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ARTIGO ORIGINAL

# IMPACTO DA ADESÃO A UMA DIETA ALTA PROTEÍNA EM ENSAIOS CLÍNICOS: CONSIDERAÇÕES METODOLÓGICAS EM GRUPOS DE IDOSOS

# *IMPACT OF ADHERENCE TO A HIGH-PROTEIN DIET IN CLINICAL TRIALS: METHODOLOGICAL CONSIDERATIONS IN ELDERLY GROUPS*

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## Resumo

Antecedentes/objetivos: vários ensaios clínicos randomizados (ECRs) não demonstraram respostas consistentes dos tratamentos dietéticos aos desfechos clínicos. Especula-se que seja devido à baixa adesão às orientações dietéticas. Objetiva-se identificar a proporção de amostras que aderiram à dieta rica em proteínas e o efeito da adesão em diferentes desfechos de saúde em mulheres na pós-menopausa. Métodos: foi realizado em 52 mulheres participantes de um programa de atividade física, todas com dieta rica em proteínas por 12 semanas, com acompanhamento nutricional. A dieta prescrita continha 1,3-1,6g/kg/dia de proteína, ingestão mínima de 1,2g/kg/dia foi considerada adesão. Oito recordatórios de 24 horas foram realizados por participante. A adesão também foi analisada na excreção urinária de ureia e ácido úrico. O efeito foi analisado nos parâmetros antropométricos e cardiometabólicos. A análise de variância unilateral foi usada. Resultados: apesar do aumento significativo na ingestão proteica, apenas 38,5% alcançaram a ingestão desejada. Um aumento significativo na ureia foi observado apenas no grupo alta proteína (1,16 x 2,57, $p < 0,05$). As mulheres que aderiram à dieta rica em proteínas (n = 20) tiveram resultados clínicos significativos no índice de massa corporal, níveis plasmáticos de colesterol e de ureia, ambos com valor de $p<0,05$. Conclusão: mulheres na pós-menopausa demonstraram baixa adesão à dieta rica em proteínas, conforme análises de metabólitos e estatística feita pela análise de variância unilateral. Assim, em ECRs é essencial considerar a ingestão de nutrientes e não apenas a prescrição, destacando também a importância de ações de educação alimentar e nutricional para estimular a adesão ao proposto.

PALAVRAS-CHAVE

Dieta rica em proteínas. Adesão. Idosos. Ensaios clínicos. Terapia Nutricional.

## Abstract

*Background/objectives: several randomized clinical trials (ECRs) showed no consistent responses of dietary treatments to clinical outcomes. It is speculated that it is due to low adherence to dietary guidelines. It is aimed at identifying the proportion of samples that joined the protein-rich diet and the effect of adhesion in different health outcomes in postmenopausal women. Methods: it was performed in 52 women participating in a physical activity program, all with a protein -rich diet for 12 weeks, with nutritional follow -up. The prescribed diet contained 1.3-1.6g/kg/day of protein, minimum intake of 1.2g/kg/day was considered adhesion. Eight 24 -hour memories were performed by participant. Adhesion was also analyzed in the urinary excretion of urea and uric acid. The* *effect was analyzed in anthropometric and cardiometabolic parameters. The analysis of unilateral variance was used. Results: Despite significant increase in protein intake, only 38.5% reached the desired intake. A significant increase in urea was observed only in the high protein group (1.16 x 2.57, p <0.05). Women who joined the protein -rich diet (n = 20) had significant clinical results in body mass index, plasma cholesterol and urea levels, both with p <0.05. Conclusion: postmenopausal women showed low adherence to the protein-rich diet, according to metabolite analysis and statistics by unilateral variance analysis. Thus, in ECRs it is essential to consider nutrient intake and not just prescription, also highlighting the importance of food and nutritional education actions to stimulate adherence to the proposed.*

KEYWORDS

*High protein diet. Adherence. Elderly. Clinical Trials. Nutritional Therapy.*

## 1 Introduction

The adoption of a high-protein diet combined with physical exercise has been associated with efficient weight loss among postmenopausal women, which promotes lean body maintenance related to changes in adiposity (BACKX et al., 2016; DALY et al., 2014; DEER; VOLPI, 2015; LEIDY et al., 2007; MOJTAHEDI et al., 2011; PADDON-JONES; LEIDY, 2014; RIZZOLI, 2015; VERREIJEN et al., 2015). However, not all studies have shown positive results when patients adhere to a high-protein diet without protein supplements in the meal plan (GARCÍA-UNCITI et al., 2012; IGLAY et al., 2009; SHLISKY et al., 2015). This can be attributed to possible poor adherence to the proposed dietary plans, and consequently, lower protein intake compromised the results after the dietary follow-up. The absence of assessing the bias generated by adherence in studies with dietary interventions has been identified since 1996 (BUZZARD et al., 1996).

