

**Fecal Microbiota Transplantation via Rectal Enema
as an Approach for Insulin Resistance in Metabolic Syndrome:
A Double-Blind, Sham-Controlled Randomized Trial**

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Background

The gut microbiota plays a crucial role in various physiological processes, including metabolism. Fecal microbiota transplantation (FMT) involves transferring fecal matter from a healthy lean donor to rebalance intestinal dysbiosis. While the impact of FMT on metabolic syndrome (MetS) is debated, this study aimed to assess the effects of FMT on MetS via rectal enema.

Methods

In a double-blind, randomized controlled trial, subjects with MetS were assigned to receive either FMT (n=8) or a sham intervention (n=10) via rectal enema. Participants were followed at 6 and 12 weeks. The primary outcome was changes in the homeostatic model assessment of insulin resistance (HOMA-IR). Secondary outcomes included fasting blood glucose (FBG), body mass index, inflammatory markers, and hepatic steatosis. Mean-adjusted differences (MAD, 95% CI) between groups were reported as treatment effects using a linear marginal model for repeated measures.

Results

The study included patients with a mean age of 50.4±10.7 years, 44% of whom were male. Baseline BMI and HOMA-IR were similar between groups. Over 6 weeks, FMT significantly improved HOMA-IR (MAD -1.63 (-2.63, -0.64); p=0.001). The FMT group also showed significant improvements in serum FBG, and hs-CRP compared to the sham group (p=0.044 and 0.025, respectively). However, no significant changes occurred in MetS-associated variables or liver steatosis at 12 weeks. Minor adverse events were reported.

Conclusion

FMT via rectal enema demonstrated favorable changes for insulin resistance in MetS. FMT might be an alternative effective treatment for patients with metabolism-related diseases. Further research is needed to sustain long-term benefits.

Keywords: Dysbiosis, Fecal microbiota transplantation, Insulin resistance, Metabolic syndrome