UNIVERSIDADE FEDERAL DO RIO DE JANEIRO
INSTITUTO DE NUTRIÇÃO JOSUÉ DE CASTRO
PROGRAMA DE PÓS-GRADUAÇÃO EM NUTRIÇÃO

IMPACT OF GENETIC POLYMORPHISMS ON WEIGHT LOSS PROGRESSION WITH THE DASH DIET IN CLIMACTERIC WOMEN WITH METABOLIC SYNDROME

79705724.2.0000.5257

April 26, 2025

INFORMED CONSENT FORM

Dear Sir/Madam, you are being invited to participate in the research project "Association between genetic polymorphisms (changes in genetic material) and the DASH dietary plan (calorie-reduced and salt-restricted dietary plan) on inflammatory markers in patients with metabolic syndrome," under the responsibility of researchers XXXXXX and XXXXX. The study aims to analyze the interaction of your genetics with a calorie-reduced and salt-restricted diet on weight loss and laboratory tests (blood and saliva) in patients with metabolic syndrome. The results obtained from this research will contribute to treating metabolic syndrome through diet, pointing to a possible strategy to assist in weight loss and maintenance and reduction of inflammation in patients with metabolic syndrome. You will initially need to visit the Instituto Nutrindo Ideais in Ipanema to collect data related to this study. You will need to answer a general information and dietary questionnaire. In this first consultation, you should arrive at the institute fasting for twelve hours, bringing the completed dietary records provided by the researchers. At the exact location, saliva will be collected for genetic evaluation (5 mL – about one teaspoon), and blood will be collected (22 mL – about three tablespoons) to evaluate glucose, insulin, blood fat, and inflammatory markers. The blood will be used only for this research and collected from your forearm vein by trained personnel with asepsis (cleaning) and hygiene, following all safety standards, using disposable material. The collection will be carried out at the Instituto Nutrindo Ideais, located at Rua Almirante Saddock de Sá 207 in Ipanema/RJ, including its storage only during the study period and subsequent disposal following the recommendations and rules of the National Health Surveillance Agency (ANVISA). Next, we will evaluate your blood pressure, weight, height, and waist measurements using a measuring tape, and body composition using an electric scale (bioimpedance), with no embarrassment to you. In the end, you will receive one capsule of 500mg of dietary fiber daily to aid in digestion. You may experience nausea, diarrhea, or abdominal discomfort using the capsule. Additionally, you may receive a calorie and salt-reduced, balanced, and individualized dietary plan. Follow-up will be conducted every 15 days to assess your progress and clarify any doubts regarding the treatment. You will be re-evaluated at the end of the period, as done in the first meeting. During and at any research stage, damage to your physical, psychic, moral, intellectual, social, and cultural health is possible. Thus, measures will be taken to avoid and/or reduce effects and conditions that may cause any harm to your health. The risks of this research are as follows, and are minimized through the following measures: 1) Regarding the discomfort associated with blood collection. Occasionally, blood collection may cause bruising (purple spots). We emphasize that the equipment and materials used for blood collection will be disposable. 2) Depending on the genetic test result, there may be emotional, social, and/or family risks. 3) The collection of your socioeconomic data, weight, waist circumference, height, and dietary intake will be conducted individually and in a calm environment to avoid embarrassment and fatigue

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Name of participant Date: ___/___/_____

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XXXXXX Silva (Researcher)

4) Regarding the diet's adherence and the possible side effects of the daily capsule, we will be immediately available to provide your care to avoid any discomfort or harm to your health. 5) Regarding bioimpedance, the exam does not pose a health risk, except for pregnant women, pacemaker users, and those with metal pins or plates. Before the exam, the researcher will provide preparation instructions, including not eating 2 hours before the exam, going to the bathroom before the exam (empty bladder), wearing light clothing, and removing jewelry and metal objects. 6) All collected material will be used only for this research and discarded according to ANVISA regulations. If any personal harm results from the study, you will have full access to care from the researchers or any doctor on the team at Instituto Nutrindo Ideais, which has office hours from 8 AM to 9 PM and is located at Rua Almirante Saddock de Sá, 207 in Ipanema/RJ. The research results, whether partial or complete, can be provided at any time during the study. At the end of the study, you will be guided regarding your diet to help with your treatment, based on the results obtained in the study and established recommendations. At any stage of the study, you will have access to the responsible professional who will be available daily, 24 hours a day, at the phone number: XXXXX principal investigator). Alternatively, contact: (21) 97695-9339 (Instituto Nutrindo Ideais) or XXXXX researcher). If you have any considerations or questions about the ethics of the research, contact the Research Ethics Committee (CEP) of the Hospital Universitário Clementino Fraga Filho/HUCFF/UFRJ – R. Prof. Rodolpho Paulo Rocco, n° 255, Cidade Universitária/Ilha do Fundão, 7th floor, Wing E - by phone 3938-2480, Monday to Friday, from 8 AM to 4 PM, or by email: cep@hucff.ufrj.br

It is guaranteed the freedom to choose not to participate in the research project or to withdraw consent at any time, in case of acceptance, without prejudice to the continuity of your treatment at the institution. The results will be analyzed together with the results of the other participants in the research, without disclosing the identification of any research participant. The results will be presented in scientific journals and at congresses. The evaluation of your test results will be carried out by the researchers of this study and the professionals who will be related to your care and who will be taking care of you, and it will not be allowed for other people to see your results, ensuring protection against any discrimination. You may, at any time during the study, request information and even update yourself on the partial results of the research. You will receive a copy of the document, signed by the research participant and researcher, and initialed on both pages. This research will not incur any expenses, meaning you will not pay for the tests, transportation, food, or other evaluations. There will also be no financial compensation for your participation during and at the end of the study. You have the right to free assistance from the researchers if direct/indirect and immediate/late damages are associated with the research. You will be guaranteed the right to seek compensation for damages resulting from the research. If you agree to participate in this research, sign at the end of this document, which has two copies, one for you and the other for the responsible researcher. All pages of this document will be initialed.

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Name of participant Date: ___/___/_____

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XXXXXX (Researcher)

After being presented with and clarified about the research information, if you agree to participate as a volunteer, you must initial all pages and sign at the end of this document prepared in two copies. Each copy will also be initialed on all pages and signed by the responsible researcher, with one copy remaining with you, so you can consult it whenever necessary.
I agree to participate in the study.

_____
Name of research participant

_____ Date:_____
(Signature of research participant)

_____ Date:_____
XXXXXX (Principal Investigator)

_____ Date: _____

XXXXXXX (Researcher)