

A NEW ALLY TO PUBLIC HEALTH FOR PREVENTING METABOLIC AND CARDIOVASCULAR RISK: SYNBALANCE® PROBIOTIC COMPLEX AGAINST METABOLIC SYNDROME.

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ABSTRACT

Objective: to assess the ability of a probiotic formulation containing *L. plantarum* PBS067, *L. acidophilus* PBS066 and *L. reuteri* PBS072 to exert a positive effect on metabolic syndrome by improving body circumference, lipid metabolic profile, chronic inflammation and also overall quality of life.

Methods: after the selection of the most performing strains in specific *in-vitro* models, as the downregulation of inflammation and the modulation of the enzymes involved in lipid and carbohydrates metabolism, we carried out a randomized, double-blind, controlled clinical trial on 60 subjects diagnosed with metabolic syndrome. Following 14 days of run-in, in which subjects were asked to improve their lifestyle, the probiotic and placebo supplements were administered for 2 months. Patients were evaluated by physical, laboratory, hemodynamic analyses and by Quality of Life questionnaire (EuroQoL- 5 Dimension - EQ-5D) at T0 and T60 (end of the study). They were randomized to be treated with a combination of three specific probiotic strains *L. plantarum* PBS067, *L. acidophilus* PBS066 and *L. reuteri* PBS072 to evaluate whether their metabolic and inflammatory parameters were influenced by this probiotic combination versus placebo treatment.

Results: after 2 months, results showed a significant ($p < 0.05$) global reduction of circumference of the waist, visceral adipose index, levels of triglycerides, LDL cholesterol and fasting plasma insulin compared to baseline and placebo. HDL cholesterol showed a significant improvement versus baseline and placebo ($p < 0.05$).

In addition, there was a significant decrease of hsCRP protein ($p < 0.05$) which is known to be a marker of inflammation that predicts the risk of developing cardiovascular diseases and it is closely associated to abdominal obesity, metabolic syndrome, and atherosclerotic cardiovascular disease. Together with hsCRP, there was also a reduction of Tumor Necrosis Factor alpha (TNF- α), the principal cytokine involved in the rising of inflammation ($p < 0.05$).

At the end of the study, the number of patients diagnosed with metabolic syndrome was strongly reduced (-23%) in the active group with respect to placebo (-10%) pinpointing that the sole improvement of life style is not enough to overcome this condition, but a multiple approach is recommended.

INTRODUCTION

Metabolic Syndrome - A serious health condition

Metabolic Syndrome is a set of conditions that can increase the risk of diseases:

- Type 2 diabetes
- CV disease
- Nonalcoholic fatty liver disease
- Osteoarthritis
- Stroke
- Musculoskeletal disorders

The connection between **gut dysbiosis** and **inflammation** has an important role in the pathogenesis of metabolic syndrome (MetS). However, there is a lack of evidences regarding the efficacy of probiotics in reducing **cardiovascular risks**, most of them are only "cholesterol centered".

Here we reported the results of a randomized, double-blind, placebo-controlled, clinical study (RDBPC) on patients diagnosed with **Metabolic Syndrome**.

How to recognize if you suffer from Metabolic Syndrome?

At least, 3 of the following:



IN-VITRO DOSSIER

Carbohydrates metabolism

Probiotic strains are effective in modulating the carbohydrate digestion and reducing the absorption of sugars through the inhibition of α -amylase and α -glucosidase activity.

Lipids metabolism

SynBalance® strains improve the exploitation of lipid mass and keep under control cholesterol blood level by the inhibition of HMG-CoA reductase and the enhancement of Bile Salt Hydrolase activity.