A meta-analysis showed that dietary adherence is the most difficult health treatment to follow (DIMATTEO, 2004). Adopting healthy eating habits can prevent the occurrence of many chronic diseases and improve treatment outcomes (JANKOVIC *et al.*, 2014; OTTO *et al.*, 2016; USDA, 2014), especially considering the association of these conditions with excess weight gain and its increasing progression over the years (NG *et al.*, 2014). Compared to the male population, overweight is more prevalent in the female population, with the highest prevalence at the age of 65 years (NG *et al.*, 2014), coinciding with the postmenopausal period (BOSCO, 2010). However, the process of weight loss for this specific population is more complex due to hormonal, physical, and physiological changes resulting from senescence and the menopause itself (BOSCO, 2010).

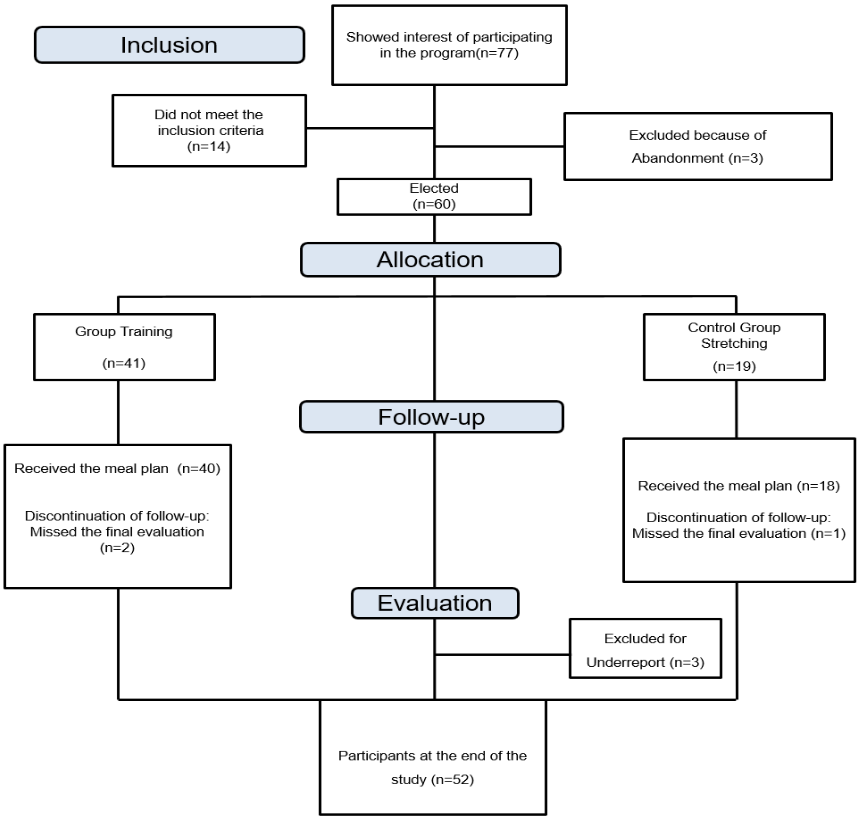
Studies have reported the importance of assessing adherence to treatment in randomized controlled trials (RCTs) and its effect on the causality and certainty to detect treatment effectivity (AGBLA; DIAZORDAZ, 2018; ZHANG, Ze *et al.*, 2014). Although there are no studies that have evaluated the effect of adherence to dietary treatment in RCTs, some studies that evaluated reporting of adherence in RCTs identified that a minority of RCTs showed adherence information with gaps in the definition, monitoring, and evaluation of adherence (AGBLA; DIAZORDAZ, 2018; ZHANG, Ze *et al.*, 2014).

Therefore, this study aimed to identify the proportion adhering to a high-protein diet in an RCT and the effect of adherence to a high-protein diet on different health outcomes.

