Comparison of Neuromuscular Characteristics of Strict Vegetarians and Non-Vegetarians Women and Their Adaptations After 16 Weeks of Strength Training

52472821.6.0000.5347 – Date:03/28/2022

STUDY PROTOCOL

Study design and sample

This is a randomized clinical trial study to be carried out with healthy, strength-untrained women adult, with a strict vegetarian or non-vegetarian dietary pattern.

Inclusion criteria

- Age ≥ 19 and ≤ 50 years;
- Body mass index (BMC) < 30 kg/m²;
- Be a strict vegetarian or non-vegetarian for at least 6 months;
- Not performing regular physical exercise for at least 6 months.

Exclusion criteria

- Having chronic diseases, such as systemic arterial hypertension, diabetes mellitus, cardiomyopathy, etc.;
- Present physical limitations or musculoskeletal problems, which contraindicate the performance of strength exercises;
- Make use of protein or amino acid food supplement, caffeine or other thermogenic substances;

Sample size calculation

The sample size was calculated generating 2 experimental groups: strict vegetarians (SV) and non-vegetarians (NV). 5% significance level and 95% statistical power will be considered. The result of the calculation (72 participants) was considered with a possible sample loss of 22.2%. Thus, 44 subjects will be needed in each group, totaling 88 participants. The sample size was calculated using the SAS Studio software (SAS Institute Inc., Cary, NC, USA).

Ethical aspects

This study was designed in accordance with the Regulatory Guidelines and Norms for Research Involving Human Beings (Resolution CNS/MS 466/13) and was submitted to the Research Ethics Committee of the Federal University

of Rio Grande do Sul (CEP/UFRGS). No data collection was initiated before the approval of this committee. Likewise, the researchers undertake to maintain the anonymity and confidentiality of the participants' data, which will be identified by codes and handled only by the research team, being used only for scientific purposes and presented in a grouped manner. All participants will be asked to sign the Consent Form at the time they enter the study.

Logistics

The recruitment of individuals for research will take place in a continuous flow, through dissemination through posters that will be fixed on the university premises, flyers that will be distributed at the Ecological Fair of Redenção (where there is a large circulation of vegetarians), vegetarian restaurants in region, as well as through social networks. Interested parties may contact the team via email, social media or in person. After the preliminary verification of the inclusion and exclusion criteria, a virtual meeting (phone or video call) will be held to provide information about Phases I (baseline) and II (16 weeks of strength training protocol participation) of the study and also to clarify doubts. Interested parties will be informed that participation in Phase I of the study is not conditioned to participation in Phase II, since, even if there is interest, only those who meet the specific eligibility criteria for such, referring to the evaluation of the average daily protein intake. Interested parties will receive a virtual copy of the Free and Informed Consent Term, which will clarify the research objectives and other relevant aspects, and will only participate in the research upon confirmation of agreement with the Term, which can be obtained by text, image or audio. Then, participants will be instructed to complete the 3-day food record and also to count the number of steps with the pedometer during 7 consecutives days. In the week following the end of data collection, participants will be invited to attend face-to-face assessments at the Exercise Research Laboratory at UFRGS.

At the first meeting, an anamnesis will be applied, body mass and height will be evaluated to determine the body mass index for a detailed review of the eligibility criteria. Then, the following evaluations will be performed: Body composition (Anthropometry, Dual Emission X-ray absorptiometry and ultrasonography), maximum and dynamic strength by isokinetic dynamometer (familiarization) and vertical jump power (familiarization). On the same day, the

International Physical Activity Questionnaire will be applied to also assess the participants' level of physical activity (CRAIG et al., 2003).

