Informed Consent

Official title:

EFFECT OF A NUTRIGENETIC INTERVENTION ON BLOOD LIPID MARKERS AND BODY COMPOSITION OF ADULTS WITH OVERWEIGHT AND OBESITY

INFORMED CONSENT

June 20, 2021

Research Information

Informed Consent

Dear participant,

The Institute of Technological Studies (ITESO) in agreement with the Institute of Technological Studies of Tepic (IIT) and the University of Guadalajara (UDG-CUCS) will implement a clinical intervention as part of this research project. The principal objective of this study is to evaluate the effects of nutritional interventions on blood lipid levels and body composition in overweight/obese adults, with the purpose of providing nutritional tools that may help to prevent dyslipidemias and cardiovascular diseases. (CVD) among the Mexican population who have existing risk factors.

DESCRIPTION OF THE STUDY/PROCEDURES:

The duration of this nutrigenetic intervention will be for a period of 2(two) months. During this time, 4 evaluations will be implemented. We are requesting access and commitment during this time frame to be able to implement the following interventions:

1) Collecting blood samples at CUCS Campus or at home (in exceptional cases): Availability is required to attend the University Center of Health Sciences (UDG CUCS), located at Sierra Mojada 950, Independencia Oriente, 44340 Guadalajara, Jalisco. In exceptional cases, nursing staff can attend their home residence / work address if they are in the city of Guadalajara during morning hours to collect a blood sample (genetic diagnosis, lipid profile evaluation and glucose) and anthropometric measurements (weight, height, waist circumference and hip circumference), the individual is required to be fasting. IN person attendance is requested to collect the sample on 4 occasions: Visit 0 (genetic diagnosis), subsequently, visit #2 (half: week 4), visit #3 (end of intervention: week 8).

2) Availability and willingness to adhere to specific meal plans: Different dietary menus will be provided every 15 days, availability and commitment is requested to follow the indicated meal plan for 2 months (8 weeks). The effect of 3 scientifically supported dietary patterns on blood lipid values and body composition of overweight or obese adults will be evaluated. Pattern A comprises the dietary recommendations set forth by the WHO, AHA and NOM for the treatment of obesity and dyslipidemias, patterns B and C comprise nutrigenetic recommendations according to the presence of genetic variants related to lipid metabolism.

3) Availability for follow-up virtual consultations:
5 online consultations (video calls) will be held during the intervention period to collect various data, provide new menus, and monitor the progress of each participant. The first virtual consultation, will query information regarding personal and family medical history, eating habits, current medications, and physical activity. Subsequently, nutritional counseling, a meal plan, and various support materials will be provided. These video calls will last approximately 20-30 min and will be scheduled at a comfortable time for the participant.

POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY

-Participants will undergo a genetic diagnosis to determine specific genetic variants of cardiovascular risk they may possess.

- Dietary evaluation and nutritional diagnosis, as well as personalized online nutritional care for 2 months, free of charge.

- Potential personal improvement in body composition, blood pressure, blood biochemical markers, and general health.
- Upon completion of project participants will be informed of the results obtained and the pertinent conclusions. Participants will also receive personal nutrigenetic information.

- Participating in the study will also contribute to the scientific and technological development in Mexico.

Informed Consent

CONFIDENTIALITY

All information provided is strictly confidential, will be used only by the project's research team, and will not be available for any other purpose. Participants will be identified with a folio number and not with their personal name. The results obtained from this study will be published for scientific purposes, but the confidentiality of the participants will never be violated. The information or evidence obtained will be eliminated after fulfilling the scientific purposes for which this intervention was proposed. The residence addresses provided, emails, and telephone numbers will never be disclosed or made available to third parties.

To comply with the statutes of Personal Data Protection in accordance with the Federal Law on Protection of Possession of Individuals Personal Data, the data provided by the owner. to ITESO, will be protected in our databases under physical, technical, and administrative measures to ensure its correct application in accordance with the data protection strategy established by ITESO.

POTENTIAL RISKS OF PARTICIPATING IN THIS STUDY

This project will comply in accordance with the provisions of the General Health Law of Mexico regarding health research, articles 13 to 17, which indicate that this type of studies are classified as "low risk" or "null". For which no compensation is generated.

VOLUNTARY PARTICIPATION / WITDRAWAL:

Participation in this study is voluntary. The individual is free to withdraw from the intervention at any time. However, you are asked to consider that this project has a non-profit, scientific purpose and the information provided by your participation contributes to developing strategies that mitigate public health problems in Mexico and the world.

If you voluntary accept to participate in this study write your full name and signature:

Email:

Cellphone number:

Date: