Influence of Walnut (Juglans regia) Intake on Acute Adverse Effects Induced by High Saturated Fat Meals in Obese and Diabetic Women

20 August, 2024

INFORMED CONSENT FORM (ICF)

**** RESOLUTION 466/2012 ****

I invite you _____ to participate in the research project titled "Influence of Acute Walnut Consumption on the Effects of Meals Rich in Saturated Fats in Obese and Diabetic Women"**, which will be conducted by myself, Nayane Maria Vieira, a Nutritionist and PhD candidate in the Postgraduate Program in Clinical Medicine Pathophysiology, under the supervision of Professor Dr. Marcos Ferreira Minicucci, a physician and tenured professor at the Botucatu Medical School – UNESP.**

The purpose of this study is to evaluate whether acute walnut supplementation reduces inflammatory and oxidative stress mediators, interferes with metabolomics, and affects the levels of circulating microRNAs induced by a saturated fat-rich meal (SFRM) in women with obesity and type 2 diabetes.

Upon the participant's agreement to take part in the study, their characteristics such as age, education level, weight, and height will be collected. Subsequently, the participants will be evaluated in two sessions, with an interval of at least one week between them.

- In the first session, participants will arrive at the clinic after a 10-hour fast and will be offered the SFRM with or without 30g of walnuts. The high-fat meal will consist of the following foods: plain croissant (150g), unsalted butter (Aviação®, 30g), processed cheese (Tirolez®, 40g), chocolate-coated wafer (Kitkat® - Nestlé, 45g). The total caloric value of the meal is 1067 kcal, with 54% fat (64g total fat, 30g saturated fat), 37.3% carbohydrates, and 8.6% protein.

- **In the second session,** participants who did not consume walnuts in the first session will now receive them alongside the SFRM, and vice versa. The meal will be provided in the hospital clinic, and participants must consume the entire meal and all the walnuts.

Participants will be instructed to avoid consuming walnuts two weeks before the first session. Blood samples will be collected at 0, 15, 30, 60, and 150 minutes after the interventions. From 0 to 60 minutes, serum insulin and glucose levels will be measured, and at 0 and 150 minutes, additional evaluations will be performed.

Potential Risks and Discomforts: Bleeding and pain at the site where the needle is inserted and formation of a hematoma (a localized swelling containing blood).

To evaluate psychomotor speed and flexibility, cognitive precision, and multitasking ability, participants will perform the following tests: Stroop Test, N-back task (2-back), and multitasking. Satiety will be assessed using a visual analog scale (VAS) at 15, 30, 60, and 150 minutes after the meal.

The biological material collected (blood samples) will not be used in its entirety. Part of it will be stored at the Faculty of Medicine. For any future reuse of this material, a new research project will be written, accompanied by a new consent form for your signature, granting authorization for its use.

I also request your consent to review **your medical records** to gather additional necessary information.

Risks related to participation in the study: Allergic reactions to walnuts. After consuming the walnuts, participants will be monitored during their time in the clinic for blood collection. They will also be instructed to contact the researchers immediately if they experience adverse symptoms such as rashes or shortness of breath. Participants will be cared for at the Botucatu Medical School Hospital (HC-FMB).

Benefits of participating in the study: We hope this study contributes valuable information to the scientific literature. The researchers are committed to disseminating the results obtained. This study may provide insights that could improve the quality of life for women with obesity and type 2 diabetes in the future.

Regarding expenses that participants and their companions may incur due to the research: The research participant will not have any expenses for participating in the study, as the interventions and blood collection will take place during the participant's scheduled appointments at HC-FMB.

Participation in this study is voluntary, and even after giving consent to participate, the participant may withdraw consent at any time.

Participants are informed of their right to seek compensation in case of any harm caused by the study.

The researchers commit to using the collected data exclusively for research purposes. The results will be analyzed collectively with data from other participants, maintaining anonymity and confidentiality. Findings will only be published in scientific journals, without any mention of personal data.

This Informed Consent Form will be prepared in two identical copies, one of which will be provided to the participant, duly signed, while the other will be filed and retained by the researchers for five years after the study's conclusion.

If you have additional questions, you may contact the Research Ethics Committee at (14) 3880-1608 or 3880-1609, available Monday through Friday from 8:00 AM to 11:30 AM and 2:00 PM to 5:00 PM, at Chácara Butignolli s/nº in Rubião Júnior – Botucatu, São Paulo. The researchers' contact details are provided below:

After all my questions about this study have been addressed, I AGREE TO PARTICIPATE voluntarily, fully aware that all my data will be protected and kept confidential by the researchers. I understand that the results of this study may be published in scientific journals, but my identity will remain confidential.

Botucatu, _____/_____/_____

_____ _____

Researcher **Participant of research**

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