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EFFECTS OF BARK FLOUR OF PASSION FRUIT ON METABOLIC SYNDROME: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objectives: To analyze the effects of a treatment with bark flour of passion fruit in people with metabolic syndrome. **Method:** randomized clinical trial with a sample of 50 people with metabolic syndrome, assigned randomly to two groups: intervention group (n=25) or thecontrol group (n=25). The intervention consisted in consumingbark flour of passion fruit for eight weeks. Anthropometric measures, biochemical parameters and blood pressure were measured as the markers of metabolic control. The Mann-Whitney test was used for inter-group comparison before and after the intervention. The Chi-square test was used to verify possible associations between categorical variables. **Results:** Fat percentage, blood pressure and triglycerides decreased into the intervention group after the 8-week period, but this decrease was not significant when compared with placebo group. **Conclusion:** Consumption of bark flour of passion fruit can improve markers of metabolic syndrome, but the findings of this study were not significant.

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INTRODUCTION

Metabolic Syndrome (MS) is a chronic metabolic disease influenced by interactions between genetic and environmental components. It is considered asa significant precursor to the development of serious cardiovascular risk and type 2 diabetes (Pinho, 2017 and Saad, 2017).

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It is likely that more than one billion people around the world are affected by MS (Bortoletto, 2017 and Saklayen, 2018). Usually, the diagnosis of MS is based on the presence of at least three of the following conditions: dyslipidemia, abdominal obesity, elevated blood glucose and triglycerides, reduced HDL-C, and use of antihypertensive or antidiabetic oral drugs (Saklayen, 2018). Issues related to lifestyle are crucial in preventing MS. Diet itself can act not only to prevent but to treat MS considering that the syndrome has a strong inflammatory base (Barbalho, 2015 and Saboya, 2017). Authors state that there is an inverse relationship between fiber intake and inflammatory markers in chronic diseases such as type 2 diabetes, cancer, heart disease and MS (Lottenberg, 2017). For example, previous studies have attested to the benefits of fiber consuming from the albedo of the passion fruit peel in glycemic control in people with type 2 diabetes. Furthermore, this plant is a source of niacin (vitamin B3), iron, calcium and phosphorus (Salgado, 2017 and Silva, 2017). Currently, about 90% of passion fruit peels and seeds are processed into food co-products. Its bark is used in the production of flour and, because of its pectin, it is also used in candy making and jams due to its thickening property (Silva, 2017). Given these benefits, functional food attributes of the bark flour of passion fruit have been identified and studied for glycemic control in people with diabetes. Particularly, this product forms agel into the digestive tract (derived from contact with gastric fluids) and slows the absorption of glucose derivatives (Zeraik, 2010 and Zaparolli, 2017). Studies have measured the effects of this product on blood glucose levels of people with diabetes (Janebro, 2008; Medeiros, 2017; Queiroz, 2017 and Miot, 2011). However, we question whether there would be benefits for people with MS. The aim of this study was to analyze the effects of a treatment with bark flour of passion fruit in people with metabolic syndrome.

MATERIALS AND METHODS

Design: This is a prospective randomized clinical trial (RCT) without blinding. The study was conducted in a primary healthcare setting of a city located in the northeastern Brazil. The study was carried out from November 2015 to March 2016. The study was approved by the Research Ethics Committee of the University for International Integration of the Afro-Brazilian Lusophony (UNILAB), process #828534. The clinical trial was registered by the Brazilian Clinical Trials Registry (ReBec), process #RBR-9jth8n. All participants signed a free and informed consent prior to their inclusion in the study.

Study subjects: The study population consisted of people with MS registered and monitored in the mentioned setting. Eligibility criteria included meeting the minimal standards for being classified as having MS (for at least 60 days),and 2) age between 18 and 65 years. Exclusion criteria included use of insulin, tobacco, alcohol or psychotropic substances (as they affect glucose), liver or kidney problems, and allergy to passion fruit products. To obtain the sample size we used a pair-matching model for comparison of quantitative variables [16].The necessary number of pairs was estimated based on a Zα=1.96 (two-sided 5% error), β error of 0.84, and post hoc power of 0.8. From the standard deviation of the difference between pairs of observations (Janebro, 2017), a total of 20 pairs (n = 40 participants) were recruited and distributed between intervention and control groups (Figure 1). Adhesion of <70% was established as a criterion of discontinuity.