## 2 Methodology

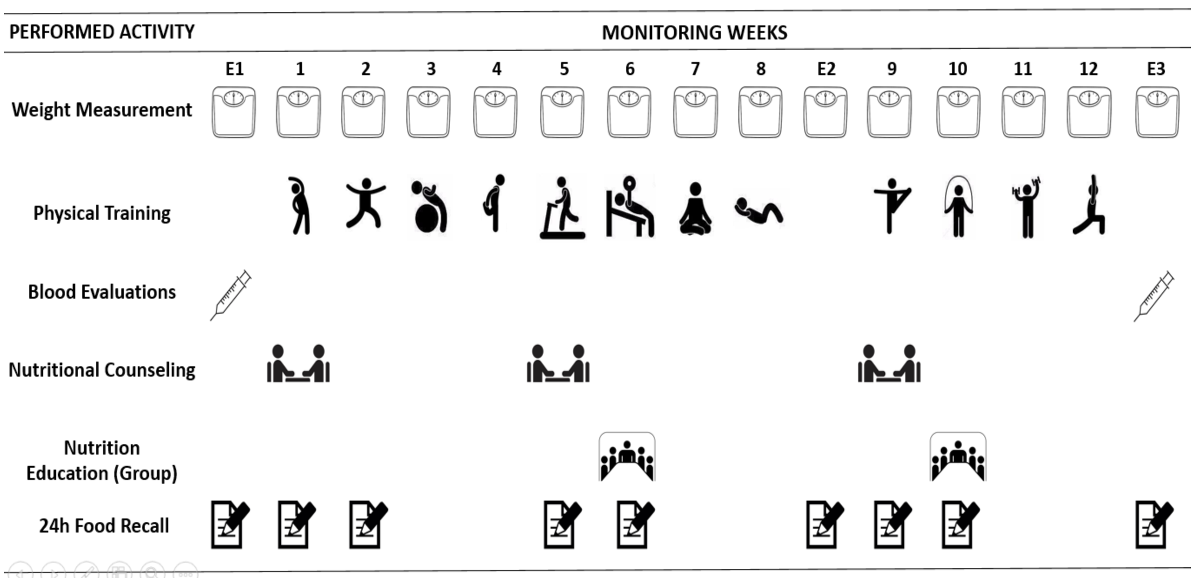
This is a clinical, controlled, randomized, interventional study that involved physical training and nutritional guidance for 12 weeks. The sample was chosen randomly according to the age and body mass index of individuals and categorized into two groups (multicomponent training and control). The participants were part of a physical activity program held at the university (Figure 1). All participants received an individualized meal plan to adopt and adhere to a high protein diet, being delivered in consultation with nutritionist. In addition, they had moments of food and nutritional education actions to explain the importance of protein intake in the elderly. All were evaluated before intervention (E1) and after 12 weeks after intervention (E2) (Figure 2).

**Figure 1.** Flowchart of the study with experimental design.




Source: Author himself.

**Figure 2**. Intervention of 12 weeks.




E: Evaluation
Source: Author himself.

### Trial population

The study population comprised 52 noninstitutionalized women aged between 57 and 81 years. They were recruited within and outside the university community through posters and announcements on the university's radio. The inclusion criterion was female individuals in the postmenopausal stage. The exclusion criteria were the presence of comorbidities that might confer participants with risk during the physical exercise program (e.g., unstable cardiovascular disease), serious musculoskeletal conditions that impede locomotion, undergoing nutritional monitoring, and underreporting of food intake. All survey participants received explanation, following which they agreed and signed an informed consent form. The study protocol was approved by the Research Ethics Committee at the Federal University of Sergipe, under the number of opinion 1.586.11 and CAAE 54635316.1.0000.5546.

### Dietary guidance (meal plans)

Three nutritional consultations were performed: first session was for the delivery of the three meal plan options (attended by all study participants), the second session was to identify difficulties with adhering to the meal plans, and the third session was to provide advice for better adherence to the meal plans. Based on these consultations, two educational activities were performed in groups of 10-15 women with the objective of facilitating increased protein intake and providing support to follow the guidelines.

The first activity focused on smart food choices which encouraged proper replacement of foods in the food groups, especially with high protein-containing foods like swapping butter for cheese. During the second activity, we performed a trivial game on common myths and truths about food habits, which aimed to elucidate issues relating to meal plans and eating habits. Nutritionists prepared meal plans based on energy expenditure calculated using the Food and Agriculture Organization of the United Nations (FAO) formula (CONSULTATION, 2001). For participants who were overweight, a restriction of 400 kcal/day was recommended to promote a weight loss of 5% of the total body weight in 3 months (WGO, 2011).

All participants received three individualized meal plans with a high protein content (between 1.3 and 1.6 g/kg/day). The meal plans, distributed across 6 days, contained 70% animal protein and 30% plant protein. The menus were prepared according to the principles of healthy nutrition. Among animal protein sources, eggs and milk were chosen based on the participants' affordability.

### Dietary evaluations

Eight 24-hour food recalls (R24hs) were conducted to identify the usual food intake of study participants before and during the various stages of the intervention. The recalls were completed with the aid of a photo album for greater accuracy of the portions consumed (LOPEZ; BOTELHO, 2008; SALES; COSTA; SILVA, 2004; VITOLO, 2008; ZABOTTO; VIANNA, 1996). The data were tabulated in the Nutrition Data System for Research, version 2011 (NCC, University of Minnesota, Minneapolis, MN, USA).

The statistical modeling incorporated in the Multiple Source Method (MSM) online platform was used to calculate the habitual intake of nutrients (DIFE), [s.d.]). The MSM facilitated the removal of intrapersonal variability by recording two or more R24hs and calculating the habitual intake of each nutrient for each individual using three statistical steps. First, the probability that an individual would consume a certain nutrient on a random day was estimated. Second, the usual quantity of nutrient intake during the day of consumption was estimated. Finally, the numbers resulting from steps 1 and 2 were multiplied to estimate the usual daily intake (HARTTING *et al.*, 2011).

