at the start of the intervention and the second at the end of the follow-up period, as well as fortnightly consultations. The assessments included the following: anamnesis of eating habits, a 24-h record of food intake, a 2-day record of food intake, and anthropometric evaluation. In each consultation, a 24-h record of food intake was assessed to monitor diet adherence. In addition, targets for the following consultation were set; weight and AC were measured; healthy eating topics such as food labels, trans fats, functional foods, food pyramid, sodium intake, and five-a-day program were discussed; and doubts were clarified. At each consultation, the correct use of capsules was checked and the DIP and DIS3 groups were instructed to provide a brief report on the adherence to physical exercise.

The anthropometric evaluation included the measurement of body weight, height, and AC. Body weight was measured using a calibrated Cauduro® scale with a maximum capacity of 160 kg; the patients were barefoot and wore light clothes during measurement. Height was measured using a vertical millimeter stadiometer, with a maximum extension of 2 m and a scale of 0.5 cm attached to the scales. The AC was measured in the abdominal region where there is maximum extension, as recommended by Lohman et al<sup>15</sup>, using a common 150-cm inextensible and inelastic tape measure.

The dietary intervention included an eating plan, which was given to the patients during the first consultation. The eating plan was based on the recommendations of the First Brazilian Guideline for the Diagnosis and Treatment of Metabolic Syndrome (I DBSM)<sup>1</sup>, which recommends the following composition: total calories, to reduce weight by 5% to 10%; carbohydrates, 50% to 60% of total calories, with an emphasis on complex carbohydrates; fibers, 20 to 30 g/day; total fat, 25% to 35% of total calories; saturated fatty acids, < 10% of total calories; polyunsaturated fatty acids, up to 10% of total calories; cholesterol, < 300 mg/day; proteins, 0.8 g to 1.0 g/kg current weight/day or 15% of total calories; micronutrients, in accordance with the recommendations of the Dietary Reference Intakes (DRIs)<sup>16</sup>, with an emphasis on antioxidants.

There were a total of 36 physical exercise sessions, including walking on a treadmill for 30 min 3 times a week. Speed and inclination were maintained within a range of 65%–75% of the maximum heart rate according to the patient's age<sup>1</sup>.

Analysis of the overall cardiovascular risk score (OCRS) estimate included the following factors: age, gender, TC levels, HDL-C levels, SAP, smoking history, use of antihypertensive medication, and diabetes mellitus. A calculator available on the study website, which was based on the lipid profile, was used to calculate the risk score and VA for each individual<sup>17</sup>. The stratification of the score for assessing the overall cardiovascular risk profile over 10 years is as follows: low risk, <6%; intermediate risk, between 6% and 20%; and high risk, >20%<sup>11</sup>.

Descriptive statistics were used to analyze the data, namely frequency distribution and relative frequency distribution, mean, and standard deviation. The Kolmogorov–Smirnov test was used to study the symmetry of data distribution. To compare the continuous variables between the initial and final moments as well as between groups, analysis of variance (ANOVA) was used for repeated measurements,

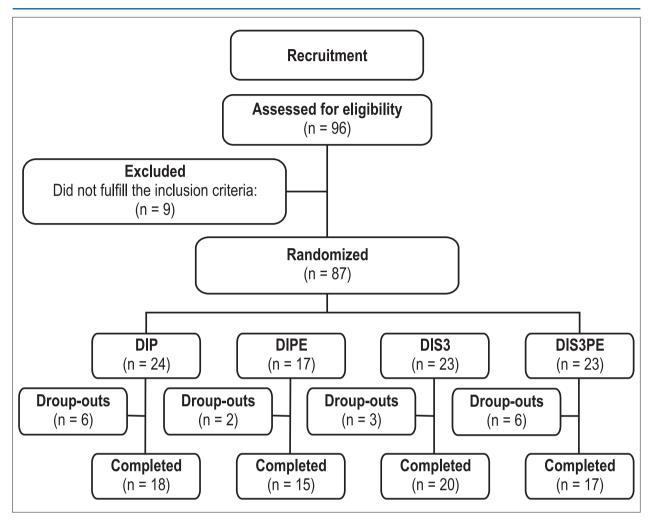


Figure 1 – Study scheme.