A second face-to-face meeting will be scheduled with an interval of at least 48 hours after the first one to carry out the maximum and dynamic strength by isokinetic dynamometer and vertical jump power tests. Also, the knee extensors, knee flexors and plantar flexors, one maximum repetition test (1MR) familiarization will be realized. At third face-to-face meeting, the 1MR tests of knee extensors, knee flexors and plantar flexors will be evaluated. Body composition assessments of all participants and performance tests will be performed by physical educators. The 3-day food record and anamnesis will be performed and anayised by a nutricionista, equally trained for these tasks. Thus, the participants will started the 16 weeks of strength traning protocol. After 1 week of the ending of strength training protocol the participants will repeat the measurements and tests realized at baseline in more three daysto of face-to-face meeting. All face-to-face meetings with the participants to carry out the assessments will take place in the Neuromuscular Sector of the Exercise Research Laboratory, located at the School of Physical Education, Physiotherapy and Dance at UFRGS.

Research team

The research team will be composed by nutritionists (Gabriela Lucciana Martini, Carolina Guerini de Souza, Cláudia Dornelles Schneider and Mariana Cardoso de Lemos) and physical education professionals (Márcio Beck Schemes, Ronei Silveira Pinto and André Pozzuelo), who will carry out the recruitment, selection, as well as the collection procedures referring to their respective areas.

Statistical analysis

The results will be presented using descriptive statistics mean ± standard deviation (SD) for variables with normal distribution and median (minimum – maximum) for non-parametric data. The normality of data distribution will be assessed using the Kolmogorov-smirnov test. In order to compare the neuromuscular characteristics, food intake and body composition of both groups, the T Test - independent, or the non-parametric alternative, Mann Withney's U

Test will be used. To assess whether the protein intake of strict vegetarians and non-vegetarians reaches the daily recommendation, the simple T-test or Wilcoxon's Test for Single Sample will be used, according to the data distribution. For correlations between neuromuscular parameters, food intake and body composition of strict vegetarians and non-vegetarians, the Pearson test (r) will be used for continuous variables that presented normal distribution and the Spearman (Rho) test will be used when the variable does not present a normal distribution and/or or in ordinal variable. Correlation values (r or Rho) will be classified as: “biologically negligible” (between 0.3 and -0.3); “weak” (between 0.31 and 0.5 or -0.31 and -0.5); “moderate” (between 0.51 and 0.7 or -0.51 and -0.7); “strong” (between 0.71 and 0.9 or -0.71 and -0.9); and “very strong” (when > 0.9 or < -0.9) (MUKAKA, 2012). The level of physical activity will be evaluated using the chi-square test of homogeneity of proportions. Calculations will be performed in SPSS software (version 25) and a significance level of 5% ($p > 0.05$) will be adopted.

INFORMED CONSENT FORM

Comparison of neuromuscular characteristics of strict vegetarians and non-vegetarians women and their adaptations after 16 weeks of strength training

Studies have shown that the practice of strength training promotes adaptations such as increased strength, muscle quantity and quality, generating several health benefits. Along with training, adequate protein consumption can further improve the results obtained. Thus, we want to test the results of strength training and assess whether there are differences in these parameters between people who do not consume foods of animal origin and those who consume meat, eggs and dairy products, before and/or after the training period.

Therefore, you have being invited to participate as a volunteer in this research, which has 2 main objectives: (Phase 1) to compare muscle quantity and quality, in addition to muscle strength and power, among strict vegetarians (who do not consume any food of animal origin) and non-vegetarians, who are untrained (Phase 2) to evaluate these same aspects after 16 weeks of weight training in strict vegetarians and non-vegetarians who maintained their dietary pattern during this period.

If you accept to participate in the research, you must inform the research team by video, text or photo that you agree with the present. Then we'll explain about the 3-day food record, during which you must record everything you've consumed (food, quantity...) and counting the number of steps.

Thus, a member of the research team will then contact you to schedule the three days of initial assessments. Each day of assessments will last up to 3 hours and will be held at the School of Physical Education, Physiotherapy and Dance at UFRGS, within the Exercise Research Laboratory, in the Neuromuscular sector. The procedures are:

1) An initial questionnaire will be taken to confirm some information about you and then we will assess your weight and height to calculate your body mass index (BMI). This step is a final confirmation that you can participate in Phase 1 of the study.

