


FECAL-INTESTINAL MICROBIOTA TRANSPLANTATION: STATE OF THE ART AND CLINICAL CHALLENGES <https://doi.org/10.63330/aurumpub.034-025>**Tiffani Casarin¹, Isabela Yukari Sakai², Manoel Armando Delgado Junior³ and Kelly Cristina da Silva Brabes⁴****Abstract**

The gut microbiota is a complex community of microorganisms that inhabit the human gastrointestinal tract and play essential roles in maintaining health, including participation in nutrient digestion, immune system modulation, metabolite production, and protection against pathogenic microorganisms. However, several factors, such as antibiotic use, dietary changes, environmental conditions, and hygiene practices, can compromise the balance of this microbial ecosystem, leading to dysbiosis. This condition is characterized by an imbalance between beneficial and potentially pathogenic microorganisms and is associated with the development of various diseases, including gastrointestinal disorders, metabolic, inflammatory, autoimmune, and neurological diseases. In this context, fecal microbiota transplantation (FMT) has emerged as a promising therapeutic strategy to restore the balance of the gut microbiota. This technique consists of transferring fecal material from a healthy donor to the gastrointestinal tract of a recipient, with the aim of restoring microbial diversity and functionality. The procedure can be performed via different administration routes, such as colonoscopy, enemas, nasogastric tubes, or oral capsules, with the latter two and colonoscopy being associated with better therapeutic results. MFT (Metabolic

¹ Medical Student
Federal University of Grande Dourados
Lattes: <https://lattes.cnpq.br/1529578669906164>

² Medical Student
Federal University of Grande Dourados
Lattes: <https://lattes.cnpq.br/0921729390998929>

³ Doctoral Candidate in Environmental Science and Technology
Federal University of Grande Dourados
Lattes: <https://lattes.cnpq.br/0362678292880555>

⁴ PhD in Food Science and Technology
Federal University of Grande Dourados
Lattes: <https://lattes.cnpq.br/4397388543222105>

Transplantation) shows high efficacy in the treatment of recurrent *Clostridioides difficile* infections, with high cure rates reported in the literature. Furthermore, recent studies are investigating its therapeutic potential in other conditions associated with dysbiosis, such as irritable bowel syndrome, inflammatory bowel diseases, obesity, type 2 diabetes, and neurodegenerative diseases. Despite advances, the clinical application of MFT still faces challenges related to the standardization of protocols, rigorous donor selection, microbiological safety of the transplanted material, and monitoring of long-term effects. Therefore, more studies are needed to consolidate this approach as a safe and widely applicable therapeutic strategy in clinical practice.

Keywords: Intestinal dysbiosis, Human microbiome, Microbiological therapy, *Clostridioides difficile* infection, Modulation of the gut microbiota.

INTRODUCTION

In recent decades, there has been growing recognition of the importance of the gut microbiota for human health and well-being, since, when healthy and diverse, it plays a crucial role in digestive support, the promotion of metabolism, the regulation of the immune system, and the inhibition of bacterial growth, among other functions essential to the normal functioning of the human body (Hou et al., 2025).

However, the diversity and beneficial function of the gut microbiota may be affected by methods of drug administration, antibiotic use, environmental changes, hygiene practices, and diets, leading to the transient or irreversible loss of beneficial functions performed by the microbial ecosystem (Rahman; Marcolla; Willing, 2025).

This alteration of the gut microbiota is termed dysbiosis, the term used to describe the imbalance between protective and harmful microorganisms (Hauser et al., 2025). Consequently, diseases and disorders arise, ranging from cardiovascular, neurological, respiratory, and metabolic diseases to cancer, inflammatory bowel and skin diseases, Alzheimer's disease, autism, multiple sclerosis, and allergies.

Likewise, there is an increased risk of metabolic syndromes, including type 2 diabetes mellitus and obesity (Nemzer et al., 2025).

A new opportunity to modulate the gut microbiota (GM) and reestablish qualitative and quantitative microbial balance has been identified in fecal microbiota transplantation (FMT), an innovative therapeutic approach in which beneficial exogenous commensal bacteria can colonize the intestinal environment, restoring the composition and functionality of the microbial community, reducing disruption of the intestinal barrier, increasing resistance against opportunistic pathogens, and inhibiting intestinal and systemic inflammation (Sala et al., 2025).

