



The World's First Award-Winning Gut-Brain Axis Nutrition System



# **CLINICAL STUDY**



The World's First Award-Winning Gut-Brain Axis Nutrition System. Amare's flagship product line features our most popular products, MentaBiotics, MentaFocus and MentaSync. These cornerstone products are designed to improve every aspect of the gut-brain axis for optimal mental wellness.\*

# Effect of Coordinated Probiotic/Prebiotic/Phytobiotic Supplementation on Microbiome Balance and Psychological Mood State in Healthy Stressed Adults

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## Abstract

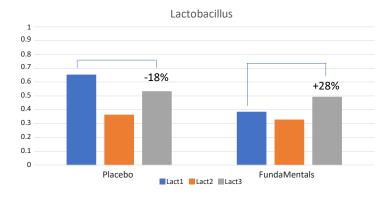
**Background:** Interest in and knowledge of the gut microbiome has increased exponentially in the past decade. This once overlooked component of the gastrointestinal tract is now implicated in multiple aspects of human health, including mental wellness (e.g. depression, anxiety, stress), metabolic (e.g. diabetes, obesity), neurologic (e.g. Alzheimer's, Parkinson's, Autism Spectrum Disorder), gastrointestinal (e.g. irritable bowel syndrome, Crohn's), and immunologic (e.g. inflammation, cancer), among others.

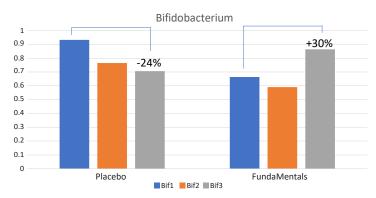
**Purpose/Objectives:** Previous research has demonstrated the "strain specificity" of probiotic therapy—elucidating that targeted health benefits are related to the specific strain of bacteria (e.g. Lactobacillus helveticus R0052 for serotonin/depression; Bifidobacterium longum R0175 for GABA/anxiety; Lactobacillus rhamnosus R0011 for cortisol/stress). Similarly, probiotic bacteria demonstrate different growth trajectories based on availability of preferred fiber substrates (e.g. prebiotics) and phytonutrients such as flavonoids/polyphenols (e.g. phytobiotics). Thus, our objective was two-fold: to determine the change in microbiome ecology/balance; and to assess the change in psychological mood state (e.g. depression/anxiety/vigor) following a coordinated pro-/pre-/phytobiotic supplementation regimen.

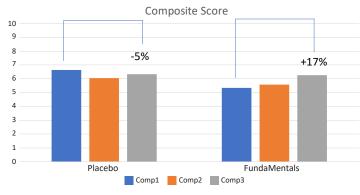
**Methods:** Thirty-two healthy subjects screened for "moderate" levels of psychological stress were randomly assigned to 30-days of Supplement (Amare Fundamentals containing specific strains of probiotic bacteria, prebiotic fibers, and phytobiotic plant extracts, N=21) or look-alike Placebo (N=11). Microbiome balance was assessed in fecal samples using a PCR-based analysis (BiomeTracker) that has previously compared favorably to 16S sequencing (ACN 2017) for abundance quantification for major phyla/families of bacteria. Psychological mood state parameters were assessed using the validated Profile of Mood States survey (POMS) to generate scores for Global Mood State, and six sub-scales (Depression, Tension, Fatigue, Anger, Confusion, and Vigor).

**Results:** Following 30-days of supplementation, there was a significant increase in populations of "good" bacteria in the Supplement group (+28% Lactobacillus; +30% Bifidobacterium) and overall composite score (+17%) versus Placebo (p<0.05). The composite score is an overall average of many different aspects of microbiome balance, including Bifidobacterium, Lactobacillus, Akkermansia, Firmicutes/Bacteroidetes (F/B) ratio, and others. Psychological indices were significantly improved in the Supplement group for both positive (+25% Global Mood; +44% Vigor) and negative (-55% Depression; -45% Tension; -64% Fatigue; -43% Confusion; -54% Anger) mood state parameters versus Placebo (p<0.05).

### **Microbiome Results**



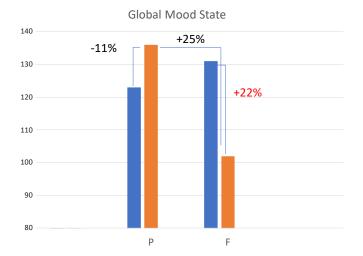


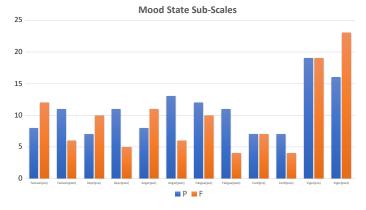


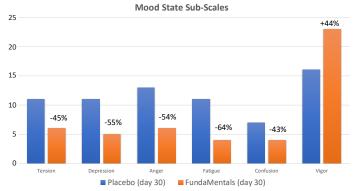
Following 30-days of supplementation, there was a significant increase in populations of "good" bacteria in the Supplement group (+28% Lactobacillus; +30% Bifidobacterium) and overall composite score† (+17% versus Placebo (p<0.05).

<sup>†</sup>The composite score is an overall average of many different aspects of microbiome balance, including Bifidobacterium, Lactobacillus, Akkermansia, Firmicutes/Bacteroidetes (F/B) ratio, and others.

#### **Mood State Sub-Scales**







Psychological indices were significantly improved in the Supplement group for both positive (+25% Global Mood; +44% Vigor) and negative (-55% Depression; -45% Tension; -64% Fatigue; -43% Confusion; -54% Anger) mood state parameters versus Placebo (p<0.05).

**Conclusions:** The World Health Organization has identified mental wellness issues as the leading contributor to global health burden – highlighting the urgency to develop lifestyle interventions to effectively manage depression, anxiety, and stress. These results demonstrate the close relationship between microbiome balance and psychological parameters – and the utility of targeted supplementation to positively influence the gut-brain axis for improved mental wellness.