The ratio of reported energy intake to predicted total energy expenditure (*GETp*) was calculated to identify underreporting (implausible energy report).(Mccrory, Hajduk e Roberts, 2002) *GETp* was calculated using the equation of Vinken *et al.* (1999): The cutoff point was calculated using the following formula:

±2 *DP* = $2 \times \sqrt{CV^2wEI/d + CV^2wGETp + Cv^2tmGET}$,

where $CV^2wEI$ is the intrapersonal variation coefficient of energy intake (0.36),

*d* is the average number of dietary surveys applied (0.8),

$CV^2wGETp$ is the intrapersonal variation coefficient of *GETp* (0.177), and

$Cv^2tmGET$ is the coefficient of variation of *GET*, calculated according to the doubly labeled water method (0.082 - corresponding error of measurement + biological variation).

*The* $CV^2wEI$ was calculated using our own sample. The cutoff point ±2.0 SD was used to identify underreporting of intake. After the estimation of usual intake and the exclusion of participants with underreporting, dietary data were analyzed based on the planned protocol. Participants who adhered to an intake of ≥1.2 g/kg/day were classified as having a high-protein diet (HP group) (CERMAK *et al.*, 2012), whereas those who adhered to an intake of <1.2 g/kg/day were classified as having a normal-protein diet (NP group).

**Multicomponent Physical Training**

Thirty-six physical training sessions were conducted under the supervision of physical education professionals. Each session lasted for 50 minutes and occurred on three non-consecutive days per week. In the week before the intervention period, adaptation to the exercises were facilitated by applying 50% of the intensity planned for the first training session. The 0–10 OMNI-GSE scale was used to control and standardize the overall training intensity. An intensity of 6–8 (moderate to intense) was prevalent (DA SILVA-GRIGOLETTO *et al.*, 2013).

The exercises performed during the multicomponent training (MT) involved pulling, pushing, squatting, and lifting, performed at the maximum speed. The load was progressively increased to maintain a limited number of repetitions per series. To maintain the sample during the intervention period, the control group performed relaxation and stretching three times a week on non-consecutive days.

**Clinical Outcomes**

**Anthropometric Assessment**

Body mass was measured using a scale (Digital Lider®, P150C), and height was measured using a stadiometer (Sanny®, ES2030). The circumference values of the relaxed arm and waist were obtained using an inelastic tape with calibrations in millimeters (Sanny®). Each measurement was performed in triplicate by a qualified professional.

Muscle body mass was quantified using the formula of Janssen *et al.* (2000). All anthropometric measurements were performed according to the method described (LOHMAN; ROCHE; MARTORELL, 1988).

**Biochemical assessments**

For participants who were under fasting for 12 hours, blood samples were collected from the antecubital vein, through venipuncture by a technically qualified professional. The equipment and materials used in all biochemical procedures were sterile and/or disposable. Blood samples were collected at two time points (E1 and E2; Figure 2). Levels of total cholesterol, high-density lipoprotein-cholesterol, low-density lipoprotein-cholesterol, and triglycerides were analyzed using the CMD 800i system (Wiener Lab Group®).

Serum levels of urea and uric acid were determined using enzymatic-colorimetric and enzymatic methods, respectively. These two variables were used as markers of protein intake pre- and post-intervention.

**Statistical analysis**

In descriptive statistical analysis, we calculated the means, standard deviations, and absolute and relative frequencies. Initially, data distribution was analyzed using the Kolmogorov–Smirnov test. Independent and paired *t* tests, Wilcoxon test, and Mann–Whitney *U* test were performed to compare the dietary intakes.

One-way analysis of variance was used in both scenarios, considering and disregarding adherence to a high-protein diet, to compare biochemical and anthropometric variables in the pre- and post-intervention periods. All statistical analyses were performed using IBM SPSS Statistics, version 20.0. Statistical significance was set at a *p*-value of <0.05, and the confidence interval was set at 95%.

## 3 Results and discussion

The sample consisted of 52 women with an average age of 65 years (SD 5), and 63% worked as housewives. Most of the participants had middle school as the highest level of education (50%) and were overweight (49.1%). The most prevalent diseases were osteoarticular diseases (60%), hypertension (56.4%), and diabetes (21.8%). A high proportion of participants had medication adherence (81.8%) and regular practice of physical exercise (69.1%).

Table 1 shows a comparison of habitual intake from the R24h at pre-follow-up (two R24hs per person) and during follow-up (six R24hs per person), and the prescribed diets. A significant difference was observed between the prescribed and consumed amounts for all nutrients except total carbohydrates, which suggested poor adherence to dietary prescriptions. However, there were changes in nutrient intake before and after the follow-up, wherein there was a significant increase in protein (animal) and fiber intake and a decrease in caloric contribution from fat.