Despite promising results, FMT still faces significant challenges, such as the standardization of protocols, the definition of rigorous criteria for donor selection, the microbiological control of transplanted material, and the monitoring of long-term effects (Chaves; Roncolato, 2025). Thus, the objective was to review the main aspects related to fecal microbiota transplantation, addressing the role of the gut microbiota in human health, the mechanisms associated with dysbiosis, the principles and procedures of transplantation, as well as its clinical applications, limitations, and challenges for the consolidation of this therapeutic approach.

DEVELOPMENT

GUT MICROBIOTA AND DYSBIOSIS

The human body harbors trillions of microorganisms that coexist in a symbiotic relationship with the host, performing essential functions such as regulation of the immune system, vitamin production, nutrient metabolism, and protection against pathogens, and approximately 95% of these microorganisms are located in the gastrointestinal tract, forming what is known as the gut microbiota (Maia; Pereira; Schachter, 2025).

The gut microbiota (GM) refers to the intricate and diverse community of microorganisms that inhabit the gastrointestinal tract of humans and animals (Yang et al., 2025), composed of approximately

100 trillion cells, with a combined mass of 1 kg to 2 kg, forming a dynamic internal ecosystem of bacteria, fungi, protozoa, archaea, and viruses (Peterle et al., 2025).

The GM colonizes the gastrointestinal tract (GIT) early in life, after birth, from maternal and environmental bacteria, and establishes a symbiotic interaction with the host (Sala et al., 2025), undergoing transitions during childhood until stabilizing around three years of age (Maia; Pereira; Schachter, 2025), although it may be influenced by diet, medication use such as antibiotics, infections, pollution, and other environmental factors (Peterle et al., 2025).

In healthy individuals, the GM is characterized by high taxonomic diversity and microbial richness, dominated by obligate anaerobes, mainly from the phyla *Firmicutes* and *Bacteroidetes*, followed by *Actinobacteria* and *Verrucomicrobia*, with *Proteobacteria* typically present in low abundance (Sala et al., 2025).

A healthy and diverse gut microbiota plays a fundamental role in maintaining human health and in protecting against the development of disease. It significantly affects host physiology, acting as a barrier against pathogen colonization, modulating mucosal permeability, and interacting with the immune system. In addition, it regulates energy metabolism and the utilization of ingested food, influences neurological functions, participates in xenobiotic metabolism, and produces a wide range of biologically active metabolites that affect distant organs and systems (Sala et al., 2025).

However, the diversity and beneficial role of the gut microbiota may be compromised by methods of drug administration, antibiotic use, environmental changes, hygiene practices, and diets, leading to the transient or irreversible loss of the beneficial functions performed by the microbial ecosystem. This alteration of the gut microbiota is termed dysbiosis and has been associated not only with gastrointestinal diseases, but also with metabolic, autoimmune, and infectious diseases (Rahman; Marcolla; Willing, 2025).

Dysbiosis, defined as an ecological imbalance of the gut microbiota, occurs when there is an alteration in the composition, abundance, or functions of the microorganisms inhabiting the intestine

(Nemzer et al., 2025). This imbalance disrupts the integrity of the intestinal barrier, activates the immune system, and triggers chronic inflammation (Hou et al., 2025). According to Hou et al. (2025), the most common alterations include the reduction of beneficial bacteria such as *Lactobacillus* and *Bifidobacterium*, the depletion of *Clostridia* groups, and the excessive growth of potentially pathogenic microorganisms such as *Clostridioides difficile* and *Escherichia coli*; these changes are associated with various gastrointestinal disorders, including constipation, irritable bowel syndrome, and recurrent *C. difficile* infections.

Dysbiosis is also related to the development of inflammatory, metabolic, allergic, and autoimmune diseases, highlighting its central role in human health and its relevance as a therapeutic target (Chaves; Roncolato, 2025). In addition, microbiota imbalance may affect other systems, including the central nervous system (Maia; Pereira; Schachter, 2025).

The consequences of dysbiosis are broad, ranging from cardiovascular, neurological, respiratory, and metabolic diseases to cancer, inflammatory bowel and dermatological diseases, as well as conditions such as Alzheimer's disease, multiple sclerosis, autism, and allergies; there is also a greater risk of metabolic syndromes, such as type 2 diabetes mellitus and obesity (Nemzer et al., 2025).

