Instituto Politécnico Nacional

Centro de Desarrollo de Productos Bióticos

Official Study Title:

Effect of Agave Consumption on Performance and Gut Microbiota in Adults Undergoing Physical Training

Document Date:

March, 2025

Version:

Version 1.0

Investigator Name

Amalinali portillo ayala

Ethics committee approval number

CEPROBI-2025-3

INFORMED CONSENT FORM FOR RESEARCH

Project registration number: CEPROBI-2025-3

Project title: Effect of agavin consumption on performance and the intestinal microbiota of adults undergoing physical training

Justification

An imbalance in the bacteria that inhabit the intestine can lead to dysbiosis, which may manifest as undesirable digestive tract discomfort such as inflammation, gas, diarrhea, or nausea, or may trigger gastrointestinal diseases. People who engage in physical exercise commonly have a healthier microbiota; however, there are studies showing that strenuous or poorly planned training may cause an imbalance in the microbiota. These effects are also associated with low dietary fiber intake or with the use of ergogenic aids that may decrease the number of beneficial bacteria. Supplementation with soluble dietary fiber such as agavins could improve gastrointestinal health by improving and increasing both the number and diversity of microbiota bacteria. Numerous studies have demonstrated the benefits of physical exercise and, likewise, of dietary fibers for intestinal and metabolic health; however, the relationship between exercise, the intestinal microbiota, and the consumption of prebiotic dietary fibers has been a scarcely explored field of study. Therefore, the objective of this study is to evaluate the effect of agavin consumption on the intestinal microbiota and physical performance of adults who engage in physical exercise.

General objective

To evaluate the effect of agavin consumption on the intestinal microbiota and physical performance of adults who engage in physical exercise.

Specific objectives

- To quantify the products of intestinal microbiota metabolism in a quasi-experimental intervention study in people undergoing physical training after supplementation with agavins.
- To evaluate changes in and the composition of the intestinal microbiota in people undergoing physical training after supplementation with agavins.

- To determine physical performance, through the evaluation of physiological parameters, in people undergoing physical training after supplementation with agavins.
- To analyze indicators of metabolic stress in people undergoing physical training after supplementation with agavins.
-

Benefits:

Volunteers will not receive any kind of payment, economic remuneration, or payment in kind; however, the dietary fiber, as well as everything related to the study, including blood tests, performance tests, medical and nutritional consultation, and the necessary equipment, will be provided at no cost. As soon as the researchers obtain the analysis results, they will communicate them to the volunteers and, if the volunteers so wish, they may be provided with information about the results of the study of their samples, together with their interpretation and dietary recommendations, if applicable, in order to improve intestinal health. This will be done individually, in whichever way is most feasible for the volunteer, either in person or remotely. This will be beneficial for them to learn about their physical status and performance, based on which they may, with the help of a professional, take measures to improve or maintain their optimal condition. Likewise, they may have access to the results of the complete study once it has concluded, through websites or conferences where it is published.

If you agree to participate in the study, a medical history will be taken by Dr. Herminia López Salazar, professional license No. 4364420. Anthropometric measurements and nutritional consultation will be carried out by Nutritionist Amalinali Portillo Ayala, professional license No. 12007979, in a nutrition office located in Chiconcuac, Xochitepec. Weight, height, waist circumference, hip circumference, BMI calculation, and body composition will be determined by means of a bioimpedance scale and by taking skinfold measurements, which do not hurt or cause any type of discomfort.

Likewise, a 24-hour recall (24HR) will be performed, which is a questionnaire in which all foods consumed in one day are reported, in order to know the quantity and quality of the diet consumed by the volunteers; and, in addition, to calculate the amount of carbohydrates, lipids, and proteins consumed, as well as micronutrients and the total energy consumed, measured in total calories.

To take gastrointestinal symptoms and improvements into account, you will be given a questionnaire in which you will record whether you experience symptoms or changes in defecation.

For microbiota analysis, you will be asked to provide an approximately 5 g stool sample in a sterile container that will be provided by the researchers, with the recommendation not to mix it with urine residues. This is a simple and painless procedure, although it may be uncomfortable mainly because of sample handling.

For the determination of VO_2max, you will be fitted with a mask that measures the amount of oxygen consumed while exercising on a treadmill. The effort (speed) will gradually increase until the maximum level of performance is reached. During this test, fatigue may be felt due to the effort, and the mask may feel uncomfortable for breathing, but it is not painful. This test is similar to performing intense exercise.

For blood sample collection, a healthcare professional will use a needle to draw a small amount of blood from your forearm, first disinfecting the area. You may feel a small prick when the needle is inserted, and there may be some discomfort in the area during the blood draw. In some cases, slight pain or bruising may occur, generally very mild and disappearing within a day.

Information on results and treatment alternatives:

Once the results of all analyses and tests are obtained, they will be published in a scientific article, conferences, and theses that form part of the academic procedures of the Center for the Development of Biotic Products, respecting the privacy and anonymity of all volunteers, without publishing names or any additional information about the individuals.

Researcher

I have explained to Mr./Ms. _____ the nature and purposes of the research, as well as the risks and benefits involved in participation. I have answered his/her questions to the best of my knowledge. I declare that I have read and know the applicable regulations for conducting research with human beings and that I adhere to them.

Name and signature of the researcher

_____

Participant

I declare that I have been widely informed about the possible risks, inconveniences, discomforts, and benefits derived from my participation in the study. I have read and understand the information related to the study, and my questions have been answered satisfactorily. I have been informed and understand that the data obtained in the study may be published or disseminated for scientific purposes. Therefore, my decision to participate in the study is completely voluntary. If I decide to participate in the study, I may withdraw at any time I wish, and I may choose not to inform the reasons for my decision if I so wish, which will be respected in its entirety.

There will be no unfavorable consequence for me in case I do not accept the invitation. I will not have to incur any expense during the study, and I will not receive payment for my participation.

The information obtained in this study, especially that referring to my personal data, will be kept under strict confidentiality by the research group and safeguarded by the Institution.

Place, date, and time: _____

I agree to participate in the research study: Effect of agavin consumption on performance and the intestinal microbiota of adults undergoing physical training

Yes ( ) No ( )

Name and signature of the participant and/or the responsible person or guardian

_____

Name and signature of witness _____

Name and signature of witness _____

Articles 20, 21, and 22 of the REGULATIONS of the General Health Law on Health Research