To allocate participants, we applied apair-matchingrule: Triglycerides values should be the most similar as possible. After the minimal sample size needed was achieved, the recruitment continued. A total of 150 subjects was included in the study. Data collection started by the collection of biochemical data from all subjects. Then, subjects were randomized by flipping a coin.

Conduct of the trial: At baseline, nursing consultations were conducted to collect anthropometric and biochemical measures, as well as blood pressure at time zero. Participants were interviewed individually in a private room, with the application of a semi-structured questionnaire with questions regarding demographic data (age, gender, skin color, marital status, employment and economic status), anthropometric data (weight, height, central adiposity index, BMI and waist circumference), and clinical conditions (physical activity, use of alcohol and/or tobacco and mini mental test result). Economic classes was categorized as recommended by the Brazilian Association of Companies for Research. The diagnosis of MS can be based on the six criteria recommended by the International Diabetes Federation (Alberti, 2017), orby the criteria recommended by The National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III). However, we have chosen the revised NCEP ATP III criteria due to its easy application and strong clinical evidence. Following the mentioned recommendations, we defined that a patient with MS should have at least three of the following characteristics: abdominal obesity, characterized by waist circumference >88cm for women and>102cm for men; high triglycerides levels ≥150mg/dL; low HDL cholesterol, characterized by values <50mg/dL for men and <40mg/dL for men; high blood pressure, characterized by values ≥130/85mmHg, and high plasma glucose≥100mg/dL.

Skinfold measurements were made using a Primer Vision® skinfold caliper with high accuracy and sensitivity of 0.1 mm, calibrated by the Brazilian Calibration Network. The mean of the three measurements was used as the representative value for each site. These measures were taken in the following order: subscapular, abdomen, and suprailiac (Moreira, 2009). The secondary outcome variables were: neck circumference, abdominal circumference, LDL cholesterol and VLDL cholesterol. In addition, the following anthropometric markers were analyzed: triceps, sub scapular, abdominal and suprailiac skinfolds, and fat percentage. The central adiposity index was obtained by dividing the hip circumference value (cm) by the height value (m) multiplied by the square root of time. Then, the result was subtracted from 18 and came to the following stratification: normal weight (8-20 / 21-32), overweight (21-25 / 33-38), and obese (> 25 / >38)for men and women, respectively (Bergman, 2017). The same nurses were always involved in the process of evaluating the MS criteria using recommendations and guidelines from the literature (Bergman, 2017). In addition, anthropometric and laboratorial standards were adopted to ensure uniformity in the evaluations. The collection and analysis of biochemical data were performed by a private laboratory. The findings were analyzed based on guidelines from the American Diabetes Association (American Diabetes Association, 2016).

Study foods: The passion fruit flour was prepared in a private laboratory that processes food and herbs. To ensure quality, this laboratory is submitted to periodic analysis from public and federal organizations. On the occasion of the study, the product analysis found: carbohydrates (82.7%), protein (9.1%), ash (5.8%) and lipids (2.2%). One-hundred grams of the passion fruit flour had approximately 388 kilocalories. Micro and macroscopic analyses were made to ensure that the product had a characteristic color, odor, flavor and texture, and that it was free of fragments from parasites, insects, rodents or general dirt. This analysis was guided by quality inspection guidelines from the Brazilian Association of Technical Standards (ABNT) number 5426.

Testing: Participants in the intervention group were evaluated and instructed about how to consume the passion fruit flour by a nurse, who was trained for this study.