2) You will receive a questionnaire with questions to assess your level of physical activity, called the International Physical Activity Questionnaire

3) After that, you will perform an exam called Dual Emission X-Ray Absorptiometry, which is like an X-ray exam, which will record an image of your entire body as you lie on an evaluation table. Also, the anthropometric measurements with fat caliper, anthropometric tape and paquimeter will be realized. Theses exam are used to assess body composition (lean and fat mass)

4) On the same day, you will perform 3 more tests to evaluate muscle mass and muscle power and strength. An ultrasonography (US) exam will be done, which records an image of what your thigh and leg muscles are like, to assess your muscle mass. For muscle power assessment, you will perform vertical jumps (upwards) on a mat. As for the muscle strength assessment tests, you will perform a knee extension and flexion exercise, with maximum strength, as quickly as possible.

5) At a third day, you will realized the other performance test. You will have to do the same knee extension, knee flexion and plantar flexion exercises with a maximum of 10 repetitions, on a specific machine with a load.

6) As soon as you complete the procedures described above, your data will be analyzed and the nutritionist will inform you if you are able to participate in Phase 2 of the study. If possible, you will be assigned to the group according to the type of diet you follow (with or without foods of animal origin). This process occurs by drawing lots (randomization) with the use of a specific program for this purpose.

7) Then, strength training classes will be scheduled, which you will have to take twice a week for 16 weeks (4 months). These classes will be held at the ESEFID gym, located at Felizardo Street, nº 750, Jardim Botânico – Porto Alegre RS, free of charge and supervised by a physical educator professional.

The procedures listed in items 2,3,4 and 5 will be performed in 2 moments: at the beginning (Week 0) and at the end (Week 17) of the study. At weeks 4, 8, and 12, the nutritionist will ask you to perform the 3-day food record and activity level assessment again. Throughout your participation in the study, you will be contacted to check if there have been any difficulties.

Both physical assessments and strength training sessions may cause you some discomfort, such as: tiredness, pain in the leg muscles or sweat, but that will pass in a few minutes, and you will be assisted all the time by a physical educator professional. No other risks are known for participating in this research, but the participant may have to maintain their eating habits in order to meet the recommended protein intake, which may cause some discomfort. As a benefit of participating in any phases of this research, you will have, free of charge, a complete assessment of your body composition, food intake and muscle strength, knowing how you are in relation to parameters considered healthy. Those who meet the eligibility criteria and are able to participate in phase 2 will have free strength training sessions supervised by a qualified professional at the ESEFID gym. However, participation in this study is completely voluntary, and your consent to the study can be withdrawn at any time and non-participation or withdrawal will not cause any harm or embarrassment to you, in the same way that you will not incur any cost, nor will you receive any payment for the procedures involved. However, when necessary, researchers will be able to pay for bus tickets for the participant to travel to ESEFID on assessment and/or training days.

The researchers undertake to maintain the confidentiality of the participants' personally identifiable data and the results will be disclosed in a grouped manner, without the identification of the individuals who participated in the study. All your doubts can be clarified before and during the course of the research, by contacting the responsible researcher Prof Dr Ronei Silveira Pinto, from the Federal University of Rio Grande do Sul through the phone (51) 3308-5894 or with the Ethics Committee in Research (CEP) at the Federal University of Rio Grande do Sul, who is evaluating this work, via e-mail etica@propesq.ufrgs.br.

I,_____
_____, accept to voluntarily participate in the project “Comparison of the neuromuscular characteristics of strict vegetarians and non-vegetarians and their adaptations after 16 weeks of strength training, after having been duly clarified and informed about the research, the procedures involved in it, as well as the possible risks and benefits . This document will have two copies, one of which will be delivered to you and the other kept by our research group.

Name (participant)
_____Signature_____

Name (researcher)
_____Signature_____

Local and
date:_____