Despite a significant increase in protein intake, not all women were able to adhere to the high-protein meal plan. Upon individual analysis, 32 women (61.5%) did not reach the minimum cutoff of 1.2 g/kg/day and thus were classified as the NP group.

The objective biological variables for confirming adherence to a high-protein diet are presented in Table 2. The plasma concentration of urea corroborates the difference between the two groups' protein intake evaluated according to the R24h. A significant increase in urea concentration was observed only in the HP group. However, the values did not increase above the cutoff point. No significant changes in uric acid levels were observed over time.

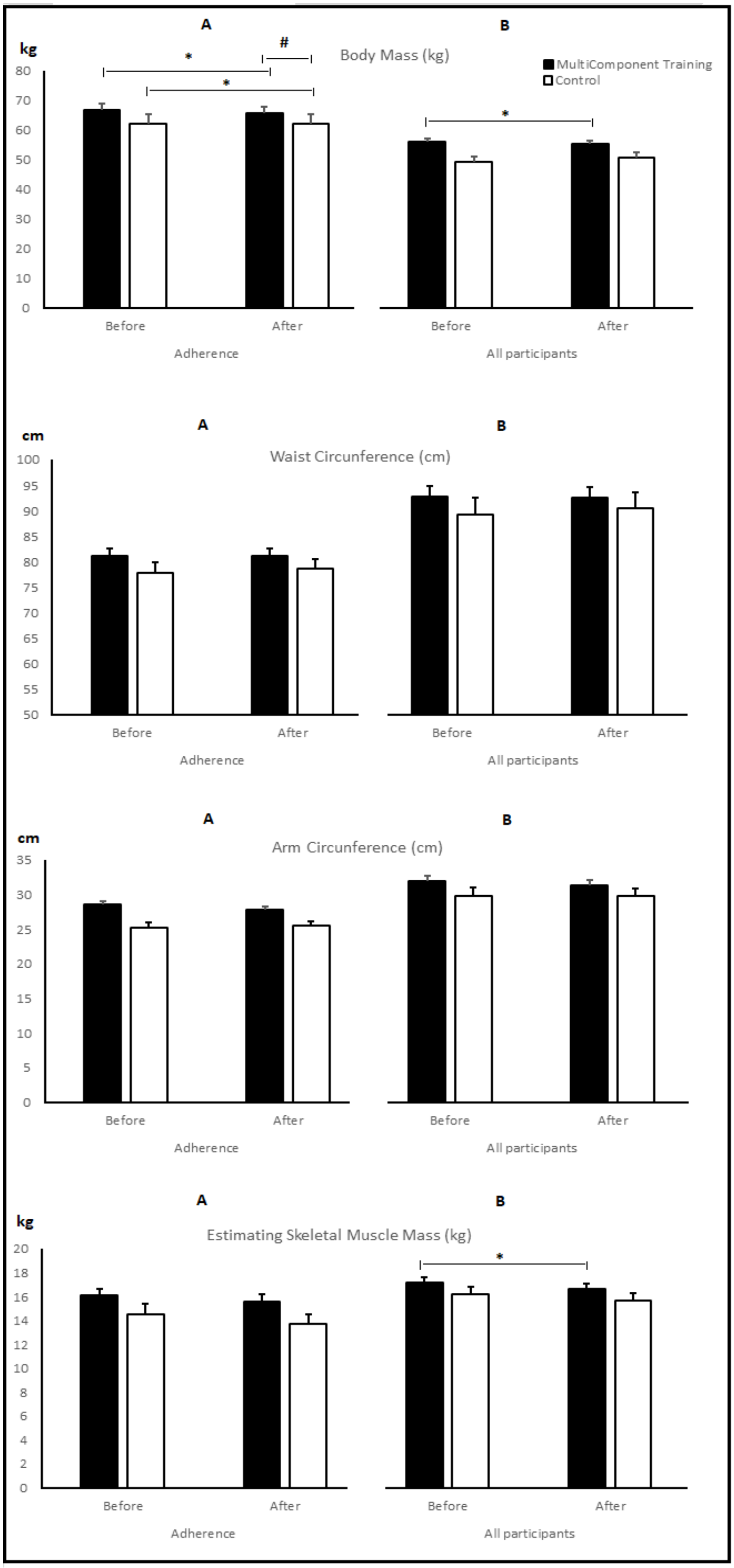
Figures 3 and 4 show changes in anthropometric and biochemical measurements after 12 weeks of the multicomponent training or stretching (control) intervention, respectively. In situation A, only women who adhered to the high-protein diet (n = 20) were considered, and in situation B, all participants were considered, without considering adherence to the diet (n = 52). When considering adherence to the diet (Figure 3), it was observed that some variables had changes in their interpretation when compared with the data presented by all participants. Body mass changed in both groups after 12 weeks, with a significant difference between the groups (multicomponent training versus control). Regarding the muscle mass index, there was a loss of significance for the data of all participants. Likewise, in Figure 4, triglyceride levels showed no statistically significant difference when analyzed only among those who adhered to the HP diet.