DP: dietary intervention; DIPE: dietary intervention + physical activity; DIS3: dietary intervention + omega 3 fatty acid supplementation; DIS3PE: dietary intervention + physical activity + omega 3 fatty acid supplementation.

with measurements relating to the intragroup factor and intervention as an intergroup factor. The Bonferroni test was used for *post-hoc* analysis (p < 0.05).

The baseline characteristics of patients were compared using one-way analysis of variance (one-way ANOVA) followed by *post-hoc* Bonferroni and Kruskal–Wallis tests, which were followed by *post-hoc* Dunn's test. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) software,  $20.0^{13}$ . The level of significance ( $\alpha$ ) was set at 5%.

Confidentiality and professional secrecy criteria related to the information collected during the study were met according to resolution 196/96, which establishes the guidelines for research in human beings. The study was approved by the Research Ethics Committee of the PUC-RS under process 0603024.

### **Results**

Of the 87 eligible individuals, 17 discontinued their participation in the study because of travelling difficulties, personal situation, or inability to perform physical exercise.

Eventually, 70 patients participated. Of these, 71.4% were women. The mean age of patients was  $51.4 \pm 6.52$  years. The distribution of patients in each group was as follows: DIP, 25.7%, n = 18; DIS3, 28.6%, n = 20; DIPE, 21.4%, n = 15; and DIS3PE, 24.3%, n = 17).

Before the intervention, there was no significant difference between the groups with regard to the variables under analysis; the group as a whole was thus homogeneous (Table 1).

The mean OCRS was lower after the intervention than before the intervention in all groups; these scores were between 9.7% (DIPE group) and 21.6% (DIP group), and the difference was significant (p < 0.05) in the DIP and DIS3PE groups. The mean score before and after the intervention was not significantly different among groups (p > 0.05).

Repeated measurement analysis revealed that the effect of time was significant (p < 0,001). Regardless of group, the mean values were lower after the intervention. Considering only the group effect, the differences observed were not significant (p > 0.05), i.e., the mean OCRS in all groups were statistically similar at the beginning and end of the study (Table 2).

Characteristics	DIP	DIPE	DIS3	DIS3PE
Age#	51.6 ± 13.4	50.8 ± 13.7	52 ± 12.5	51 ± 14.7
Weight#	81.6 ± 21.5	84.7 ± 23.6	88.78 ± 22.7	90.3 ± 24.9
Height#	1.60 ± 0.1	1.60 ± 0.2	1.61 ± 0.2	1.60 ± 0.2
BMI#	32.8 ± 8.1	32.3 ± 8.9	34.1 ± 7.9	33.5 ± 8.6
AC#	104.0 ± 24.7	102.2 ± 26.4	109.9 ± 25.3	108.1 ± 27.2
TG¶	199.6 ± 126.3	194.5 ± 96.3	193.8 ± 93.2	198.6 ± 76.3
HDL¶	47.3 ± 14.1	45.7 ± 15.7	44.65 ± 14.9	40.8 ± 12.3
Glucose	95.1 ± 23.1	112.9 ± 69.0	111.75 ± 41.4	110.1 ± 33.3
SAP#	134.4 ± 35.1	131.1 ± 36.6	130.2 ± 31.7	131.6 ± 36.3
DAP#	85.3 ± 21.2	84.3 ± 22.4	83.9 ± 23.1	78.2 ± 20.3

#### Table 1 – Characteristics of the sample

# One-way analysis of variance (One-way ANOVA) – Bonferroni test (post-hoc); ¶ Kruskal–Wallis test (post-hoc Dunn's). DIP: dietary intervention; DIPE: dietary intervention + physical activity; DIS3: dietary intervention + omega 3 fatty acid supplementation; DIS3PE: dietary intervention + physical activity + omega 3 fatty acid supplementation; BMI: body mass index; AC: abdominal circumference; TG: triglycerides; HDL: high-density lipoprotein; SAP: systolic arterial pressure; DAP: diastolic arterial pressure.