Restoring microbial diversity and reintroducing a healthy microbiota, for example through fecal microbiota transplantation (FMT), may effectively modulate the intestinal microbiome and relieve diseases resulting from dysbiosis. By modulating the gut microbiota and restoring its balance and diversity, there may be potential benefits in the treatment or prevention of diseases associated with microbial dysbiosis (Hou et al., 2025).

PRINCIPLES OF FECAL MICROBIOTA TRANSPLANTATION (FMT)

Historically, there have been several ways of attempting to alter the intestinal microbiome; among the most common methodologies are the use of probiotics, prebiotics, or specific dietary restrictions. However, the effectiveness of these options is inconsistent and, therefore, a more recent modality of

altering the intestinal microbiome that has proven effective is fecal microbiota transplantation (Baske et al., 2024).

Fecal Microbiota Transplantation, also called “stool transplantation,” “human intestinal microbiota transfer,” and “fecal bacteriotherapy” (Hou et al., 2025), is based on correcting dysbiosis in recipients and seeks to restore microbial homeostasis through the transplantation of a healthy community of fecal microbiota from a stool donor, administered in various ways, but commonly performed by means of endoscopy, colonoscopy, or oral capsule (Baske et al., 2024).

Among the benefits of FMT are the prevention of pathogen colonization through direct competition and increased host resistance, the rebalancing of microbial diversity resulting in the recovery of host immune function and intestinal integrity, and the restoration of essential metabolites necessary for host metabolism and function (Sala et al., 2025).

Thus, its main objective is to reconstruct damaged or imbalanced gut microbiota, promote the diversity and balance of intestinal microorganisms and, in this way, improve certain gut-related diseases; although FMT is a relatively new medical term, its concept and practice date back to antiquity (Hou et al., 2025).

The earliest documented use of fecal suspension therapy dates back at least 1,700 years in traditional Chinese medicine; the renowned practitioner of traditional Chinese medicine Ge Hong mentioned in his writings the use of a so-called “yellow soup” to treat food poisoning and severe diarrhea, which was in fact a mixture of feces (Hou et al., 2025).

In the sixteenth century, another Chinese physician, Li Shizhen, documented in his writings several fresh or dried fecal preparations to treat a series of gastrointestinal disorders, including constipation, fever, vomiting, and pain (Ren et al., 2025). In more modern history, during the Second World War, Bedouins in Africa advised German soldiers stationed on the continent to consume fresh camel feces as a treatment for bacterial dysentery; however, although primitive, this practice

demonstrated the concept of using microbially based treatment derived from feces for disease (Hou et al., 2025).

It was only at the beginning of the twentieth century that advances in microbiology provided a scientific basis for understanding fecal therapy, and in 1907 Metchnikoff proposed the potential benefits of microbes for health (Hou et al., 2025). However, it was only in 1958 that Dr. Ben Eiseman, an American surgeon, first described the use of fecal enemas for the treatment of patients with fulminant pseudomembranous enterocolitis due to antibiotic use, with successful treatment and rapid resolution of symptoms, marking the first documented record of FMT in modern medicine (Hauser et al., 2025).

In the last decade, FMT has been analyzed as a possible therapy for several diseases (Hauser et al., 2025). Currently, FMT is approved by the FDA only for the treatment of patients with recurrent *Clostridioides difficile* infections (rCDI), with a cure rate of 90% (Baske et al., 2024). However, this innovative therapy has demonstrated efficacy in several other diseases, such as inflammatory bowel disease, irritable bowel syndrome, and metabolic syndrome (Zhou et al., 2025).

Therefore, most of the available data on FMT derive from case reports and clinical trials for recurrent CDI, which have demonstrated that this approach is highly effective, easy to use, minimally invasive, and relatively free of adverse effects (Sala et al., 2025).

PROCEDURES AND ROUTES OF ADMINISTRATION

Despite advances and the growing body of favorable evidence, the clinical application of FMT still faces important limitations, with great variability in the protocols used, including methods for preparing the fecal material, routes of administration (colonoscopy, oral capsules, enemas, or nasogastric tube), and patient selection criteria (Chaves; Roncolato, 2025).

Usually, fecal microbiota for transplantation is obtained from volunteer donors, who may be a person known to the recipient or someone who donates stool to a frozen donor bank (Sala et al., 2025). According to Hauser et al. (2025), these volunteers undergo detailed screening to exclude transmissible

diseases such as viral hepatitis, HIV, COVID-19, gastrointestinal infections, parasitic diseases, inflammatory and autoimmune diseases, and hereditary metabolic disorders; in addition, a family history of cancer and recent use of antibiotics or illicit substances may also disqualify a candidate.

