MEDICAL LITERATURE

Cardiosmile as a promising adjuvant therapy for metabolic syndrome patients.

Based upon: Palmeiro, Y., et al. (2020). Effects of Daily Consumption of an Aqueous Dispersion of Free-Phytosterols Nanoparticles on Individuals with Metabolic Syndrome- A Randomised, Double-Blind, Placebo-Controlled Clinical Trial. Nutrients, 12(8): 2392.

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INTRODUCTION

Cardiosmile is a novel plant sterol formulation in which free sterol nanoparticles have been stabilized in water using a proprietary process. This process improves the clinical efficacy of sterols as previously shown (Amir Shaghaghi et al 2014). In this new study Cardiosmile was administered for six months to metabolic syndrome patients, improving some metabolic syndrome criteria, and replicating non-HDL and triglyceride reduction efficacy. The full text can be viewed at www.mdpi.com/2072-6643/12/8/2392.

STUDY OBJECTIVE

The primary purpose of this study was to evaluate the therapeutic effect of daily supplementation of Cardiosmile in individuals with MS over six months of intervention, compared with placebo.

DESIGN

Inclusion criteria considered participants who had been diagnosed with metabolic syndrome or met diagnosis criteria (three out of five metabolic syndrome markers) at the beginning of the study.

BACKGROUND

Metabolic syndrome (MS) is a cluster of interrelated physiologic and metabolic alterations that reaches a prevalence between 5% and 40% worldwide, and is highly related to short and long-term cardiovascular risks. (Grundy 2016).

Plant sterols are known to reduce LDL cholesterol, but not all formulation have been shown to improve lipid markers in MS patients. (Hernández-Mijares, et al 2011).

Table 1: MS criteria

Criterion	Categorical cut-off point
Waist circumference	Depends on ethnic and country-specific definitions*
Triglycerides	≥150 mg/dL or specific treatment (fibrates or nicotinic acid)
HDL-cholesterol	<40 mg/dL in males; <50 mg/dL in females, or specific treatment (fibrates or nicotinic acid)
Blood pressure	Systolic BP ≥130 or Diastolic BP ≥85 mmHg, or treatment of previously diagnosed hypertension
Fasting glycaemia	≥100 mg/dL or previously diagnosed with type 2 diabetes

*South American population is used in this study: ≥90 cm (males) and ≥80 cm (females) (Alberti et al, 2013).

Participants were not eligible if they: (i) had alcohol-related problems; (ii) had familial sitosterolaemia or hypercholesterolaemia; (iii) were consuming phytosterols at the moment of this study; (iv) were pregnant or breastfeeding; (v) had a medical history of myocardial infarction, stroke, decompensated diabetes or hypertension; (vi) not able to make decisions for themselves; (vii) people consuming weight management pills. During this study, there was no restriction on medication intake or dietary patterns.

The study included a screening period, one baseline visit (V1) and 24-weeks of the intervention phase, which included three visits (V2 at week 4, V3 at week 12 and V4 at week 24).

Baseline characteristics by group did not differ significantly.

Table 2: Average baseline participants' characteristics

Variable	Value
Presence of underlying health condition	82 %
Use of concomitant medication	60 %
Waist perimeter	100 cm
Tryglicerides	141 mg/dL
HDL-cholesterol	43 mg/dL
Systolic blood pressure	120 mm Hg
Dyastolic blood pressure	82 mm Hg
Fasting glycaemia	92 mg / dL

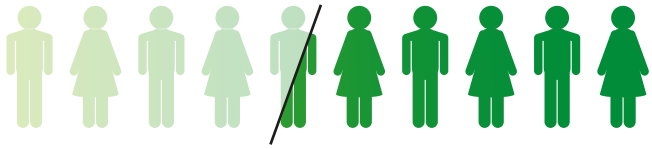
RESULTS

Considering the analysis of each MS criterion, the proportion of participants with high or 'abnormal' TG levels (150 mg/dL) between phytosterol and placebo groups was significantly different at V4 (week 24) reaching 15.65% of the difference between groups. This difference was explained by a decrease in participants with high TG levels in the PS group and an increase in the placebo group. For all other criteria, the proportion of participants with 'abnormal' levels at V4 was not statistically different between groups.

In terms of the difference between V4 and V1 for each parameter, waist circumference and tryglicerides were significantly different between groups. Half of the participants in the phytosterol group decreased waist circumference.

in comparison the placebo group, which means that participants in the phytosterol group outperformed placebo, decreasing waist circumference by 5.05%. Similarly, half of the participants in the phytosterol group decreased triglyceride levels up to 16.5 mg/dL.

This finding means that the phytosterol group outperformed placebo group, showing a 15.17% reduction in triglyceride levels. Notably, waist perimeter and high levels of triglycerides are among the most relevant risk factors for cardiovascular diseases occurrence (Taverne et. al., 2013).