	Bivariate					Multivariate		
Variables	Groups				p between	p time	p group	p Interaction
	DIP (n = 18)	DIPE (n = 15)	DIS3 (n = 20)	DIS3PE (n = 17)	groups	effect//	effect¶	effect#
OCRS								
Before	13.4 ± 2.3	12.4 ± 2.1	13.3 ± 1.8	14.3 ± 2.1	0.784‡	0.001	0,957	0,770
After	10.5 ± 1.7	11.2 ± 2.3	11.4 ± 1.5	11.9 ± 1,8	0.881§			
p intra†	0.034	0.427	0.082	0,029				
<b>DOCRS</b>	2.9	1.2	1.9	2.4				
% AOCRS	21.6	9.7	14.3	16.8				
VA								
Before	67.9 ± 3.4	67.6 ± 3.3	68.1 ± 3.4	69.5 ± 4.1	0.802‡	0.003	0.962	0.966
After	64.4 ± 3.4	64.0 ± 3.9	65.6 ± 3.2	66.9 ± 4.1	0.772§			
p intra†	0.151	0.055	0.199	0.183				
ΔVA	3.5	3.6	2.5	2.6				
% ΔVA	5.2	5.3	3.7	3.9				

#### Table 2 – Mean and standard deviation for the overall risk score (OCRS) and vascular age (VA) before and after the intervention for each group

//: time effect (before versus after); ¶: group effects; #: effects of interaction time versus group; ‡: comparison among groups before the intervention; §: comparison among groups after the intervention; †: comparison before and after the intervention; Δ: mean variation (initial – initial). DIP: dietary intervention; DIPE: dietary intervention + physical activity; DIS3: dietary intervention + omega 3 fatty acid supplementation; DIS3PE: dietary intervention + physical activity + omega 3 fatty acid supplementation.

The mean VA was higher than the chronological age of all the volunteers in all groups. The effect of time was significant (p < 0.01), indicating a decrease in the mean score after the intervention. At the end of treatment, all groups exhibited a lower mean VA. On comparing the preand postintervention evaluations, the greatest decrease in VA was observed in the DIPE (5.3%) and DIP (5.2%) groups. All groups exhibited the same behavior pattern (p > 0.05) and did not differ among themselves. In addition, they did not differ with regard to their responses over time (p > 0.05; Table 2). Before the intervention, the individuals were classified in the following risk categories: 24.3% were at low risk, 50% were at intermediate risk, and 25.7% were at high risk. After the intervention, 14.3% patients at high risk exhibited a decrease in their scores and fell into the intermediate-risk group, i.e., the prevalence of individuals at high risk decreased to 11.4%, while that of individuals at intermediate risk increased to 64.3%.

To analyze the risk factors associated with MS that are included in the calculation of the OCRS, it was necessary to stratify the AC and HDL-C levels according to gender because the cut-off values are different.

The TC levels varied significantly with time (p < 0.05). However, the mean scores for the groups before and after the intervention did not follow a pattern. The DIP, DIPE, and DIS3 groups exhibited a decrease in TC levels after the intervention, whereas the DIS3PE group exhibited an increase. However, all groups exhibited the same pattern of behavior in regard to the group effect (p > 0,05) and interaction (p > 0.05), indicating that the treatments and responses did not differ over time (Table 3).