In addition to selecting a healthy donor, it is also important that the donor be suitable and that there be proper compatibility between donor and recipient (Hauser et al., 2025). FMT recipients must meet specific preparation criteria, such as discontinuing antibiotic use 12 to 48 hours before fecal infusion (Sala et al., 2025) and fasting for a few hours before the procedure; in some cases, the administration of antacids or laxatives may be indicated, with the aim of reducing the presence of residual fecal material and favoring graft implantation. In addition, studies report the use of loperamide to delay intestinal transit, ensuring that the transferred fecal material remains in the intestine for at least four hours (Hauser et al., 2025).

Fecal microbiota transplantation may be administered orally, through a nasogastric or jejunal tube, endoscopy, or encapsulation, or rectally, through colonoscopy or retention enema; among these methods, colonoscopy and capsules have demonstrated a higher cure rate compared with nasogastric administration, which may be attributed to the limited protection that nasogastric tubes provide against gastric acid, unlike capsules and rectal administration (Alaeddin et al., 2025).

Although capsules currently represent the least invasive method for administering FMT, some individuals may have difficulty swallowing them because of their quantity (15–20) and size (23.3 mm). Dysphagia may occur in 14% of older patients, sometimes resulting in nonadherence to treatment or inappropriate medication modification (Chen et al., 2026).

And according to Hauser et al. (2025), FMT is a relatively safe procedure and may be performed even in immunocompromised patients, although data concerning long-term risks (≥ 5 years) are limited. Theoretically, there is the possibility that potentially harmful bacteria may be transplanted, whose negative effect may not become apparent for years. Therefore, further prospective follow-up studies of patients who have received FMT are needed.

CHALLENGES AND CLINICAL LIMITATIONS

Despite the proven efficacy of Fecal Microbiota Transplantation (FMT) in several gastrointestinal disorders, its clinical application still faces significant obstacles (Hou et al., 2025). The lack of standardization in therapeutic protocols is one of the main limitations, since there is great variability in the stages of fecal material preparation, the routes of administration (colonoscopy, oral capsules, enemas, or nasogastric tube), and patient selection criteria, and this heterogeneity compromises the reproducibility of results and makes comparisons between studies difficult (Chaves; Roncolato, 2025).

Another critical point concerns individual differences among patients and the type of disease treated, factors that directly influence therapeutic response, since pretreatment preparation, the number and volume of fecal infusions, and donor selection criteria significantly impact clinical outcomes (Hou et al., 2025).

In addition, the long-term safety of FMT remains inadequately defined (Hou et al., 2025). Although FMT presents good short-term results, there are still uncertainties about future risks, including possible pathogen transmission, metabolic alterations, and associations with autoimmune or cardiovascular conditions (Chaves; Roncolato, 2025). Failures in the donor screening and testing process may result in severe infections and, therefore, the establishment of stricter donor selection criteria and long-term safety monitoring mechanisms has become one of the critical issues to be addressed for the clinical application of FMT (Hou et al., 2025).

Despite its success and worldwide use in the treatment of rCDI (recurrent *Clostridioides difficile* infections), the mechanism of action of FMT is still not fully understood, because FMT transfers a complex mixture of donor-derived material, including bacteria, viruses, and fungi, unlike probiotics, which introduce only selected bacterial strains. Studies suggest that even sterile filtrates, without living microorganisms, may be effective, indicating the potential role of metabolites, microbial structural components, or bacteriophages. Furthermore, the simple engraftment of donor strains in the recipient does

not necessarily predict clinical improvement; overall compatibility between microbiomes appears to be a more relevant factor than the transfer of specific taxa (Alaeddin et al., 2025).

On the other hand, many clinical trials present methodological limitations, such as absence of blinding and a small number of participants, which compromises the strength of the evidence; thus, the consolidation of FMT as a safe and widely recommended clinical practice requires advances in the standardization of protocols, the rigorous definition of donor selection criteria, and long-term patient follow-up (Chaves; Roncolato, 2025).