Table 1. Distribution of participants with metabolic syndrome, according to sociodemographic characteristics

Variables	Groups				p value
	Intervention		Control		
	n	(%)	n	(%)	
Gender					0.185*
Male	4	16.0	108	32.0	
Female	21	84.0	17	68.0	
Skin color					
White	8	32.0	5	20.0	0.372*
Black	2	8.0	5	20.0	
Brown	15	60.0	15	60.0	
Occupation					
Retired	18	72.0	20	80.0	0.331†
Formal employment	2	8.0	1	4.0	
Informal employment	4	16.0	1	4.0	
Unemployed	1	4.0	3	12.0	
Marital status					
Married	10	40.0	14	56.0	0.729†
Not married	4	16.0	3	12.0	
Widower	8	32.0	6	24.0	
Separate	3	12.0	2	8.0	
Living situation					
Living with family	21	84.0	16	64.0	0.226†
Living with a partner	2	8.0	6	24.0	
Living alone	2	8.0	3	12.0	
Physically active					
Yes	2	8.0	5	20.0	0,417ǂ
No	23	92.0	20	80.0	

*Pearson's chi-square test; †Likelihood Ratio; ǂFisher's exact test.

Participants in the intervention group were instructed to ingest 12 grams of vegetable flour during the study, three times a day, before the three main meals (breakfast, lunch and dinner), daily, for eight weeks. These subjects received polyurethane sachets with 12 grams of the product, as analytical balance, in a sufficient amount for four weeks. They were instructed to consume the product along with other food or any liquid. The remaining sachets that were necessary for the next four weeks were delivered at home. At this time, used sachets were counted and cases in which adherence was below 70% were excluded (discontinuity criteria). Meanwhile, participants in the control group received the usual treatment provided by their own health care providers. At the end of the eight-week period, anthropometric, biochemical and BP values were measured again.

Statistical analysis

Summary statistics were tabulated using Microsoft Excel® spreadsheets, and statistical tests were processed using the statistical software Epi Info™version 7.2 (Atlanta, USA) and the SPSS statistical package version 22 (Chicago, USA). First, the Kolmogorov-Smimov test was used to test normality. In case of asymmetric distribution, the Mann-Whitney test was used to analyze the differences in the clinical variables between groups. Intra-group means and medians werealso evaluated. The Pearson chisqu are test was used to compare categorical variables. The statistical analysis considered a significance level of 5%.

RESULTS

The study groups were mainly composed of women (84% and 68%, intervention and control group respectively), married, retired, living with their family, and people who declared themselves as mulatto (60%). In regards to age, there was a predominance of young-elderly in both groups: the mean age in the intervention group was 63.6 (± 10.8 years) and in the control group was 66.3 (± 10.6 years) (p=0.382).

Sedentary lifestyle was found in 92%of the intervention group and in 80% of the control group (Table 1). Subjects from the control group had higher monthly incomes than subjects at the intervention group (US$ 309.1 ± 118.9 versus US$247.9 ± 69.0 respectively, p=0.030). Low-income class was the predominant category for people in both groups (76% participants were under the categories D or E). Mild cognitive impairment (achieving 21-24 points in the mini mental test) was also frequent in both groups (64% in the intervention group and 48% in the control group).

Based on the Kolmogorov-Smirnov test results, the following variables had a normal distribution: fat percentage (p=0.024), plasma glucose (p<0.001), and triglycerides (p=0.002). After eight weeks, nostatistical significant differences in these variables were found between the groups. After eight weeks of intervention, we found differences between the groups in some criteria such as adiposity index, BMI, fat percentage, blood pressure and triglycerides. However, these differences were not statistically significant (Table 2). No statistically significant differences were found in the values of anthropometric measures within each group, nor using time (before and after intervention) as a predictor, norusing LDL-C and VLDL-C values as predictors (Table 3).

After eight weeks of intervention, we found differences between the groups in some criteria such as adiposity index, BMI, fat percentage, blood pressure and triglycerides. However, these differences were not statistically significant (Table 2). No statistically significant differences were found in the values of anthropometric measures within each group, nor using time (before and after intervention) as a predictor, norusing LDL-C and VLDL-C values as predictors (Table 3).

DISCUSSION

We did not find significant differences in the indicators of metabolic syndrome between patients that ingested passion fruit flour during eight weeks and control subjects.