The differences in HDL-C levels observed before and after the intervention and between groups were not significant for women, although the DIS3PE group exhibited a mean increase of 10.2% at the end of the study (compared with that at baseline). The remaining groups exhibited a decrease at the end of the intervention. There was a significant difference in HDL-C levels among the men in terms of both the group effect (p > 0.05) and interaction (p > 0.05). However, there was a significant difference with regard to time (p < 0.05), indicating that after the intervention, the mean HDL levels differed significantly among men, regardless of the group. According to the estimated means, the DIS3PE group exhibited a significant increase in HDL-C levels after the intervention (p < 0.05), whereas the remaining groups exhibited an insignificant decrease in the mean levels after the intervention (Table 3). With regard to mean glucose levels, only time had a significant effect (p < 0.001), suggesting that, regardless of the group, there was a significant decrease at the end of the intervention. Therefore, we believe that the treatments had a similar effect with regard to this variable. The same was observed for the mean values of SAP; only the effect of time was significant ( $p \le 0.001$ ). This indicated that, regardless of the group, the mean SAP values were lower after the intervention than before the intervention (Table 4).

A significant difference in AC with time was observed for women, indicating a significant decrease in the mean AC after the intervention (p < 0.001). At the end of treatment, all groups exhibited a lower mean AC. According to the data collected before and after the intervention, the greatest decrease occurred in the DIS3PE group (6.9%), which showed a significant effect (p < 0.05). This suggested that the decrease in the mean AC was greater in this group than in the DIP (p < 0.05), DIPE (p < 0.05), and DIS3 (p < 0.05) groups; there were no differences between the means in the latter groups.

In men, only time had a significant effect on AC (p < 0.001), which demonstrated a significant decrease after the intervention, regardless of the group (Table 4).

Variables _	Bivariate				Multivariate				
	Groups				p between			p interaction	
	DIP (n = 18)	DIPE (n = 15)	DIS3 (n = 20)	DIS3PE (n = 17)	groups	p time effect//	p group effect¶	effect#	
TC									
Before	233.9 ± 12.3	227.5 ± 13.6	223.8 ± 11,7	213.1 ± 12.7	0.064‡	0.020	0.995	0.130	
After	203.9 ± 11.4	212.2 ± 12.5	215.6 ± 10.8	219.2 ± 11.8	0.056§	- 0.032			
p intra†	0.089	0.070	0.100	0.554					
ΔCT	30.0	15.3	8.2	6.1					
% ΔCT	12.8	6.7	3.7	2.9					
HDL women									
Before	48.5 ± 2.2	48.1 ± 3.2	48.6 ± 3.1	44.1 ± 2.4	0.321‡	0.077	0.973	0.495	
After	47.0 ± 3.1	45.0 ± 2.1	46.2 ± 2.3	48.6 ± 3.4	0.755§	- 0.077			
p intra†	0.507	0.348	0.157	0.074					
∆HDL women	1.5	3.1	2.4	4.5					
% AHDL women	3.1	6.4	4.9	10.2					
HDL men									
Before	43.0 ± 6.5	36.0 ± 3.5	37.3 ± 3.7	34.8 ± 2.1	0.212‡	- 0.047	0.659	0.484	
After	$40.0 \pm 4.8$	32.7 ± 0.3	36.0 ± 3.1	40.8 ± 8.3	0.145§				
p intra†	0.431	0.477	0.921	0.021					
∆HDL men	3.0	3.3	1.3	6.0					
% AHDL men	7.0	9.2	3.5	17.2					

Table 3 – Mean and standard deviation for total cholesterol (TC) and high-density lipoprotein cholestrol (HDL-C) levels before and after the intervention for each group

//: time effect (before versus after); ¶: group effect; #: interaction effect time versus group; ‡: comparison among groups before the intervention; §: comparison among groups after the intervention; †: comparisons before and after the intervention; Δ: mean variation (initial – initial). DIP: dietary intervention; DIPE: dietary intervention + physical activity; DIS3: dietary intervention + omega 3 fatty acid supplementation; DIS3PE: dietary intervention + physical activity + omega 3 fatty acid supplementation.

