## Potential of a short-term, high-dose probiotic supplementation as adjuvant therapy in depression

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## **Abstract**

Introduction: Depression is a highly prevalent and burdensome psychiatric disorder. Even though antidepressants and further therapeutic approaches are widely applied, up to 30% of treatment resistant patients experience residual symptoms when receiving optimized treatments. Therefore, the development of novel and more efficient treatment approaches is urgently needed. There is compelling evidence that alterations in the gut microbiota composition have an impact on human physiology and contribute to diseases including psychiatric disorders like depression. The manipulation of the gut microbiota as part of the gut-brain axis has emerged as promising novel target for the treatment of depression.

Methods: We conducted a randomized controlled clinical pilot trial in depressed patients investigating the effect of a four-week high-dose probiotic add-on therapy on depressive symptoms. Symptoms were recorded at baseline, after the intervention and at an 8-weeks follow-up. Trajectories of clinical symptoms were compared between the probiotics and the placebo group. In addition to the Hamilton Rating Scale for Depression (HAM-D) as primary outcome, secondary clinical measures such as gastrointestinal symptoms and anxiety were analyzed.

Results: Out of 60 included patients, 47 completed the intervention. A decrease of HAM-D scores over time and interactions between time and group were found, indicating a greater decrease in the probiotics group compared to placebo. To test pairwise interaction contrasts, comparisons of change scores were conducted and showed higher changes in the probiotics group from baseline to post-intervention and from baseline to follow-up with a medium and large effect size respectively. No significant interaction effects were shown in secondary clinical measures.

Conclusions: Probiotics ameliorated depressive symptoms compared to placebo with a strongest effect after 8 weeks. Compared to many currently available treatments, probiotic interventions might be an accessible, pragmatical and non-stigmatizing adjuvant therapy for patients with depression.