INFORMED CONSENT

Evaluation of the effect of consuming yogurts fortified with dietary sources of vitamin E and omega-3 on classical biomarkers of cardiovascular disease and blood levels of vitamin E.

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BOGOTÁ, COLOMBIA.

APRIL 27 2021

1 TITLE

Evaluation of the effect of consuming yogurts fortified with dietary sources of vitamin E and omega-3 on classical biomarkers of cardiovascular disease and blood levels of vitamin E in adult population.

2 INVESTIGATORS AND CONTACT INFORMATION

+ **Principal Investigator:** Lilia Yadira Cortés Sanabria. *Cellphone: 310-6095223*
+ **Co-Investigator:** Ruby Alejandra Villamil Parra. *Cellphone: 301-7721894*
+ **Co-Investigator:** Diana Cristina Patiño Cuervo. *Cellphone: 310-5672651*

3 INVITATION

Dear participants:

You are invited to participate in a research study conducted by the Department of Nutrition and Biochemistry at Pontificia Universidad Javeriana. The aim of the study is to describe the effect of consuming dairy products enriched with lipid sources rich in gamma-tocotrienol (vitamin E) and alpha-linolenic acid (omega-3) on the profile of plasma lipids and lipoproteins.

4 PURPOUSE

The aim of the study is to describe the effect resulting from the consumption of two dairy products enriched with Sacha Inchi and Hybrid Palm oils on biomarkers of cardiovascular disease and blood levels of vitamin E. The research will be conducted by monitoring plasma lipids related to cardiovascular diseases over a period of 90 days. To this end, blood samples will be taken following the biosafety protocols for COVID-19, according to Resolution 538 of 2020 from the Ministry of Health and Social Protection, and the following variables will be analyzed:

+ Blood levels of total cholesterol, triglycerides, low-density lipoproteins (LDL), high-density lipoproteins (HDL), apolipoprotein A and B.
+ Serum levels of Vitamin E.

5 PROCEDURES

If I agree to participate in the study, the following procedures will be required:

+ I will attend the meeting convened by the researchers to evaluate my health and nutritional status in the following way:

.1 I will answer the Nutritionist Dietist questions, about my sociodemographic information, health status and my diet, for about 40 minutes.

.2 I will allow the taking and recording of body measurements such as weight, height and waist circumference, with which the Body Mass Index (BMI) will be calculated and a concept of my nutritional status will be given, for approximately 30 minutes.

.3 I will allow the measurement of my body composition, by bioimpedance or densitometry, for approximately 20 minutes.

+ I will participate in the study for 90 days, in accordance with the following:

.1 For the blood tests I will attend the clinical laboratory of the San Ignacio University Hospital (HUSI) at the specified time and follow the instructions given. The blood will be processed for biochemical studies. The results will be published, following the personal data processing policy of the Pontificia Universidad Javeriana.

.2 I understand that they are a total of 4 days, one first take before the intervention and another 3 takes, with intervals of 30 days between each take.

.3 During phase II, which lasts 90 days (3 months) I will carry out the record of the daily consumption of two days, every two weeks and my diet pattern will be my usual diet with a modification in the intake of milk that will be indicated to me the nutritionist. I will receive the study food which includes a defined portion. The study food is a fermented milk drink that has been modified in its fat content, I will receive them on the days indicated by the researcher,

.4 During phase II, I will allow the nutritionist to contact me once every two weeks, without notice, to carry out the 24-hour recall.

.5 During phase III, I will attend an evaluation of my health and nutritional status at the end of the intervention, as well as participate in the final socialization meeting of results.

6 CONDITIONS FOR PARTICIPATION IN THE STUDY

In order to be eligible to participate in the study you must comply with the following aspects: be an adult male < 50 years old or female < 45 years old, healthy, with total cholesterol levels above normal or above 200 mg/dl, with regular consumption of fermented milk drinks at least three times/week and must sign the informed consent. In addition, it should not have triglyceride levels greater than 400 mg/dl, nor should it be under pharmacological treatment for cholesterol management, should not be addicted to drugs or alcohol, must not be a smoker, or have a history of allergy to red palm oil olein and/or milk and its derivatives, must not be consuming nutritional supplements, or to be pregnant or lactating, nor to have menopause, or the presence of chronic disease (HBP, Diabetes Mellitus, hypothyroidism, among others) and must not have a body weight exceeding 150% of the ideal weight.