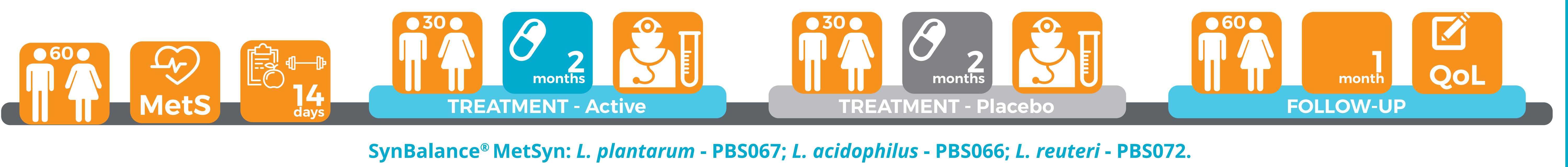
Protection from oxidative stress⁽¹⁾

MetSyn strains can strongly improve cells anti-oxidant potential (FRAP) enhancing also the activity of anti-oxidant enzymes (Catalase, Superoxide dismutase and Glutathione peroxidase).

Modulation of systemic inflammation⁽¹⁾

Probiotic strains positively modulate the inflammatory response through the reduction of TNF- α and the improvement of IL-4 cytokine release.

STUDY DESIGN



CLINICAL DOSSIER

RDBPC clinical trial to evaluate the efficacy of a probiotic supplementation (SynBalance® MetSyn) in improving metabolic syndrome-associated conditions. This work is in collaboration with S. Orsola-Malpighi University Hospital, Internal Medicine Unit.

Improvement of obesity markers

Waist circumference in overweight people was reduced by 4 cm in the active group together with visceral adipose index (-10%).

Modulation of metabolic profile

All dyslipidemic and glycemic markers statistically improved in MetSyn group with respect to the baseline and to placebo group (with exception for FPG).

Reduction of systemic inflammation

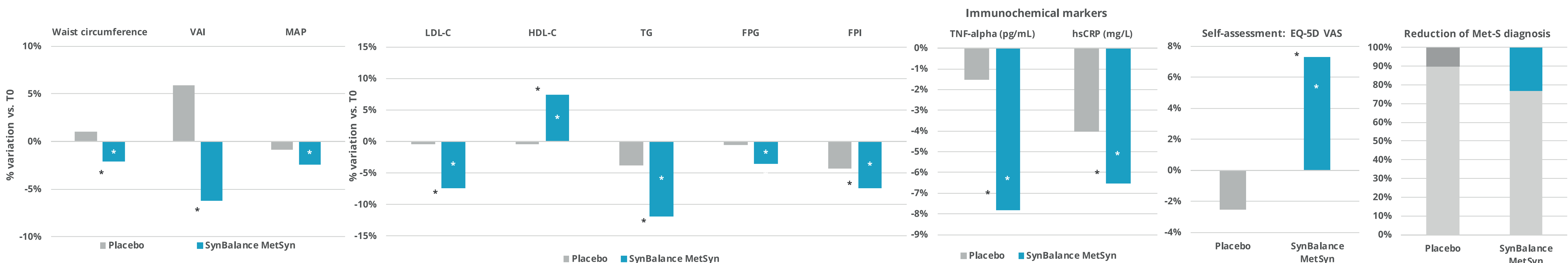
TNF- α and hsCRP consistently decreased in the active group, showing a positive influence on chronic inflammation by the probiotic complex.

Improvement of quality of life

Self-perception is significantly improved in active group, even after one month of wash-out, showing a strong effect of the treatment with respect to the sole life style changes.

Diagnosis of metabolic syndrome

At the end of the study, 23% of the patients belonging to the active group did not comply with MetS diagnosis anymore compared with only 10% in the placebo group.



* p value < 0.05 vs placebo and baseline.

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CONCLUSIONS

This work is the first evidence about the efficacy of a probiotic supplement to positively modulate MetS related markers. Moreover, it also underlines a preventive role of probiotics, together with a healthy life style, in reducing the onset of metabolic syndrome.

*Probiotic treatment with *L. plantarum* PBS067, *L. acidophilus* PBS066 and *L. reuteri* PBS072 provides the reduction of MetS prevalence, several cardiovascular risk-related factors and insulin resistance markers.*

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The corresponding author has a working relationship with ROELMI HPC srl which is developing products related to the research being reported.

References:

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