Variables	Bivariate				Multivariate				
	Groups			p between	p time	p group	p interaction		
	DIP (n = 18)	DIPE (n = 15)	DIS3 (n = 20)	DIS3PE (n = 17)	groups	effect//	effect¶	effect#	
Glucose									
Before	95.1 ± 8.9	112.8 ± 9.7	111.7 ± 8.4	110.1 ± 9.1	0.087‡	0.000	0.385	0.562	
After	90.6 ± 4.3	95.1 ± 4.7	100.1 ± 4.1	101.7 ± 4.4	0.112§	0.002			
p intra†	0.042	0.192	0.040	0.009					
∆ glucose	4.5	17.7	11.6	8.4					
% Δglucose	4.7	15.7	10.4	7.6					
SAP									
Before	134.4 ± 3.8	131.1 ± 4.2	130.2 ± 3.6	131.6 ± 3.9	0.667‡	0.001	0.702	0.935	
After	127.0 ± 2.9	122.4 ± 3.2	123.4 ± 2.8	126.7 ± 3.0	0.702§				
p intra†	0.075	0.070	0.091	0.281					
ΔSAP	7.4	8.7	6.8	4.9					
% ΔSAP	5.5	6.6	5.2	3.7					
AC women									
Before	102.2 ± 1.5	101.7 ± 2.5	108.1 ± 2.6	107.2 ± 1.9	0.357‡	-0.004	0.233	0.017	
After	100.1 ± 1.7	97.1 ± 2.8	103.2 ± 3.0	99.8 ± 2.3	0.102§	<0.001			
p intra†	0.016	0.005	0.004	<0.001					
ΔCA women	2.1	4.6	4.9	7.4					
% AAC women	2.1	4.5	4.5	6.9					
AC men									
Before	110.6 ± 5.4	104.3 ± 2.2	113.6 ± 2.6	109.7 ± 1.9	0.202‡	<0.001	0.413	0.074	
After	103.2 ± 6.1	98.7 ± 3.8	107.1 ± 9.7	103.2 ± 1.8	0.285§			0.974	
p intra†	0.068	0.196	0.020	0.005					
ΔAC men	7.4	5.6	6.5	6.5					
% ΔAC men	6.7	5.4	5.7	5.9					

Table 4 – Mean and standard deviations for glucose levels, systolic arterial pressure (SAP), and abdominal circumference (AC) before and after the intervention for each group

//: time effect (before versus after); ¶: group effect; #: interaction effect time versus group; ‡: comparison among groups before the intervention; §: comparison among groups after the intervention; †: comparisons before and after the intervention; Δ: mean variation (initial – initial). DIP: dietary intervention; DIPE: dietary intervention + physical activity; DIS3: dietary intervention + omega 3 fatty acid supplementation; DIS3PE: dietary intervention + physical activity + omega 3 fatty acid supplementation

### Discussion

In this randomized clinical trial, score evaluation showed that 25.7% patients were at a high risk of developing coronary events within 10 years. After the intervention proposed in this study, the prevalence decreased to 11.4%, indicating that lifestyle modification contributes to a decrease in cardiovascular risk. Therefore, the present study had a positive impact and reinforced the importance of lifestyle modification for the prevention and treatment of cardiovascular diseases.

All interventions proposed in this study led to a decrease in the assessed cardiovascular risk score by decreasing the risk of coronary events occurring within 10 years. Wister et al<sup>7</sup> investigated the effects of lifestyle modification counseling via telephone and observed a decrease in cardiovascular risk using this score in adults. According to the concept of VA proposed in Framingham's study, which aims to adjust the patients' age to their atherosclerotic state, this study found that the mean VA was higher than the chronological age in all groups. Similar data were obtained in a study conducted in the state of Rio de Janeiro, wherein the researchers observed a mean age of  $61.0 \pm 20.0$  years, which was higher than the patients' chronological age ( $56.0 \pm 10.0$  years)<sup>18</sup>.

Inadequate nutrition, physical inactivity, and genetic predisposition are some of the main factors that contribute to the occurrence of MS<sup>19,20</sup>. The aim of studying individuals with MS is to prevent cardiovascular events. A cohort that aimed to determine the incidence of MS in adult individuals without diabetes showed that AC was the best predictor of MS<sup>21</sup>. This is important data because the main metabolic alterations associated with abdominal obesity are

dyslipidemia and insulin resistance. In the present study, a significant decrease in mean AC was observed after the intervention in women (p < 0.001); the greatest decrease occurred in the DIS3PE group (6.9%), in which there was a significant effect (p < 0.05). In men, only time had a significant effect (p < 0.001), with a significant decrease in AC being observed after the evaluation, regardless of group.