In terms of secondary outcomes the phytosterol group showed consistently better results for total cholesterol, VLDL-cholesterol, and HOMA-IR index (homeostatic model assessment of insulin resistance) than the placebo group. HOMA-IR index difference was only statistically significant between V2 (week 4) and V1 (baseline).

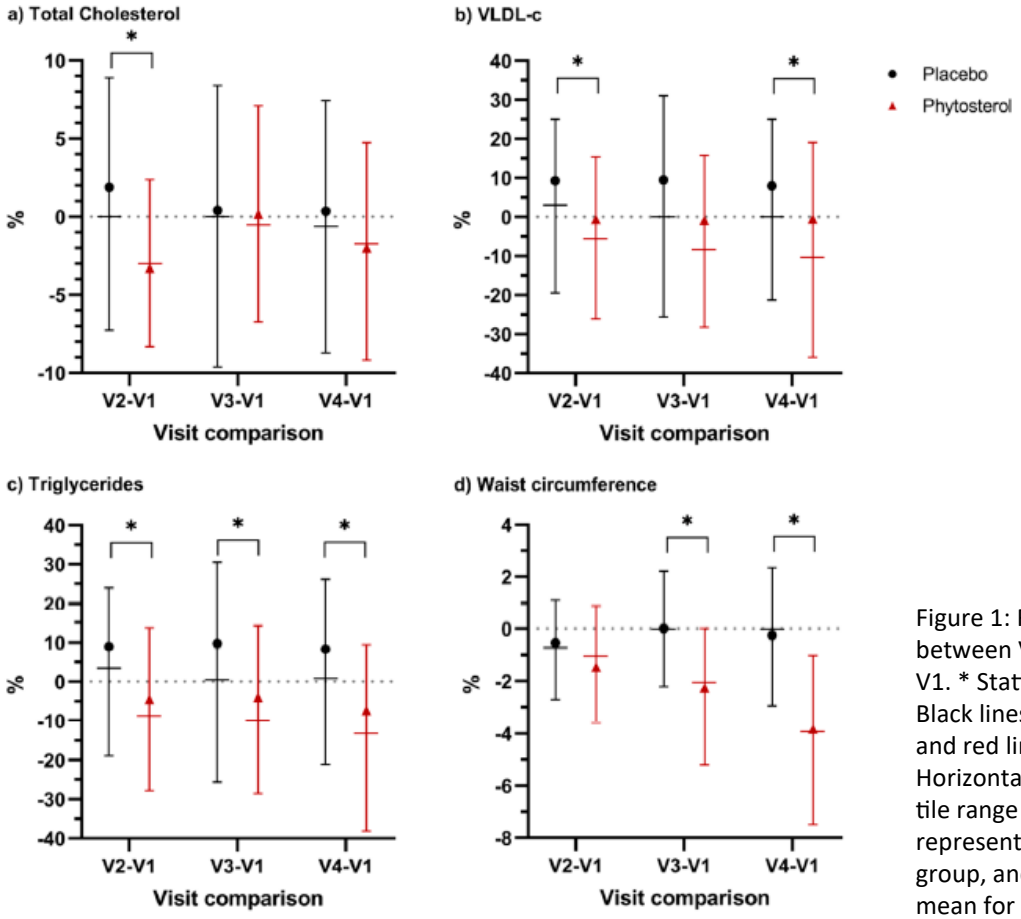


Figure 1: Relative difference (%) between V2 and V3 and V1 and V4 and V1. * Statistically significant ($p < 0.05$). Black lines represent the placebo group, and red lines the phytosterol group. Horizontal lines represent the interquartile range and the median. Black points represent the mean for the placebo group, and red triangles represent the mean for the phytosterol group.

ADDITIONAL OBSERVATIONS

Additional observations in the phytosterol group were the following:

- Waist size reduction was particularly effective in women.
- HDL cholesterol showed an upward trend, particularly among men.
- Intestinal transit improved in women with constipation issues.
- There was a downward trend in the total cholesterol to HDL cholesterol ratio, as well as an improvement in lipoproteins quality.
- There was no difference in vitamin D levels between groups.

This study is the first to evaluate free nano-dispersed phytosterols in participants with MS, including a larger sample size compared to previous studies and was done according to a real routine clinical practice. This is the first study that reported a reduction in waist circumference due to phytosterols consumption, an anthropometric parameter that is highly associated with cardiovascular risk. Finally, this study showed an improvement in bowel habit; therefore, Cardiosmile could be an interesting solution for many individuals who have physiologic and metabolic alterations, as well as constipation, without adverse effects on fat-soluble vitamins.

Conclusion

In conclusion, this study showed that Cardiosmile could be an interesting adjuvant therapy in individuals with metabolic syndrome.

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