SUMMARY: OLICOL PROJECT

The main objective of this project was to evaluate the functionality of a polyphenol-based product derived from olives on parameters related to metabolic syndrome, with special emphasis on total cholesterol levels, in subjects with overweight-obesity, compared to placebo.

The Research Ethics Committee of the University of Navarra (CEI) approved the protocol on February 12, 2024 (No: 2024.015). The study is registered in ClinicalTrials.gov with NCT06490133 number.

The study design was set as a randomized, double-blind, placebo-controlled, longitudinal, and parallel study, with a total of 100 participants (Figure 1).

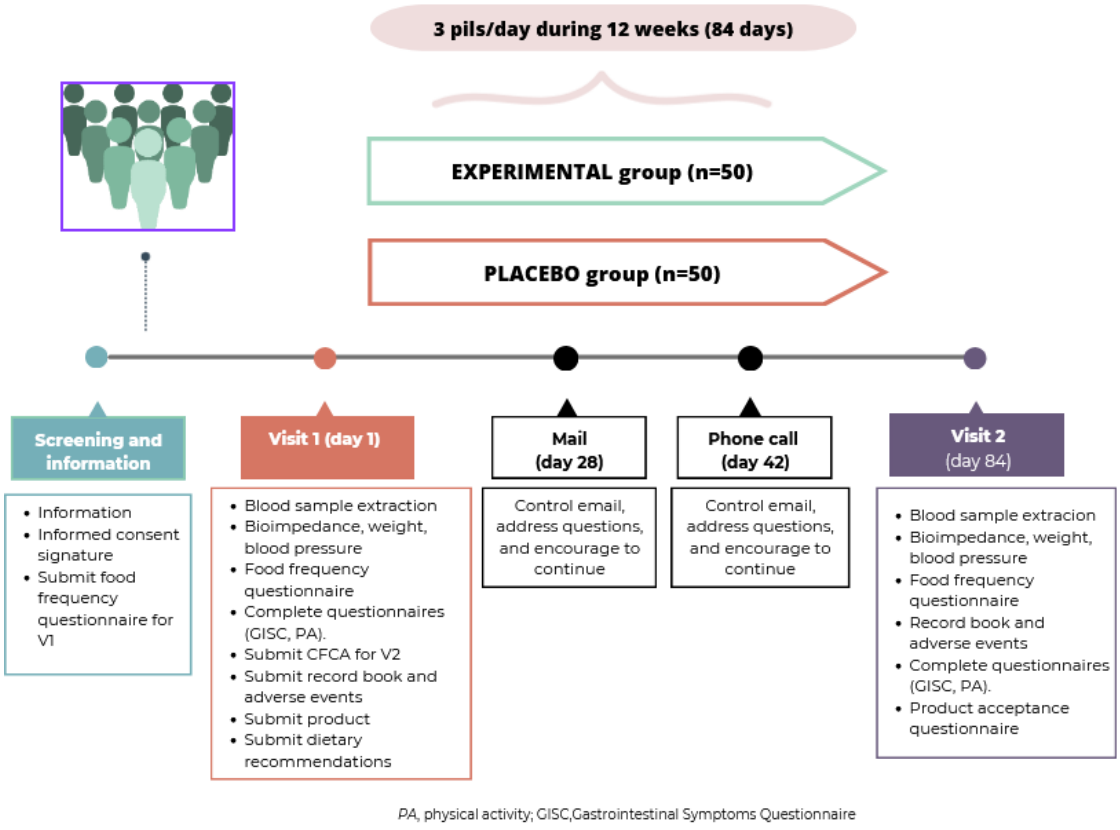

Figure 1. Study design

A total of 120 subjects attended the in-person screening, where 18 volunteers were excluded for not meeting the inclusion or exclusion criteria for the intervention. Additionally, 2 participants ultimately declined to participate.

In total, the number of participants randomized was 100, with 50 in each group. Of these, 17 were excluded or withdrew their consent during the study, resulting in 83 participants completing the intervention (41 in group 1 and 42 in group 2). This implies a dropout rate of 17%.

Regarding adherence, capsule consumption was high among all analyzed participants, with at least 85% of the prescribed supplement consumed.

