SUBCLINICAL EVALUATION OF CARDIOVASCULAR MARKERS AND WOMEN’S DIETS*

AVALIAÇÃO SUBCLÍNICA DE MARCADORES CARDIOVASCULARES E DA ALIMENTAÇÃO DE MULHERES

EVALUACIÓN SUBCLÍNICA DE MARCADORES CARDIOVASCULARES Y HÁBITOS ALIMENTARIOS DE MUJERES

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ABSTRACT

Objective: to evaluate the subclinical markers of cardiovascular disease and eating habits in women during the climacteric period. Method: this is a quantitative, descriptive, cross-sectional study that assessed nutritional status, biochemical tests, thickness of the middle intima layer of the carotid artery and the eating habits of 20 women. The study included those with thickening of the arterial layer. The data were analyzed using SPSS software version 18.0. Results: there was a state of overweight and an extremely high risk for the development of cardiovascular diseases around the waist. There were changes in LDL cholesterol and total cholesterol. Conclusion: this is a population with multiple cardiovascular risks. It is suggested that the full assessment of the health status of women in this period be carried out. Descriptors: Climacteric; Nutritional Status; Food Behavior; Carotid Artery Diseases. Cardiovascular Diseases; Comprehensive Health Care.

RESUMO

Objetivo: avaliar os marcadores subclínicos de doenças cardiovasculares e os hábitos alimentares em mulheres no período do climatómero. Método: trata-se de um quantitativo, descritivo, transversal que avaliou o estado nutricional, exames bioquímicos, espessura da camada íntima média da artéria carótida e os hábitos alimentares de 20 mulheres. Incluíram-se no estudo aquelas que apresentaram espessamento da camada arterial. Analisaram-se os dados no software SPSS versão 18.0. Resultados: observaram-se estado de sobrepeso e risco muito elevado para o desenvolvimento de doenças cardiovasculares pelo perímetro da cintura. Verificaram-se alterações no colesterol LDL e colesterol total. Conclusão: trata-se de uma população com múltiplos riscos cardiovasculares. Sugere-se que a avaliação integral do estado de saúde de mulheres nesse período seja realizada. Descriptores: Climatómero; Estado Nutricional; Comportamento Alimentar; Doenças das Arterias Carótida; Riscos Cardiovasculares. Descriptores: Climatério; Estado Nutricional; Comportamento Alimentar; Doenças das Arterias Carótida; Doenças Cardiovasculares; Assistência Integral à Saúde.

RESUMEN

Objetivo: evaluar los marcadores subclínicos de enfermedades cardiovasculares y hábitos alimentarios en mujeres durante el periodo climatérico. Método: se trata de un estudio cuantitativo, descriptivo, transversal que evaluó el estado nutricional, las pruebas bioquímicas, el grosor de la capa íntima media de la arteria carótida y los hábitos alimentarios de 20 mujeres. El estudio incluyó a aquellos con engrosamiento de la capa arterial. Los datos se analizaron con el software SPSS versión 18.0. Resultados: hubo un estado de sobrepeso y un riesgo muy alto de desarrollar enfermedades cardiovasculares alrededor de la cintura. Hubo cambios en el colesterol LDL y el colesterol total. Conclusión: esta es una población con múltiples riesgos cardiovasculares. Se sugiere realizar una evaluación completa del estado de salud de las mujeres en este periodo. Descriptores: Climatérico; Estado Nutricional; Comportamiento de Alimentación; Enfermedades de la Arteria Carótida; Enfermedades Cardiovasculares; Atención Integral de Salud.

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INTRODUCTION

It is known that female aging is a worldwide phenomenon that has grown in recent decades whose trend is the continued rise. It is pointed out that, naturally, along with the female aging process, the so-called menopause occurs, a period responsible for a series of metabolic, morphological, physiological and behavioral changes in women, which increase health risks, especially cardiovascular ones, which can be better understood in the following paragraphs and throughout this essay.

It is explained that the woman undergoes hormonal changes throughout her life and, in aging, there is a reduction in the female estrogens that characterize the climacteric, a period that promotes functional, morphological, physiological changes.1 The climacteric is divided into three phases: pre-menopause; perimenopause and post-menopause.