All the interventions had an effect on the decrease in blood glucose and SAP, as demonstrated by other studies in which diet quality improvement promoted a decrease in blood glucose<sup>22,23</sup> levels and SAP<sup>24,25</sup>. Prevention and treatment of arterial hypertension through health promotion present important clinical implications because they can decrease or even eliminate the need for antihypertensive drugs, thereby avoiding the adverse effects of pharmacological treatment and decreasing the cost of treatment for the patients and health institutions.

The variations in TC with time were significant; however, after the intervention, we observed an increase in the TC and HDL-C levels in both men and women in the DIS3PE group. This increase in TC may be associated with the increase in HDL-C levels in this group. Physical exercise promotes the increase in HDL-C levels; however, this occurs with simultaneous weight loss<sup>26</sup>. There is evidence that the omega 3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are derived from fish oil, promote the modulation of lipoprotein levels and endothelium function<sup>27,28</sup>. The increase in TC and HDL-C levels may be associated with the intervention received by the DIS3PE group, with this group standing out in terms of lipid profile treatment.

Our results suggest that the dietary counseling given to all groups may be considered to be a key tool for the overall treatment of patients with MS. The positive results of this study in regard to the metabolic and cardiovascular parameters confirm that dietary intervention is therapeutically relevant. The various interventions conducted in the 4 groups proved to be effective, suggesting that lifestyle modifications are key to the decrease in the risk of cardiovascular events and are effective in the treatment of MS. The study focused on eating habits and physical activities, two essential axes of the first-line therapy for improving modifiable risk factors for cardiovascular diseases, and it covered most modifiable risk factors indicated by the WHO<sup>29</sup>. Therefore, intervention programs that promote lifestyle changes should be encouraged to improve the quality of life of the population at risk.

It is worth noting that the size of the sample was a limitation of this study. It was difficult to confirm the results of the interaction effect (group and time repeated measurements analysis) because the differences were pronounced but not significant. Moreover, the number of patients was not sufficient to demonstrate other changes that may have occurred during the intervention period.

The small number of studies on these scores and clinical interventions (pharmacological and nonpharmacological) makes this study a preliminary study that describes the potential effects of lifestyle modification on the decrease in cardiovascular risk using the Framingham risk score. Further studies with larger samples are necessary to better understand the effects of lifestyle modification interventions on the abovementioned score and to conduct stratified analyses.

### **Conclusions**

In this study, all groups exhibited a similar pattern of behavior during the proposed intervention and did not show any intergroup differences. There was a decrease in the cardiovascular risk score, vascular age, and risk factors included in the calculation of the score. Therefore, we conclude that lifestyle modification by itself is a key tool for the overall treatment of patients with metabolic syndrome.

### **Author contributions**

Conception and design of the research and Statistical analysis: Soares TS, Gustavo AS, Macagnan FE, Feoli AMP; Acquisition of data: Soares TS, Piovesan CH, Gustavo AS, Macagnan FE, Feoli AMP; Analysis and interpretation of the data: Soares TS, Piovesan CH, Gustavo AS, Macagnan FE, Feoli AMP; Obtaining financing: Gustavo AS, Macagnan FE, Bodanese LC, Feoli AMP; Writing of the manuscript: Soares TS, Piovesan CH, Gustavo AS, Macagnan FE, Bodanese LC, Feoli AMP; Writing of the manuscript for intellectual content: Soares TS, Piovesan CH, Gustavo AS, Macagnan FE, Bodanese LC, Feoli AMP; Critical revision of the manuscript for intellectual content: Soares TS, Piovesan CH, Gustavo AS, Macagnan FE, Bodanese LC, Feoli AMP.

### Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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### **Study Association**

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