Table 2. Indicators of metabolic syndrome before and after eight-weeks of use of the passion fruit flour

Groups	Intervention				p value	Control				p value
Variables	Before		After			Before		After		
	n	%	n	%		n	%	n	%	
Adiposity index										
Normal	19	76.0	20	80.0	0.733*	20	80.0	19	76.0	0.733*
Abnormal	6	24.0	5	20.0		5	20.0	6	24.0	
BMI										
Normal	3	12.0	6	24.0	0,463ǂ	2	8.0	3	12.0	1,000ǂ
Abnormal	22	88.0	19	76.0		23	92.0	22	88.0	
Waist circunference										
Normal	2	8.0	2	8.0	1,000ǂ	2	8.0	2	8.0	1,000ǂ
Abnormal	23	92.0	23	92.0		23	92.0	23	92.0	
Fat percentage										
Normal	15	60.0	16	64.0	0.771*	17	68.0	16	64.0	0.765*
Abnormal	10	40.0	9	36.0		8	32.0	9	36.0	
Blood pressure										
Normal	3	12.0	7	28.0	0,157*	4	16.0	4	16.0	1,000ǂ
Abnormal	22	88.0	18	72.0		21	84.0	21	84.0	
Plasma glucose										
Normal	11	44.0	7	28.0	0.239*	14	56.0	9	36.0	0.156*
Abnormal	14	56.0	18	72.0		11	44.0	16	64.0	
Triglycerides										
Normal	9	36.0	12	48.0	0390*	10	40.0	11	44.0	0.774*
High	16	64.0	13	52.0		15	60.0	14	56.0	
HDL										
Normal	17	68.0	13	52.0	0.248*	15	60.0	12	48.0	0.395*
Low	8	32.0	12	48.0		10	40.0	13	52.0	

BMI - Body Mass Index; HDL - High Density Lipoprotein. Statistic: *Pearson chi-square test; ǂFisher's exact test.

Table 3. Anthropometric indicators comparison within the groups, after eight weeks of intervention

Variables	Intervention group							Control group						
	Before			After				Before			After			
	Mean	Median	Standard Deviation	Mean	Median	Standard Deviation	*p value*††	Mean	Median	Standard Deviation	Mean	Median	Standard Deviation	*p value*††
Weight (kg)	69.7	71.4	15.6	69.1	70.4	15.2	*0.861*	71.0	70.7	10.3	71.5	69.9	12.3	*0.977*
AC (cm)	99.9	97.0	11.2	97.3	95.0	10.5	*0.377*	102.4	102.0	11.2	101.4	102.0	11.7	*0.727*
WC (cm)	95.6	93.0	11.1	93.6	90.0	11.7	*0.387*	96.9	99.0	11.4	95.5	97.0	11.54	*0.698*
NC (cm)	32.6	32.5	3.0	32.0	32.0	2.7	*0.868*	34.4	33.0	4.1	34.2	33.0	3.9	*0.930*
AC (cm)	28.2	29.0	4.4	27.5	27.0	4.0	*0.436*	28.3	28.0	3.5	27.7	28.0	3.7	*0.682*
SSS	31.3	27.8	12.8	30.7	27.6	12.0	*0.793*	29.7	29.0	9.7	29.6	29.0	9.6	*0,976*
TS	21.5	18.7	9.6	21.2	18.8	9.4	*0.808*	18.1	16.4	9.5	18.0	16.3	9.4	*0.930*
MTS	26.3	23.4	14.4	25.8	22.6	14.0	*0.831*	21.5	17.7	9.9	21.3	16.6	9.6	*0.930*
SIS	29.6	28.7	12.0	29.1	29.0	11.7	*0.756*	27.0	27.5	9.0	26.7	27.9	8.8	*0.930*

AC - abdominal circumference; WC - waist circumference; NC - neck circumference; AC - arm circumference; SSS - subscapular skinfold; TS - triceps skinfold; MTS - medial thigh skinfold; SIS–suprailiac skinfold.
Statistics: ††Mann-Whitney test.