It is reported that, in the post-menopause, the so-called climacteric syndrome can occur, which presents, as main clinical manifestations, neurogenic, psychogenic, breast, osteoarticular, urogenital and metabolic alterations (alterations of bone and lipid metabolism).1

It is understood that understanding the changes in estrogen levels in postmenopausal women is of great relevance, since it helps to understand, in part, the etiopathogenesis of cardiovascular, cerebrovascular and ischemic diseases. Such aggravations can occur due to the increase in fractions of LDL cholesterol and triglycerides and the reduction of HDL cholesterol, weight gain and alteration of the pattern of body fat distribution (greater accumulation of fat in the abdominal region - typical android pattern of the period through ovarian failure). These changes also contribute to the development of arterial hypertension and insulin resistance, which are also risk factors for the development of cardiovascular diseases, the main cause of morbidity and mortality in postmenopausal women.2

In the identification of the presence of the disease, it is relevant to assess the nutritional status, the lipidic, glycemic profile and inflammatory markers of atherosclerotic disease, such as C-Reactive Protein3 and subclinical markers of cardiovascular diseases, such as the thickness of the carotid intima intima.4 It is believed that in addition to these assessments and not less important is the assessment of eating habits, since inadequate diets increase the risks for cardiovascular diseases,6 while a balanced diet may do the opposite.

Diet plays a central role in the prevention of atherosclerosis and among the potentially preventive foods (or used in the nutritional therapy of cardiovascular diseases) are fibers, plant sterols, olive oil, omega 3 fatty acids, antioxidants, minerals and soy7, whereas consumption of trans fats, for example, is associated with an increased risk of cardiovascular death,7 as well as the high consumption of red meats, simple sugars and low consumption of green leafy fruits and vegetables (Western dietary pattern) is associated with the development of Coronary Artery Disease (CAD).8

They are presented, by a healthy dietary pattern, that is, that they contain a high intake of vegetables, fruits, nuts, olive oil, legumes and fish and reduced in red meat, refined carbohydrates and dairy products with high fat content, effects beneficial on cardiovascular health9, however, a diet with such characteristics is costly, especially for the low income classes, especially in the urban environment, where everything or almost everything needs to be purchased. Furthermore, the most accessible foods and products, in general, tend to be refined and ultra-processed products, which are also destructive to health.

In this sense, it is described that the popular strata present a “disadvantage” and, in the case of women in the climacteric, the accentuation of the risks of developing chronic diseases, which therefore require assistance, identification and treatment, but, mainly prevention programs.

OBJECTIVE

• To evaluate the subclinical markers of cardiovascular disease and eating habits in women during the climacteric period.

METHOD

This is a quantitative, descriptive, cross-sectional study that assessed cardiovascular risk markers and the diet of women in the climacteric, aged 51 to 66 years old, participating in a master’s subproject entitled “Effect of the consumption of extra virgin olive oil on the thickness of the intima-media layer of the carotid artery in women during the climacteric period”, from the Regional University of the Northwest of the State of Rio Grande do Sul, in the city of Ijuí (RS), northwest of State of Rio Grande do Sul, from November 2017 to March 2018.

Participants were selected based on the total list of women linked to a larger project - “Female Aging” - in which there were 301 women, who were previously pre-selected based on specific criteria shown in Figure 1. From the total of women linked to the larger survey, participants who were under the age of 50 years, who did not carry out all the evaluations of the larger survey - “Female Aging” - and also smokers, eutrophic, non-dyslipidemic women and those who had participated in a food and nutrition education workshop or participated in research involving olive oil (subproject criteria).

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Eligible women were contacted and invited to participate in the study via telephone contact. As soon as they were accepted, they were invited to perform an ultrasound of the carotid artery whose examination was performed by only a single evaluator, a medical specialist in ecodoppler, in the Vascular Laboratory of a medium complexity hospital in the same municipality. From the ultrasound results, all participants who showed a thickening of the intima-media layer > 0.81 mm were selected, a positive result in twenty participants. Results were classified using some criteria.10

Women, after this stage, were evaluated for anthropometric data, body composition and food consumption, which were performed only by a professional (nutritionist), as well as through biochemical tests performed by a clinical analysis laboratory. It is added that the collection of anthropometric and biochemical data of the participants occurred in the respective Family Health Strategies (FHS) of the urban environment to which they were assigned.

In assessing nutritional status, body mass weight, height, waist circumference and body fat percentage were measured. The Tech Line® portable scale, model BAL-150PA, accurate to 100 grams, was used to assess body weight. Height was measured by means of a fixed stadiometer on a Filizola mechanical scale 8. Based on the weight divided by the square height (weight / height$^2$) ratio, the Body Mass Index (BMI) was calculated.

The waist circumference was checked by means of a non-elastic material, 1 mm precision, measuring tape, CESCORF®, measured in the smallest curvature of the torso region. The percentage of body fat was measured using a portable scale, provided with electrodes of the same make and model, used to verify the weight of body mass.

In the BMI classification for adult women, the World Health Organization (WHO) parameters were followed11 and, for elderly women (60 years and over), The Nutrition Screening Initiative recommendations.12 The abdominal perimeter was classified by WHO.13 All anthropometric measurements were performed according to the recommendations of the Food and Nutrition Surveillance System.14

Biochemical tests were carried out with the participants on a 12-hour fast. Lipoproteins (total cholesterol, HDL cholesterol, triglycerides and LDL), fasting glycemia and C-reactive protein were measured and evaluated. Results were classified using the parameters proposed by the Brazilian Archives of Cardiology.15 Glucose was measured using an enzymatic colorimetric method and classification using the Guidelines of the Brazilian Diabetes Society.16 C-Reactive Protein (CRP) was verified using the Immunoturbidimetry method. The classification was carried out by the parameters of Pencina.17

Food was assessed using the Food Frequency Questionnaire of the National Health Survey18 and its classification considering the indications of the Technical Notes of the National Health Survey - Lifestyle Module - Food Consumption.19

For the assessment of food consumption, regular and non-regular consumption was considered, with the frequency of five or more times a week being regular for the vast majority of food groups, with differentiation for meat and chicken, which considered healthy the removal of apparent fat and skin from birds; for fish

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**Figure 1. Flowchart inclusion and exclusion criteria for study participants. Ijuí (RS), Brazil. IMT= Intima-media thickness; BMI = Body Mass Index; FNE= Food and nutrition education; GHQ= General health questionnaire.**
consumption, he considered the frequency to be one or more times a week healthy; soft drinks and artificial juices as not recommended; regular and non-regular consumption five or more times a week.

Data was analyzed using the Statistical Package for Social Sciences (SPSS) software, version 18.0, using descriptive and analytical statistics, to analyze the correlation between quantitative variables using the Spearman Correlation test, which considered 95% reliability.

The study followed the ethical precepts referred to in Resolution 466/2014, approving it by the Ethics and Research Committee of the Regional University of the Northwest of the State of Rio Grande do Sul, under Opinion number 1,974,900 and CAAE: 63141316.2.0000.5350. All patients were informed about the processes and functioning of the study and, when consenting, they signed the Free and Informed Consent Term (FICT) to participate in the study.

RESULTS

It is described that the study participants had an average age of 58.45 (+5.33) years, with nine adult women (up to 59 years old) and 11 elderly women (60 years old and over). Table 1 shows the main data regarding the evaluation of the thickness of the carotid intima-media layer, the nutritional status and body composition and the biochemical tests of the participants.

As shown by the participants, there is a high cardiovascular risk profile to the detriment of the thickening of the arterial layer (1.040 ± 5.51), provided as a profile for the research, but also due to the assessment of nutritional status, through a high body mass profile, verified by means of BMI, classified as overweight for adult women and overweight for elderly women, waist circumference indicating central obesity and high risk for the development of cardiovascular diseases, in addition to a high percentage of body fat, allowing a classification of general obesity.

Regarding biochemical exams, adequate mean values for fasting blood glucose, triglycerides and HDL cholesterol were perceived, however, the latter showed values that were very distant between the minimum and maximum, with the lowest value being 37 mg / dl and the maximum value in excellent rating (118mg / dl). It is added that LDL and total cholesterol were within the borderline classification and, regarding the cardiovascular marker CRP, the mean value (1.15+2.97mg / dl) was classified as very high risk. In this specific case, the maximum value found (13.52mg / dl) was presented as “abnormal”, that is, too high in one participant.

Table 1 shows the descriptive statistics of the study variables referring to cardiovascular risks in women during the climacteric period. Ijuí (RS), Brazil, 2017-2018.