**Table 1.** Comparison of dietary intakes at pre-follow-up and follow-up and the prescribed intake in a duration of 12 weeks.

| Dietary variables | Pre-follow-up | Follow-up | Prescribed |
|---|---|---|---|
| | $\underline{X}$ (*SD*) | $\underline{X}$ (*SD*) | $\underline{X}$ (*SD*) |
| **Energy (kcal)** | 1432.5 (330.0) | 1472.3 (217.4) | 1730.5 (125.0) [b] |
| **Carbohydrates** | | | |
| Total (g) | 210.3 (37.4) | 221.1 (38.8) | 228.3 (25.7) |
| E% | 59.6 (6.2) | 60.0 (5.0) | 52.7 (4.1) [b] |
| **Fiber** | | | |
| Total (g) | 18.8 (2.9) | 23.5 (4.8) [a] | 32.9 (1.9) [b] |
| Insoluble (g) | 13.8 (2.1) | 17.4 (3.8) [a] | 23.5 (1.4) [b] |
| Soluble (g) | 4.8 (0.9) | 5.9 (1.3) [a] | 9.0 (0.5) [b] |
| **Protein** | | | |
| Total (g) | 61.4 (13.8) | 71.1 (11.7) [a] | 96.1 (17.0) [b] |
| E% | 17.4 (3.2) | 19.4(2.3) [a] | 22.3 (4.0) [b] |
| g/kg | 0.9 (0.2) | 1.1 (0.3) [a] | 1.4 (0.7) [b] |
| Animal (g) | 41.3 (13.0) | 48.6 (8.1) [a] | 70.2 (17.9) [b] |
| Plant (g) | 19.8 (4.8) | 22.3 (5.4) | 25.9 (1.9) [b] |
| **Fat** | | | |
| Total (g) | 42.1 (14.4) | 38.8 (8.4) | 55.3 (5.4) [b] |
| E% | 26.0 (4.3) | 23.7 (3.7) [a] | 28.7 (0.9) [b] |
| Saturated (g) | 14.7 (5.3) | 13.7 (3.5) | 19.2 (2.7) [b] |
| Monounsaturated (g) | 13.9 (4.7) | 12.9 (3.1) | 20.8 (3.5) [b] |
| Polyunsaturated (g) | 9.5 (2.1) | 8.3 (2.0) [a] | 10.5 (1.1) [b] |
| Cholesterol (mg) | 193.5 (83.3) | 203.4 (38.8) | 322.6 (67.2) [b] |

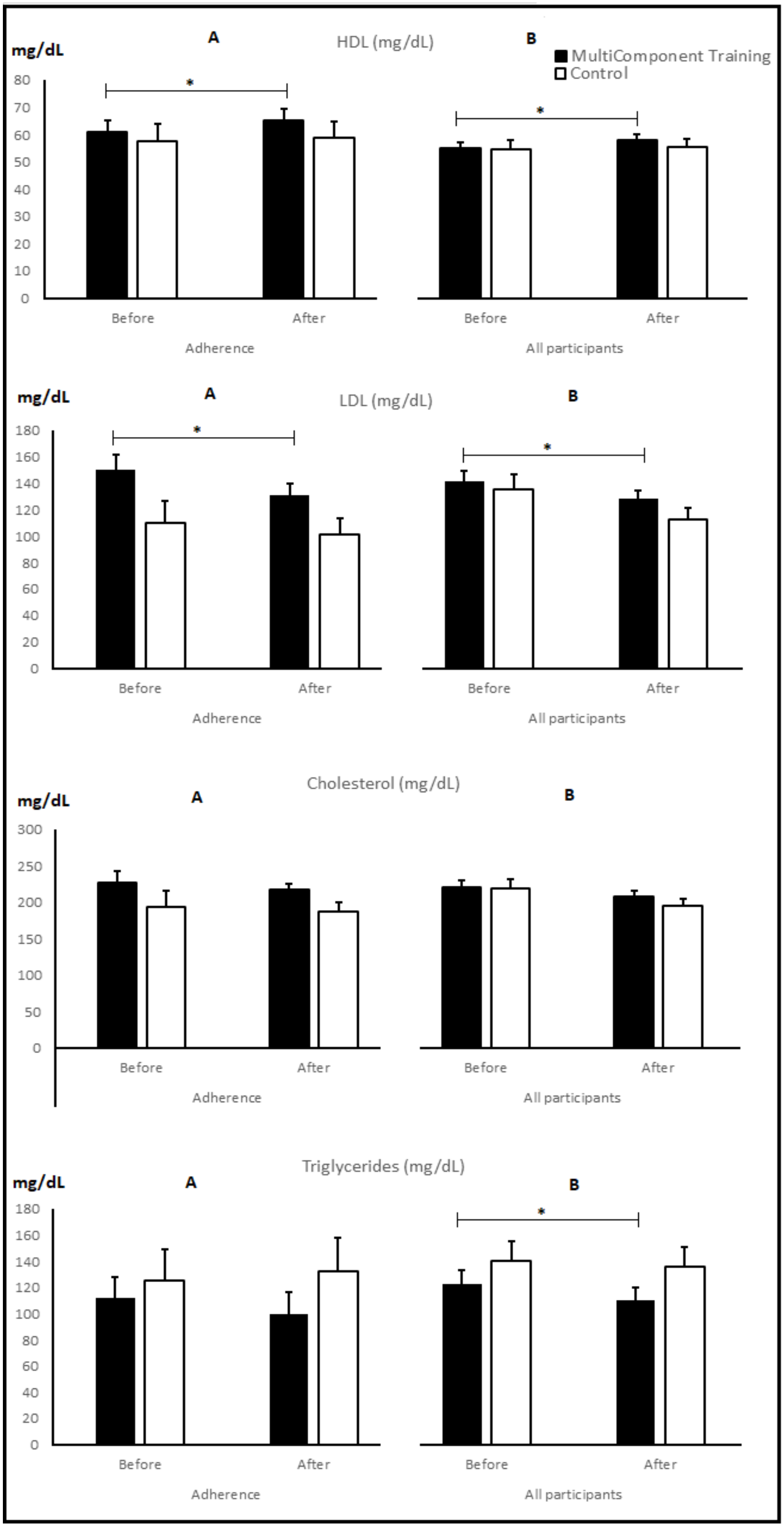
Paired *T* test and Wilcoxon test were used.
[a] Statistical difference between pre-follow-up and follow-up intakes.
[b] Statistical difference between prescribed intake and intake at follow-up.
E%: total energy percentage. SD: Standard Deviation.
Source: Author himself.