Maybe the findings would have been different if other variables had been considered, such as diet, homeostatic model assessment (HOMA) index, insulin levels, or inflammatory markers. Despite this, some parameters showed improvement in the experimental group. In addition, it is important to consider the probability for Type Ierror or false rejection of the null hypothesis, which limits the clinical relevance of any quantitative study. Authors state that, in experimental studies, tendencies that are not statistically significant do not necessarily diminish the importance of the correlations. Factors such as time and scenario of intervention should be considered (Sola, 2006). To the best of our knowledge there are no studies that have investigated the effects of the use passion fruit products on metabolic syndrome markers. Some authors have tested educational interventions coupled with omega-3 supplementation, and supplementation with fish oil or mineral oil in people with metabolic syndrome, with positive effects. In these studies, the exposure time of the intervention was superior to our research: 12 weeks (Saboya, 2017 and Soares, 2017). Some limitations must be considered in the interpretation of the results of our study. The exposure time to the compounds of the passion fruit flour is a relevant issue, since it affect the way biological parameters behave. In addition, we acknowledge the interference of medications (especially anti-diabetic and anti-hypertensive drugs) on the markers that we examined in this study. However, we could not interfere with the patients' regimen, as prescription modification or abandonment takes time and require approval from a primary physician.

We also acknowledge the fact that some patients have diabetes mellitus type 2 and this can be considered a limitation, since this predisposes subjects to metabolic syndrome (Pereira, 2017). Patients with diabetes usually have difficulty to achieve the normality of indicators of metabolic syndrome and an adequate nutritional status (based on anthropometric measures). Gender is also an important factor. In this study there was a predominance of women: 84% in the intervention group and 68% in the control group. Studies have shown an increase in the prevalence of metabolic syndrome in elderly women (Pereira, 2017 and Saboya, 2016). Women with metabolic syndrome who participated in our survey are at the climacteric period, which influences the way indicators of metabolic syndrome behave. During this stage of life, a sudden hormonal variation can occur, impairing the production of sex hormones [27,28].Consequently, the lifestyle of these women may be affected, predisposing them to weight gain, physical inactivity, and bad eating habits, among others (Lui Filho, 2017 and Freitas, 2017).

The fact that some people may have mild cognitive impairment may also have had an influence in the adherence to the consumption of the passion fruit flour and other eating habits. Cognitive changes frequently occur together with metabolic syndrome and other diseases like diabetes and cardiovascular diseases (Ferreira, 2017). Evidences show that people with metabolic syndrome have 5.9 more chances of having dementia and 2.2 more chances of having cognitive impairment (Roriz-Cruz, 2017). Although we had not found any significant differences between the groups, previous research on the use of passion fruit flour observed positive effects of this product on blood glucose and dyslipidemia (Janebro, 2017; Medeiros, 2017; Correa, 2017). The role of the fibers contained in the passion fruit flour appears to be related to the markers of metabolic syndrome control, including absorption of dietary glucose that provides lower postprandial glycemic peaks (Gusmão, 2017 and Molz, 2017). However, it is worth noting that its role is adjuvant and should not replace the recommended therapy for metabolic syndrome. Moreover, many patients use complementary and alternative medicine as a way to have autonomy about their treatment (Tackett, 2017). Providers who assist people with metabolic syndrome still face the challenge to aware and empower patients to cope with this and other chronic conditions that are debilitating, high-cost, andrelated to a high mortality rate (Ibiapina, 2017). We suggest the development and implementation of health education programs, to help people taking better decisions concerning their own care and the care of their families (Bomfim, 2017). Moreover, we recommend the use of alternative therapies as adjuvants to the therapeutic arsenal of chronic diseases. Therefore, it is important to expand the studies on the effectiveness of such therapies in different scenarios.

Conclusion

Consumption of bark flour of passion fruit can improve markers of metabolic syndrome, but the findings of this study were not significant. Further research is needed in a larger and more comprehensive sample, using a different design, or in a different socio-economic and geographical context to allow us to better understand the effectiveness of the use of passion fruit flour on metabolic syndrome control.

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