Table 2 shows the correlation between the thickness of the middle intima layer of the carotid artery, nutritional status and the cardiovascular marker CRP. It is detailed that the analysis showed no correlation with any of the other evaluations, possibly because all women had high thickness (homogeneity), thus, not correlating with the others; BMI showed a positive and statistically significant correlation with waist circumference (p <0.001) and body fat percentage (p <0.001).

The waist circumference was positively and statistically significant with the BMI (p <0.001), fat percentage (p <0.001) and CRP (p = 0.02). There was the same positive and statistically significant correlation between the percentages of fat and BMI (p <0.001) and WC (p <0.001). In relation to the CRP, a positive correlation was observed with the waist circumference (p = 0.029).

Table 2: Intima-media thickness; SD = Standard deviation; BMI: Body Mass Index.

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Correlation analysis of variables was also performed between IMT, blood glucose and lipoprotein profile (Table 3), and there was a statistically significant and negative correlation between IMT and HDL cholesterol (p = 0.043) and also between HDL and blood glucose (p = 0.007), that is, the higher the HDL, the lower the IMT and blood glucose should be. It is revealed that other statistically significant correlations, however, positive, occurred with triglycerides and total cholesterol (p = 0.014); also between total and LDL cholesterol (p = 0.001).

The analysis of the characteristics of regular and non-regular consumption of healthy or unhealthy foods can be seen in table 4. It appears that regular consumption of beans was reported by less than half of women (45%). However, the consumption of raw vegetables as regular by the majority (85%) was mentioned. It was observed, in general, as for cooked vegetables, non-regular consumption (80%), as well as natural juice (70%). Foods such as fish (65%), fruit (70%) and milk (70%) were reported regularly by the majority.

The result shows, as to the regular and non-regular consumption of unhealthy foods or considered at risk for the development of cardiovascular diseases, that the consumption of red meat and skinless / fat chicken was reported as non-regular consumption by most participants (75 and 65%, respectively). It was noted, in relation to the consumption of sweets, soft drinks / industrialized juices and the replacement of main meals (lunch and dinner) with snacks, non-regular consumption in general, however, there was a report of daily consumption of sweets by five participants.

Table 2. Correlation between the variables Intima-media thickness, Body Mass Index, Waist Circumference, % Fat and C Reactive Protein in women during the climacteric period. Ijuí (RS), Brazil, 2017-2018.

| Variables | IMT | BMI | Waist Cir. | % Fat | CRP |
|-----------|-----|-----|------------|-------|-----|
| IMT (mm)  | C   | 1.00| 0.203      | 0.216 | 0.141| 0.107|
|           | p   | .   | 0.390      | 0.373 | 0.588| 0.653|
| BMI (Kg/m²) | C   | 0.203| 1.000      | 0.892 | 0.982| 0.387|
|           | p   | .   | 0.390      | .     | 0.000| 0.092|
| Waist. Cir. (cm) | C   | 0.216| 0.892      | 1.000 | 0.797| 0.500*|
|           | p   | .   | 0.373      | 0.000 | .     | 0.029|
| % Fat (%) | C   | 0.141| 0.982      | 0.797 | 1.000| 0.232|
|           | p   | .   | 0.588      | 0.000 | .     | 0.371|
| CRP (mg/dl) | C   | 0.107| 0.387      | 0.500 | 0.232| 1.000|
|           | p   | .   | 0.653      | 0.092 | 0.029| 0.371|

** Significant correlation at the level of 0.01; ** Significant correlation at the level of 0.05 ** by the Spearman coefficient. p: correlation coefficient; C: coefficient; IMT: Intima-media thickness; BMI: Body Mass Index; Waist Cir.: Waist Circumference; % Fat: Fat percentage; CRP: C-Reactive Protein.

Table 3. Correlation between the variables Intima-media thickness, blood glucose and lipid profile of women during the climacteric period. Ijuí-RS, Brazil, 2017-2018.