**Figure 3** – Anthropometric measurements before and after 12 weeks of multicomponent training or stretching (control).




A: only those who adhered to the high-protein diet (n=20).
B: all participants, without considering adherence to a high-protein diet (n=52).
* Significance difference intragroup; # significance difference between groups.
Source: Author himself

**Figure 4** – Biochemical measurements before and after 12 weeks of multicomponent training or stretching (control).




A: only those who adhered to the high-protein diet.
B: all participants, without considering adherence to a high-protein diet.
*Significance difference intragroup; # significance difference between groups.
Source: Author himself.

**Table 2.** Variations in protein metabolites among women according to the of a high protein diet.

| Variables (mg/dL) | NP<br>(*n* = 32)<br>$\underline{X}$ (S*D*) | HP<br>(*n* = 20)<br>$\underline{X}$ (S*D*) | ANOVA effect | *F* | *p* |
|---|---|---|---|---|---|
| **Urea** | | | | | |
| Pre-intervention | 31.67 (7.95) | 32.47 (8.22) | G | 0.452 | 0.505 |
| Post-intervention | 32.83 (7.84) | 35.05 (8.92) | T | 5.467 | **0.024** |
| Δ | 1.16 (6.02) | 2.57[a] (4.45) | GxT | 4.192 | **0.046** |
| **Uric acid** | | | | | |
| Pre-intervention | 4.07 (0.85) | 3.34 (0.96) | G | 7.398 | **0.009** |
| Post-intervention | 3.97 (0.86) | 3.34 (0.96) | T | 0.392 | 0.534 |
| Δ | -0.10 (0.57) | 0.00 (0.05) | GxT | 1.032 | 0.315 |

[a] Significant increase was noted only in the HP group. SD: Standard deviation.
G: group; T: time; GxT: interaction times group.
Δ: difference between pre and post value.
Source: Author himself.

To the best of our knowledge, this is the first study to examine the effect of adherence to dietary treatment on different health outcomes in an RCT. Our results suggest that assessment of adherence to dietary treatment had an impact on the results of RCT, and this effect can lead to erroneous conclusions. Moreover, despite improvement in their previous dietary habits, postmenopausal women who participated in the nutritional counseling program in this study also presented poor adherence to the prescription of a high-protein meal plan.

Poor adherence to the prescribed diet since the intake of all macronutrients was lower than the prescribed amount. Only 38.5% of the participants adhered to the consumption of the high-protein intake, which is lower than that (59.3%) reported by DiMatteo *et al* (2004) in their meta-analysis. However, in their study, the rate of dietary adherence was significantly lower than that with other health treatments such as with medication (79.4%) and physical exercise (72.0%) (DIMATTEO, 2004). Additionally, the increased demand for protein intake was significantly higher in the group that failed to adhere to the prescribed diet. It is postulated that a radical alteration in previous dietary habits increases the level of difficulty in adhering to the prescribed meal plan.

