Official title:

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

STATISTICAL ANALYSIS PLAN

September , 30, 2021.

Statistical analysis plan

Sample size was calculated a *priori*, considering the mean difference in total cholesterol between study groups as primary outcome variable (De Luis et al. 2017). GPower V3.1.9.4 software was used for the pertinent calculations. A power contemplated: 95%, and significance α: 0.5%. The effect size: 0.9772364. One-tailed, to analyze differences with the t-test. 30% loss to follow-up was considered. A minimum of 24 participants per treatment were required. The aim was to recruit 50 subjects per treatment

All the data will be analyzed using SPSS for MAC, version 26.0 software package (SPSS Inc. Chicago, IL). Parametric tests will be applied for quantitative variables with normal distribution, and non-parametric tests for qualitative and quantitative variables with abnormal distributions. The Kolmogorov–Smirnov test will be used to determine variable distribution. The results will be expressed as average ± standard deviation.
For each treatment group, all markers will be tested using Student's paired-sample t test for possible difference between values achieved at baseline (visit 1) and 1st month (4 weeks) and visit 3 (final point, 8 weeks) , respectively. Student's two independent- samples t tests will be also performed to find possible difference regarding these markers between treatments Nutrigenetic diet and Conventional diet. Furthermore, a mixed models approach including repeated-measures modeling will be utilized to find possible significant effects of the treatment effect at baseline on treatment effect after two subsequent clinical visits. This model will considerate confounders.
Categorical variables will be analyzed with the chi-square test, with Yates correction as necessary, and Fisher's test.
The statistical analysis to evaluate the gene-diet interaction was a univariate ANCOVA.
A Chi square test will be used to evaluate the Hardy–Weinberg equilibrium.
A P- value b 0.05 was considered significant.