Regarding the results, the main differences between groups were as follows:

- Total cholesterol showed a reduction of 11 mg/dL in group 1 (about 4%, p=0.031), while in group 2, the reduction was nearly 26 mg/dL (a 9% reduction, p<0.001), with the difference between groups approaching significance (p=0.09, Figure 2).
- LDL cholesterol showed a reduction of 6% (p=0.004) in group 1 and 11% (p<0.001) in group 2, with a trend toward significance between groups (p=0.079; Figure 2B).
- Regarding plasma triglycerides, no changes were observed in group 1, while in group 2, there was a trend toward significance (p=0.068), with an interaction between groups (p=0.077; Figure 2C).
- The atherogenic index of plasma (AIP) showed a clear trend of improvement in group 2 compared to group 1 (p=0.067; Figure 2D).
- The Castelli I index, which is a ratio of total cholesterol to HDL cholesterol, indicates significant differences between groups (p=0.045; Figure 2E), with the magnitude of the decrease in the index being greater in group 2 (the mean is double that of group 1: -0.16 vs. -0.371, respectively).
- Finally, the Castelli II index, which is a ratio of bad cholesterol (LDL cholesterol) to good cholesterol (HDL cholesterol), also approaches significance (p=0.073; Figure 2F), with differences between group 1 and group 2 being nearly double (-0.181 vs. -0.349, respectively).

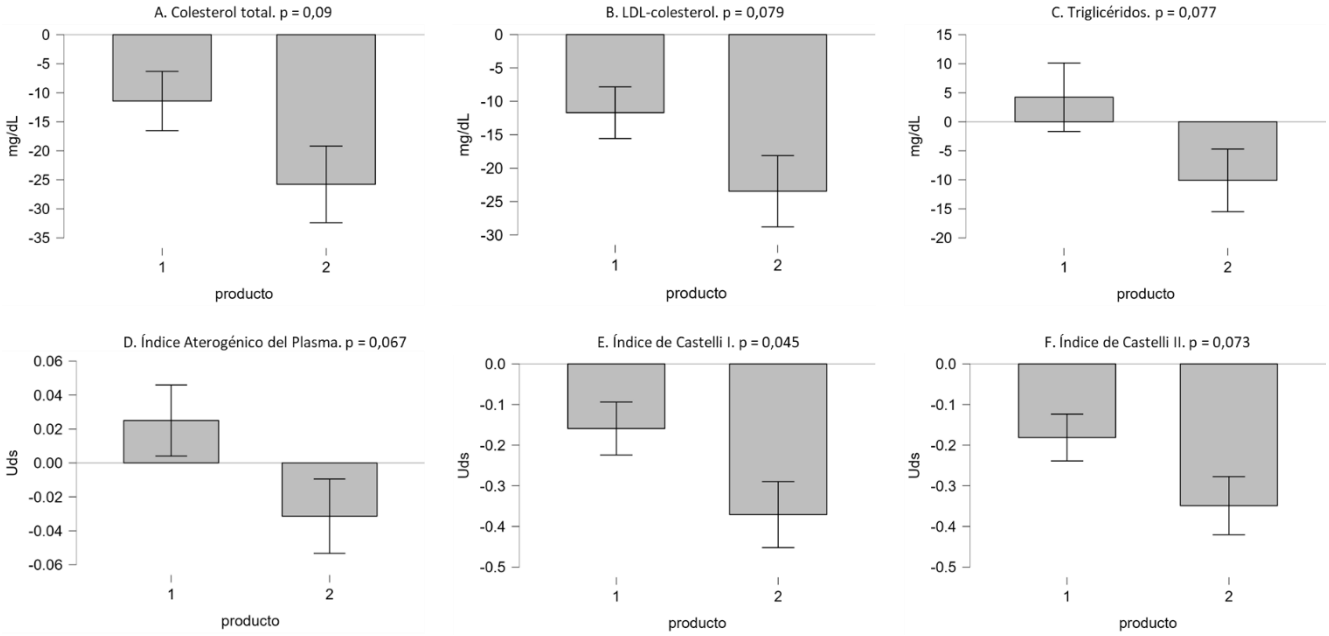

Figure 2. Differences between cardiovascular risk parameters with a tendency to significance (p-value < 0.1). Significant if p<0.05.

CONCLUSIONS

The main clinically relevant changes occur in the lipid profile, primarily due to a decrease in both total cholesterol and LDL cholesterol levels, which leads to a reduction in cardiovascular risk observed in various atherogenic risk indices.

Furthermore, this reduction is greater in group 2 than in group 1, tending toward significant differences ($p<0.08$). The reduction in lipid profile levels is 10% in group 2.

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