| Variables | IMT | Glucose | Trigl | HDL | Total C | LDL | CRP |
|-----------|-----|---------|-------|-----|---------|-----|-----|
| IMT (mm)  | C   | 0.328   | 0.380 | -0.457 | -0.144 | -0.181 | 0.107|
|           | p   | 0.158   | 0.099 | 0.043  | 0.546  | 0.446  | 0.653|
| Glucose(mg/dl) | C   | 0.380   | 1.000 | 0.245  | -0.587 | 0.041  | 0.203 | 0.155|
|           | p   | 0.158   | 0.297 | 0.007  | 0.863  | 0.391  | 0.514|
| Trigl (mg/dl) | C   | 0.380   | 0.245 | 1.000  | -0.393 | 0.542  | 0.303 | -0.099|
|           | p   | 0.099   | 0.297 | .      | 0.087  | 0.014  | 0.194 | 0.679|
| HDL (mg/dl) | C   | -0.457  | -0.587 | -0.393 | 1.000  | 0.081  | -0.156 | -0.380|
|           | p   | 0.043   | 0.007 | 0.087  | .      | 0.733  | 0.512  | 0.098|
| Total C.(mg/dl) | C   | -0.144  | 0.041 | 0.542  | 0.081  | 1.000  | .     | .     |
|           | p   | 0.546   | 0.863 | 0.014  | 0.733  | 0.000  | .     | 0.220|
| LDL(mg/dl) | C   | -0.181  | 0.203 | 0.303  | -0.156 | 0.853  | 1.000 | -0.176|
|           | p   | 0.446   | 0.391 | 0.194  | 0.512  | 0.000  | .     | 0.459|

** Significant correlation at the level of 0.01; ** Significant correlation at the level of 0.05 ** by the Spearman coefficient. p: correlation coefficient; C: coefficient; IMT: Intima-media thickness; BMI: Body Mass Index; Waist Cir.: Waist Circumference; % Fat: Fat percentage; CRP: C-Reactive Protein.
DISCUSSION

This essay brings relevant contributions on issues related to female aging, health and food through the results found, highlighting here the cardiovascular risk profile in the participating women and also regarding the relationship between nutritional status, biochemical tests and thickening of the intimate intima layer in addition to the food consumption profile.

It is evident from this study that, in general, one can often find a profile of women in the climacteric with such characteristics and that, therefore, the monitoring of nutritional status, food, biochemistry and average intima thickness can be a good protocol to assess health risks in a comprehensive manner, in addition to the sociodemographic profile, which, in this case, was not addressed in this trial.

This study confirms the findings of the literature regarding the climacteric period as a phase of greater propensity for the development of cardiovascular diseases and, at the same time, it is possible to mention the relevance of the evaluation of the health profile in this phase and before her, in particular, by increasing population aging and, at the same time, the incidence of cardiovascular diseases, especially among the female population over 50 years old.¹⁹

This study shows the nutritional, biochemical profile and the main marker of atherosclerosis, the thickness of the carotid artery, in which the presence of cardiovascular risks is identified through all the variables mentioned in a population that can be considered young, however, within a period that appears to be at greatest risk for the development of coronary artery disease.¹⁹

It is highlighted here that dyslipidemias are among the main risk factors for the development of the disease, and the low concentration of HDL cholesterol (> 50 mg / dl) is considered an independent risk factor for the development of coronary artery disease, in between 50 and 69 years old.¹⁷ It is noteworthy that coronary artery disease is more prevalent in postmenopausal women than in premenopausal women.¹⁹ It is explained that an explanation for this fact would be the higher concentration of estrogenic hormones in pre-menopausal women, which act as potential protective factors for the body while in normal concentrations. It should be noted that the majority of study participants are in the postmenopausal phase, where the decline in estrogens is even higher or there is already ovarian failure.

There will be an improvement in the nutritional status, the dyslipidemic condition and also the thickening of IMT itself through weight reduction, adherence to healthy eating and lifestyle practices (which will promote the reduction of cardiovascular risks). It is noted that the reduction of five to 10% of body weight is able to reduce risks of developing CAD by promoting improvements in cholesterol, blood glucose and blood pressure levels.¹⁹

It usually leads, through menopause, to increase the weight of body mass, by reducing basal metabolism, in particular, by reducing physical activity and increasing consumption of high-calorie foods,¹⁹ such as saturated / hydrogenated fats, sweets, sugary drinks, alcoholic drinks and refined foods.

Regarding the IMT variable, an important indicator of the risk of future development of atheroma plaque was observed,²⁰ present in all study participants, that there was no correlation with nutritional status or even with biochemical tests, however, the inadequate nutritional status was positively correlated with altered lipoproteins and CRP, while HDL cholesterol and glucose were correlated significantly and inversely with IMT.