Pontieri et al (2010) investigated the beliefs of diabetes patients in therapy and their influence on adherence to treatment, which identified that restrictive food imposition and social and behavioral factors are difficult to modify and thus negatively affect adherence. These findings suggest that poor adherence to dietary treatments is common. However, the reasons for this may vary according to population sample.

Adherence can be influenced by several factors such as those related to disease (severity, symptoms, presence of associated comorbidities), treatment (cost, required to modify habits), patient (expectations, self-esteem, beliefs), socioeconomic status, the system (effectiveness, access), and the healthcare team (good relationship, trust (WHO, 2000). In addition to adherence, food behavior itself is influenced by several factors such as social, cultural, psychological, nutritional, demographic, and environmental factors (TORAL; SLATER, 2007). Thus, prescribing a diet does not guarantee adherence.

Future RCTs designed to increase protein intake should therefore consider previous eating habits to properly identify individuals who may have a greater possibility of adhesion, which means that these individuals require less alteration in their eating habits. In addition, these studies should consider the importance of prescribing supplements to achieve desired protein intake. In addition to whey protein, options may also be suggested as albumin or essential amino acids. Food and nutritional education can be a factor that facilitates adaptation to the food plan and adhesion because it has been reported that protein intake has increased over 3 months (data not shown). A study on food counseling for women with risk factors for metabolic syndrome suggested that long-term monitoring is fundamental for changing eating habits (DIONÉIA *et al.*, 2014).

RCTs are widely used in the scientific literature to guide health professionals in decision-making regarding the efficacy and safety of using treatments (SCHULTZ *et al.*, 2019). Recent studies have shown low or inconsistent assessments of treatment adherence in clinical trials (AGBLA; DIAZORDAZ, 2018; ZHANG, et al., 2014). The study shows that considering adherence to a diet plan potentially modifies the results and conclusion of the data. This evidence suggests that not reporting and analyzing adherence may be a bias or error that could distort the observed effect (ZHANG, *et al.*, 2014).

Thus, the design of studies that investigate the role of diet in the treatment of diseases needs to assess intervention fidelity by assessing adherence among all participants, particularly in the measurement and analysis of results and the interpretation of findings. This methodological rigor can increase the external validity of the RCT and its reproducibility (MCGEE *et al.*, 2018). Subjects' adherence to the proposed treatment has an important impact on the statistical power to identify the differences between the groups. Failure to consider adherence during research planning can contribute to an increasing risk of type II error and erroneous conclusions and alter the magnitude of the observed treatment effect (ROBINER, 2005; ZHANG, SHUN et al., 2015).

In addition, the positive effect of regular exercise and adequate protein ingestion for general health of individuals is also highlighted, which is a potential means to contribute to the promotion of the postmenopausal woman's quality of life (ESCOBAR, 2010).

Adequate adherence assessment will allow healthcare professionals to provide more reliable information about the effectiveness of the intervention and its feasibility in clinical practice (MCGEE *et al.*, 2018). Adherence to treatment is a crucial factor that determines the success of healthcare (WHO, 2000). It is related to how precisely a person can follow the recommendations proposed by health professionals such as being able to take a medicine and/or modify their lifestyle. A poor adherence to treatment has been identified even in developed countries, complemented with health problems, which generates greater expenses for the economy (WHO, 2000). Studies have shown that billions of dollars could be saved each year by increasing the treatment adherence of patients with chronic diseases (IUGA; MCGUIRE, 2014; MENNINI et al., 2015; STUART et al., 2015; ZHANG, SHUN et al., 2015).

This study has several strengths. On average, eight R24hs were performed for each participant to assess adherence to the food plan. Despite the presence of underreporting, we performed statistical modeling using the MSM to remove intrapersonal variability and estimate habitual nutrient intake. These analyzes improved the quality of the data. As a limitation, approximately 50% of the study participants were overweight, which may have contributed to the difficulty in meeting the target body protein needs (1.2 g/kg/d).

However, other methods of verifying protein requirements, such as studies with stable isotopes, as well as the evaluation of other protein metabolites such as urinary nitrogen, can be an alternative. However, they involve a high cost and expertise that is more difficult to monitor in the nutritionist's clinical practice.

The findings of this study can support nutrition researchers who perform dietary monitoring to control nutrient intake and verify adherence to proposed interventions. Non-adherence to dietary treatment can have a profound impact on outcomes. Thus, health professionals can identify more effective nutritional strategies with greater adherence by the population if this information is clear and well documented in randomized clinical trials.

## 4 Conclusions

Our findings revealed low adherence to the prescription of a high-protein diet among postmenopausal women, denoting that only 38.5% achieved the desired protein intake. These results corroborate their impact on the conclusions of the effect of dietary intervention on different health outcomes, through a randomized clinical trial. Thus, the importance of considering the intake of nutrients and not just the dietary prescription is highlighted in order to better support the findings of clinical studies.

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