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A Protocol for Therapeutic Effectiveness of Psychobiotics For Eating Disorders: A Systematic Review And Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 October 2025 and was last updated on 1 October 2025.

INTRODUCTION

Review question / Objective In patients with eating disorders, are pharmacological drugs or psychobiotics more efficacious in treating eating disorders (EDs)?
The objective of our study is to evaluate the efficacy of psychobiotics in treating EDs compared to traditional pharmacological interventions in validating the therapeutic potential of psychobiotics as a means of being a safer option to supplement current treatments.

Rationale Current pharmacological treatments for EDs are limited by modest efficacy, adverse effects, possible dependency and patient adherence. Therefore, the exploration of additional therapeutic strategies is neessary. Emerging microbiome research highlights the gut-brain axis as a critical mediator of neuropsychiatric health. Patients with EDs often exhibit gut dysbiosis, which may drive neuroinflammation and neurocognitive dysfunction. Psychobiotics, probiotics and prebiotics that positively influence mental health, have emerged as a promising therapeutic avenue through modulating the gut microbiota. With these findings, our study will shed light on the possibility of psychobiotics being an adjunctive treatment for ED treatment without the adverse events or side effects commonly seen in current ED pharmacological treatments.

Condition being studied Eating disorders (EDs) pose a significant public health challenge, affecting approximately 21 million individuals in the United States. Their prevalence is exacerbated by pervasive societal influences such as weight-centric marketing, diet culture, and rapidly evolving nutritional trends. Clinically, EDs are recognized as psychiatric conditions characterized by disordered eating behaviors that negatively impact a person's physical or mental health. Anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorder (BED) are among the most prevalent EDs. AN is entails self-imposed food restriction, often accompanied by purging behaviors, excessive physical activity, and other compensatory practices geared towards weight loss. BN involves

recurrent episodes of binge eating followed by compensatory behaviors such as vomiting, fasting, or laxative use. In contrast, BED is characterized by frequent episodes of excessive food consumption without subsequent compensatory behaviors, often resulting in obesity and metabolic sequelae.

METHODS

Search strategy Two independent search strategies were employed to identify relevant studies evaluating the efficacy of (1) pharmacological agents and (2) psychobiotic interventions for the treatment of EDs. The search, using Cochrane Libraries, PubMed, and Virtual Health Library (VHL) databases, was executed from December 2024 to July 2025 in two phases. The initial search targeted pharmacological interventions using a combination of the following keywords: “pharmacological”, “CNS drug”, “treatment”, “anorexia nervosa”, “bulimia nervosa”, and “binge eating disorder.” The second search targeted microbiome-based interventions using the following key-words: “psychobiotics”, “probiotics”, “prebiotics”, “bacteria”, “treatment”, “anorexia nervosa”, “bulimia nervosa”, and “binge eating disorder.” Duplicates entries were removed, and remaining studies were screened and evaluated using the below mentioned inclusion and exclusion criteria.

Participant or population The patient population consists of only human randomized-control trials or clinical trials where participants were evaluated to have an ED. No animal-based models or trials were used in this systematic analysis.

Intervention There are two different interventions in this experiment (1) pharmacological medications and (2) psychobiotic interventions for the treatment of EDs. The interventions would not be combined with an additional combination therapy.

Comparator The comparator in each respective study was a placebo..

Study designs to be included This paper in its entirety consisted of 26 research papers whose information is organized in tables regarding sample size, type of ED evaluated, the intervention used, the outcome of the study, and any adverse events or side effects from the intervention.

Eligibility criteria Inclusion criteria were: (a) studies published in English language and involving clinical trials, especially randomized controlled trials (RCTs) between January 2000 and July 2025, (b) studies investigating mono-therapy intervention for any subtype of EDs and (c) studies reported quantitative outcomes suitable for synthesis or meta-analysis.

Exclusion criteria included (a) studies involving combination therapies except those pertaining to multi-strain psychobiotics, (b) studies without full-text access or without sufficient outcome data, or (c) studies that did not report isolated treatment effects specific for EDs.

Information sources Cochrane Libraries, PubMed, and Virtual Health Library (VHL) databases were used to conduct the systematic analysis for randomized-control and clinical trials from January 2000 - July 2025.

Main outcome(s) Outcomes are depicted as the percentage change from baseline for ED clinical outcomes. A decrease in ED clinical outcomes was marked as a positive change, whereas an increase in clinical outcomes from baseline was noted as a negative percentage change.

The overall outcome of 26 studies showed that the combined effects of all interventions and found the improvement of ED with all combined interventions (SMD = 0.407; 95% CI: 0.240 - 0.575) to be more efficacious than pharmacological treatments alone (SMD=0.359; 95% CI: 0.175 - 0.543).

Additional outcome(s) Comparison of adverse events and side effects of psychobiotics against pharmacological interventions showed psychobiotics to be the overall the safer intervention.

Data management Comprehensive Meta-Analysis (CMA) Software was used to synthesize the extracted data from the studies to formulate the forest plots for the meta-analysis. To allow comparison across diverse ED outcome measures from the research papers, all effect sizes were expressed as SMD. Percentage change from baseline for clinical outcomes was calculated in both treatment and placebo groups. This normalization allowed for aggregation of data across various ED diagnostic categories and measurement tools. Clinical outcomes across studies included both behavioral and psychometric indices such as: Number of binge-eating days per week, Yale Food Addiction Scale (YFAS), Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), Eating Disorder Inventory-2 (EDI-2), and Binge Eating Scale (BES), percentage decrease in gastric emptying, and vomiting episodes per day. Data

extraction, computation, and integration into the CMA software was conducted by one researcher.

Quality assessment / Risk of bias analysis Risk of bias analysis has not been formally assessed.

Strategy of data synthesis Data from all the studies was formulated in tables highlighting components such as sample size, intervention, outcomes, adverse events/side effects, and a direct reference. Data was extracted with the main goal of the intervention and placebo groups having post-intervention data and baseline data for the chosen ED outcome measure. This data was then used to calculate the percentage change of ED outcome measure from baseline for the intervention (pharmacological agent or psychobiotic) in comparison to that of the placebo.

Subgroup analysis When comparing pyschobiotics against pharmacologial drugs, the pooled analysis showed a statistically significant benefit in favor of psychobiotic interventions (standardized difference in means [SDM] = 0.680; 95% CI: 0.448 to 0.913; $p < 0.001$) compared to pharmacological treatments interventions (SDM = 0.359; 95% CI, 0.175 to 0.543; $p < 0.0001$).

Sensitivity analysis No sensitivity analysis is required for single-group rates.

Language restriction English.

Country(ies) involved United States of America.

Keywords Eating Disorders; Psychobiotics; Gut Microbiota; Gut-Brain Axis; Dysbiosis; Pharmacological; Medication.

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