In this sense, it was demonstrated by a study,²⁰ that, among the many inflammatory markers associated with atherogenesis, CRP has been indicated as the most important biomarker of cardiovascular events.²¹ In the present work, CRP with alterations was presented, in general, with medium and high risks for the development of cardiovascular disease.

In another study, they were evaluated by researchers,²² 62 patients with the presence of 1995
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atheromatous plaque and ultrasensitive C-reactive protein levels. In general, the marker was found to be elevated and correlated with instability of the atheroma plaque, however, in this study, CRP was correlated only with waist circumference (p = 0.029) and not with IMT.

It was found, regarding the data related to food, as to the food profile, that most participants had regular consumption for most healthy foods (with the exception of vegetables and natural juice). The study demonstrated that a risky behavior for health, as well as for the development of cardiovascular diseases, was the greater regularity in not removing the skin of birds, when compared to other foods considered unhealthy, such as regular consumption of candy by five of the 20 participants.

There are two hypotheses regarding a consumption profile considered healthy in this case: the first, that these women already have knowledge of their own lives or through access to previous consultations that proposed changes in their food profiles, or, in one second hypothesis, that the researcher may have suppressed some information because she is a nutritionist.

They were evaluated by researchers,23 the frequency of food consumption and its association with cardiovascular risk factors and biomarkers of subclinical atherosclerosis (p.43), showing that individuals who consume vegetables more times in the week had lower triglyceride values, glyc-Hb, lower TC/ HDL, DBP, while those who ingest more green leaves have lower values in the TG/HDL ratio, triglycerides, glycemia, glyc-Hb and HDL cholesteral. It is provided, by the higher consumption in the week of legumes, lower ratio of TC/ HDL and LDL, while the higher consumption in the week of oilseeds showed lower score in arterial pressures, TC, ratio TC/ HDL, LDL, TG, Glyc- Hb, IMT, while frequent consumption of “animal foods, sweets, fats and ultra-processed foods, with a greater association with cardiovascular risk factors” with higher TC / HDL, TG, ApoB and HDL, TG, GL, CRP and higher TC / ratio Highest HDL, LDL, TG, GL, Apo B, CRP and IMT. It is important to note that all participants are in the peri or post-menopause period and that these periods have a great influence on the nutritional and biochemical status and that they should also be better investigated. The importance of health care at this stage is highlighted by the progression of the aging process, as well as by the decline in estrogens, which imply changes in cardiovascular health. In this sense, the importance of the assistance provided in public health is seen - Unified Health System (UHS) whose exams and diagnoses cover from low to high complexity and which, in turn, are the only alternative to access the program of health.

It should also be noted that prevention is the best path to health in general. The assistance of the Family Health Strategies becomes essential in the process of prevention, promotion and recovery of health. “Family health” covers almost 100% of the visits in certain regions of the country, especially in primary care, which, in general, “contributed to the reduction of hospitalizations for cardiovascular diseases”.

Thus, by strengthening the UHS, family health teams invest in prevention, including guidance and food education through trained professionals, being a differential in the health / disease process in the aging process.

**CONCLUSION**

In this study, the participants presented general obesity status, altered lipid profile and C-Reactive Protein, with arterial thickening alone representing a vascular risk. Associations between the variables analyzed were identified in this work, with significant and negative associations between the mean intima thickness and HDL cholesterol being relevant, and also between HDL cholesterol and blood glucose. In general, the evaluation of eating habits was satisfactory, that is: the predominance of a regular healthy food profile for almost all food groups studied, with the exception of beans and natural juice.

It is added, regarding the unhealthy diet profile, that there was a predominance of not removing the skin of birds and consumption of sweets. It is emphasized that a more detailed assessment of food deserves to be carried out, such as the use of 24-hour food recalls and the qualitative and quantitative analysis of macro and micronutrients, in order to better detail the participants’ food consumption, as well as the relationship between food with nutritional status and the other variables evaluated. Finally, it is emphasized that the findings of this study can serve as a basis for surveying more in-depth studies, such as the population-based study, and, from it, conducts and protocols can be modified or created.

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**CONTRIBUTIONS**

It is informed that all authors contributed equally in the design of the research project, collection, analysis and discussion of data, as well
as in the writing and critical review of the content with intellectual contribution and in the approval of the final version of the study.

CONFLICT OF INTERESTS

Nothing to declare.

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