Additionally, it must commit to following the biosafety protocols COVID-19, for blood sampling (University Hospital San Ignacio) and anthropometric evaluation (Anthropometry Laboratory, Faculty of Sciences, Pontificia Universidad Javeriana), making use of elements of biosecurity, cleaning and disinfection of the elements and areas to be used, among others

7 BENEFITS

The possible benefit will be to know your nutritional status according to the anthropometric evaluation that will be performed to you, know your body composition, knowing your cardiovascular risk, as well as identify your blood lipid levels, which we hope change to benefit your health.

8 RISKS

Nutritional intervention, as well as measurements and blood tests represent a minimal risk to your health and integrity. The necessary clinical and safety measures will be taken and the people who will be examined are all experts. A minimal hematoma may occur in the area of the pinch, so it will be convenient that after each injection pressure is made on the punctuated area.

9 COSTS

I will not receive any monetary recognition for my participation as a volunteer in this research, nor compensation for the side effects caused by the treatments in the study.

I will not be charged for the tests carried out, or for the products that I must consume, nor for the nutritional evaluation, or the nutrition plan that will be prescribed to you.

10 CONFIDENCIALITY

The information obtained from this study will be treated as strictly confidential. When the results are analyzed or published, your identity or name will not be submitted.

11 PARTICIPANT RIGHTS AND ANSWERS TO QUESTIONS

You are given the opportunity to ask about this study and your participation before signing this document and you are entitled to have your questions answered to your full satisfaction. If you need further information or have questions about the rights of a person participating in an investigation, you can contact the researchers at any time at the phone numbers on the front page of this document. In the course of the project development, you will be provided with updated information if necessary.

12 RIGHT TO REFUSE TO PARTICIPATE IN THE STUDY OR TO EXIT IT

My participation in the study is entirely voluntary and I am free to refuse to take part in it or quit at any time.

13 AGREEMENTS

This consent does not grant you any legal rights, nor does it release researchers or institutions from the obligation for negligence or any act or misconduct performed with the samples and information provided by you.

I have read and understood this consent report. I agree that I will participate in this research study; I can be included in the group that will consume for 90 days a fermented dairy drink, which may contain within its ingredients Sacha Inchi oil and hybrid palm oil. It is clear to me that I should not discontinue its consumption until the study is completed. I will bring the blood samples required for the study, as well as anthropometric measurements and food consumption data. I will also participate as soon as I am notified. When I sign this document, I will receive a copy. I will receive the results of blood-measured parameters at the end of my participation.

The custody of the clinical history will be for 5 years, it will be carried out by the researcher Lilia Yadira Cortés Sanabria, of the Pontificia Universidad Javeriana.

14 AUTHORIZATION PROCESSING OF PERSONAL DATA

I_____,identified with citizenship card number _____ authorize the use of personal data I have provided for the research development carried out by Professor Ruby Alejandra Villamil Parra of the Department of Nutrition and Dietetics of the Faculty of Science of the Pontificia Universidad Javeriana.

I declare that I know and accept that the use of the information provided is intended to carry out a study of a functional food and nutritional evaluation, within the framework of the project of the Faculty of Sciences “Evaluation of the effect of consuming yogurts fortified with dietary sources of vitamin E and omega-3 on classical biomarkers of cardiovascular disease and blood levels of vitamin E” being a research activity that seeks to correct cardiovascular risk factors.

Likewise, I declare that I am aware that the data collected in any way will not be reproduced, disclosed, stored in a database or used for a different purpose.

By subscribing to this authorization, I am aware that in the event of requiring any modification, clarification or request for deletion of the data provided, or the exercise of any right, you can make

the request by sending an e-mail to usodedatos@javeriana.edu.co and that such request will result from the procedures established in the Guidelines for the Processing of Personal Data of the Pontificia Universidad Javeriana that are found on the website of the University at the link: https://www.javeriana.edu.co/documentos/tratamiento_datos_personales.pdf

The validity of this consent is five years from the signing of the consent of the research project _____(day/month/year).

_____ ***Participant's name***	_____ ***Sign***	_____ ***Date (day/month/year)***
_____ ***Name of the witness***	_____ ***Sign***	_____ ***Date (day/month/year)***
_____ ***Name of the investigator***	_____ ***Sign***	_____ ***Date (day/month/year)***