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Can Chronic Probiotic Intake Modulate Psychological Profile, Gut Microbiota and Body Composition of Women Affected by Normal Weight Obese Syndrome and Obesity? A Double Blind Randomized Clinical Trial

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Background: Evidence of probiotics effects on gut function, brain activity and emotional behaviour were provided. *Lactobacillus* appears to reduce body fat mass, anxiety and dysphoria, and improve insulin sensitivity and glucose tolerance. Body dissatisfaction has been observed to be a risk factor for obesity and eating disorders. Probiotics can have dramatic effects on behaviour through the microbiome-gut-brain axis, through vagus nerve. They produce a variety of neurochemicals, analogs of mammalian hormones involved in mood and behaviour.

Aim: Given the link between gut microbiota, body composition, and the risk of psychiatric illness, we investigated whether chronic probiotic intake could modulate psychological state, eating behavior, and body composition of normal weight obese (NWO) and preobese-obese (PreOB/OB) compared to normal weight lean women (NWL).

Methods: 60 women were enrolled. Exclusion criteria included presence of intestinal bacterial overgrowth, history of chronic degenerative or infectious diseases, medication, smoke, drug or alcohol abuse. Subjects with acute diseases, severe liver, heart or kidney dysfunctions, endocrine disorders, cancer or other conditions capable of altering body composition were excluded. We categorized the subjects according to BMI, and % of total body fat (TBFat) into three groups: NWL, (BMI <25 kg/m², %TBFat <30); NWO (BMI <25 kg/m², %TBFat ≥30); PreOB/OB, (BMI ≥25 kg/m², %TBFat ≥30). At baseline and after 4 week of a probiotic oral suspension (POS) intake all subjects underwent to: anthropometric evaluation (body weight, height, waist and hip circumferences); body composition by dual X-ray absorptiometry (DXA); gut microbiota evaluation by Glucose Breath Hydrogen test (GHBT). Moreover, all patients were also assessed by means of self-report questionnaires (i.e. Eating Disorder Inventory, Beck Depression Inventory, State and Trait Anxiety inventory, and Body Uneasiness Test). POS contained *Streptococcus thermophilus*, *Bifidobacterium animalis* subsp *Lactis*, *Streptococcus thermophilus*, *Lactobacillus bulgaricus*, *Lactococcus lactis* subsp *Lactis*, *Lactobacillus acidophilus*, *Lactobacillus Plantarum*, *Lactobacillus Reuteri* (1.5×10^{10} colony-forming unit CFU for each/day). Multivariate of interest analyses, Pearson or Spearman's rank correlation, and Partial Least Squares (PLS) were performed. Trial Registration: ClinicalTrials.gov Id: NCT01890070

Results: Of the 60 women initially recruited, 8 did not meet inclusion criteria, 4 dropped out of the study voluntarily. We found a 22% of NWO, 26% of NWL, and 48% of PreOB/OB women. Significant differences ($p < 0.05$) were highlighted between: NWL and NWO (TBFat, total body Lean, TBLearn); NWO and PreOB/OB (Weight, BMI, TBFat, TBLearn); NWL and PreOB/OB (Weight, BMI, TBFat, TBLearn). After POS treatment, a reduction of TBFat ($p < 0.001$) and syndrome of bacterial overgrowth ($p < 0.05$), as well as lower psychopathological scores (i.e. depression, state anxiety, body dissatisfaction and bulimia) ($p < 0.05$) were observed in NWO and PreOB/OB. BMI, and body composition variables co-varied with gut microbiota and psychological responses ($p < 0.001$).

Conclusion: Four-week intake of selected probiotic, by modulating body composition, bacterial contamination, psychopathological scores and eating behaviour of women affected by NWO syndrome and obesity, offers a tractable approach to problems related to obesity, psychological state and unhealthy eating. Further research is needed on a larger population and for longer period of treatment before definitive conclusions can be made.