In this scenario, organized donor selection processes are an important step toward reducing risks and ensuring the quality of transplanted material. It is necessary for the donor to be clinically healthy, without recent antibiotic use or a history of infectious diseases, and to undergo complete clinical and laboratory examinations to identify viruses, bacteria, fungi, and parasites. Additional analyses of the fecal microbiome and the use of specific exclusion criteria increase the safety of the process, in accordance with international recommendations and the most recent scientific advances (Chaves; Roncolato, 2025).

CLINICAL APPLICATIONS OF FMT

Fecal Microbiota Transplantation has become established as an effective therapeutic intervention, especially in the treatment of recurrent *Clostridioides difficile* infection (rCDI) (Hauser et al., 2025). Clinical studies demonstrate remission rates between 83% and 100%, greatly surpassing the efficacy of antibiotics alone (Alaeddin et al., 2025). In addition, its early application in severe cases of CDI significantly reduces mortality, suggesting benefit in higher-risk situations (Liu et al., 2025).

Despite its efficacy, FMT has only one formally approved indication in European and American guidelines: the treatment of rCDI, recommended from the second episode onward (Chen et al., 2026). Factors such as disease severity, previous hospitalizations, and high levels of fecal calprotectin may predict procedural failure, reinforcing the need for personalized assessment (Liu et al., 2025).

In addition, the potential therapeutic effects of FMT in conditions related to dysbiosis, such as irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), have become a focal point of current research (Hou et al., 2025). In ulcerative colitis, especially in mild to moderate cases, compared with placebo or standard treatment, risk ratios for remission induction range from 1.7 to 1.79, although the certainty of the evidence is low and the results are variable across studies (Chen et al., 2026). For Crohn's disease and pouchitis, the evidence remains insufficient (Liu et al., 2025).

According to Liu and collaborators (2025), findings in IBS are divergent: some studies demonstrate significant improvement in symptoms, fatigue, and quality of life, whereas others identify no benefit relative to placebo, indicating that microbial modulation alone may not explain clinical improvement and that administration protocols still require standardization.

Beyond the gastrointestinal tract, FMT has been investigated in extragastrointestinal diseases associated with dysbiosis, including obesity, type 2 diabetes, metabolic syndrome, liver diseases, multiple sclerosis, autism, depression, and Parkinson's disease (Sala et al., 2025). Preliminary studies also explore its role in modulating the immune response, as in resistance to anti-PD-1 treatment in skin cancer and immunotherapy-induced colitis (Chen et al., 2026). Research in systemic lupus erythematosus, psoriatic arthritis, and type 1 diabetes has shown promising results, pointing to its immunomodulatory potential (Liu et al., 2025).

According to Liu et al. (2025), more than 200 clinical trials are currently investigating FMT in inflammatory, metabolic, autoimmune, and neuropsychiatric conditions, including Alzheimer's disease, where preliminary data suggest possible cognitive stabilization.

CONCLUSION

Fecal Microbiota Transplantation (FMT) is one of the most promising therapeutic interventions in modern medicine, aimed at restoring microbial balance and treating conditions associated with dysbiosis. The success already demonstrated in combating recurrent *Clostridioides difficile* infection highlights the

potential of this method and marks an important point in the use of therapies directed toward microbiome modulation. In addition, new evidence suggests that FMT may bring benefits in gastrointestinal, metabolic, autoimmune, and neuroinflammatory conditions, thereby expanding the therapeutic options available.

Despite the progress made, FMT still faces significant challenges before becoming a widely accepted and standardized clinical practice. Diversity in protocols, the absence of universal criteria for donor selection, differences in the preparation and administration of fecal material, and uncertainties regarding long-term safety constitute considerable obstacles. The still limited understanding of the mechanisms of action, which involve not only living microorganisms but also metabolites, phages, and structural components, reinforces the need for more in-depth investigations. These elements are crucial to ensure the reproducibility, reliability, and safety of the technique.

Therefore, the future of FMT will depend on a joint effort among researchers, physicians, regulatory agencies, and health institutions to strengthen fecal biobank practices, establish international guidelines, improve diagnostic tools, and appropriately stratify the patients who may benefit from this intervention. With the advancement of knowledge regarding the human microbiome and the development of new standardized microbial formulations, it is expected that FMT will transition from an emerging intervention to a consolidated, safe, and accessible therapeutic alternative. Thus, FMT is configured not only as a biomedical innovation, but also as a gateway to a new era of personalized medicine and the therapeutic modulation of the human microbial ecosystem.

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