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REVIEW ARTICLE

Evaluation of the efficacy of fecal transplantation for restoring the intestinal microbiota

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ABSTRACT

Introduction: intestinal dysbiosis is associated with multiple digestive and systemic pathologies, driving interest in alternative therapies such as fecal microbiota transplantation (FMT).
Objective: to evaluate the efficacy of fecal transplantation in restoring intestinal microbiota across different age groups.
Methods: a systematic review of the scientific literature was conducted across multiple databases. The search employed an algorithm combining keywords and Boolean operators to identify relevant sources. Selected studies, after applying inclusion and exclusion criteria, were critically analyzed considering recency, methodological quality, and thematic relevance, and integrated into the final synthesis of the review.
Development: evidence shows that FMT is highly effective in recurrent *Clostridium difficile* infections, in both adults and children, with success rates exceeding 80%, and demonstrates acceptable safety in immunocompromised patients—though prospective studies are needed to confirm risks. In children with autism spectrum disorder, preliminary trials suggest gastrointestinal and behavioral benefits. In adults with Asperger syndrome, clinical improvement has been documented after multiple FMT rounds, opening new research avenues on the gut-brain axis.
Conclusions: fecal transplantation represents a promising therapeutic alternative for restoring intestinal microbiota in various pathologies. Its benefits are most evident in *Clostridium difficile* infections, while in neurological disorders and vulnerable populations, higher-quality controlled studies are still required. Available evidence supports its potential as an innovative strategy in digestive and preventive medicine.

Keywords: Dysbiosis; Gastrointestinal Microbiome; Complementary Therapies; Fecal Microbiota Transplantation.

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INTRODUCTION

The human body hosts microorganisms on its surface and internally. The term "microbiota" refers to the community of living microorganisms residing in a specific site of the human body. The most abundant and well-studied microbiota in humans resides in the intestinal tract, comprising numerous bacteria, viruses, and fungi that inhabit the intestinal lumen. To date, over 1,000 genera of intestinal bacteria have been identified. Thus, the gut microbiota plays a key role in health and is increasingly recognized as a contributor to various disease states when imbalance occurs.[1,2]

Its impact extends beyond the mucosal interface, as it plays an essential role in systemic functions—particularly in immune system development. The intestinal microbiota specifically refers to the living microorganisms present in the digestive system, composed of diverse microbes that can be either beneficial or harmful. Key phyla include Firmicutes, Bacteroidetes, Actinobacteria, and Proteobacteria.[3] These microbial communities can be disrupted by various factors, including poor lifestyle habits—such as excessive alcohol consumption, high stress levels, inadequate diet, or certain medical treatments—which may alter the gut microbiome, leading in most cases to a multi-microbial imbalance within the intestine.[4]

Before the advent of penicillin in the 1940s, infectious diseases were the leading cause of human death—a reality that persists in much of the world today. The widespread use of antibiotics has led to a significant rise in antimicrobial resistance, raising major concerns as this poses a barrier to treating infectious agents and has spurred interest in novel therapeutic strategies—one of which is fecal microbiota transplantation (FMT).[3] In response to gut microbiota disruption, new methods have been developed to reverse this damage; FMT has enabled the recovery of these microbial communities.

Fecal transplantation, also known scientifically as bacteriotherapy, is an ancient treatment that has recently re-emerged due to its high efficacy in a specific condition: *Clostridium difficile* infection.[5] Although administered via various techniques, FMT involves introducing a suspension of fecal matter from a healthy donor into the gastrointestinal tract of a recipient—typically a patient with a specific pathology. It can be delivered orally via specially prepared capsules or rectally via enemas or liquid infusions through colonoscopy.

After collection from a healthy donor, fecal material is mixed with saline solution and filtered, then transferred to the recipient's digestive tract via colonoscopy. To avoid colonoscopy, oral capsule delivery has been successfully tested, despite requiring ingestion of 5 to 20 capsules per treatment course.[6,7] FMT helps replace "harmful" bacteria in the colon with "beneficial" ones, thereby restoring the good bacteria diminished or eliminated by antibiotic use. Restoring this balance enhances the body's ability to combat infections.

Currently, FMT is recognized in national and international guidelines as the treatment of choice for recurrent or relapsing *Clostridium difficile* infection, as it is the most evidence-based method for restoring a healthy microbiota.[7] However, questions remain regarding its efficacy across different age groups and how it responds in diverse physiological contexts. Therefore, this research aims to determine the efficacy of FMT as a method for restoring intestinal microbiota across various age groups. This motivated the present study, which sought to evaluate the efficacy of fecal transplantation in restoring intestinal microbiota in different age groups.

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METHODS

This study was conducted as a systematic literature review following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The search period spanned from 2019 to 2024 to identify the most recent evidence on FMT efficacy in restoring intestinal balance across age groups. Both original articles and secondary reviews, as well as grey literature (theses, technical reports, institutional documents), were included provided they met quality and thematic relevance criteria.

Information sources included major biomedical and multidisciplinary databases: PubMed/MEDLINE, Web of Science, SciELO, Frontiers, Google Scholar, Healthy Children, and regional repositories such as LILACS and BVSALUD. Reference lists of key articles were also reviewed to identify additional studies not captured in the initial search. The search strategy employed an algorithm combining keywords and DeCS/MeSH descriptors ("fecal microbiota transplantation," "Clostridium difficile," "intestinal dysbiosis," "autism spectrum disorder," "immunocompromised patients") with Boolean operators (AND, OR, NOT) to optimize sensitivity and specificity. Publications in Spanish and English were included, as these are the predominant languages in scientific literature on this topic.

Inclusion criteria encompassed studies published within the defined timeframe, with full-text access, directly addressing FMT efficacy in restoring intestinal microbiota in pediatric and adult populations. Original articles, case studies, clinical trials, and systematic and narrative reviews were accepted. Duplicates, articles without full access, publications outside the timeframe, irrelevant studies, and those with significant methodological flaws were excluded.

The selection process occurred in several phases: initial title and abstract screening to exclude non-relevant studies, followed by full-text evaluation of preselected articles. Initially, approximately 1,401 records were identified (number to be finalized based on actual results); duplicates and irrelevant studies were removed, leaving 551 after screening. Finally, 202 articles were included in the qualitative synthesis. The procedure was represented using a PRISMA flow diagram (Figure 1), transparently illustrating identification, screening, eligibility, and inclusion stages.

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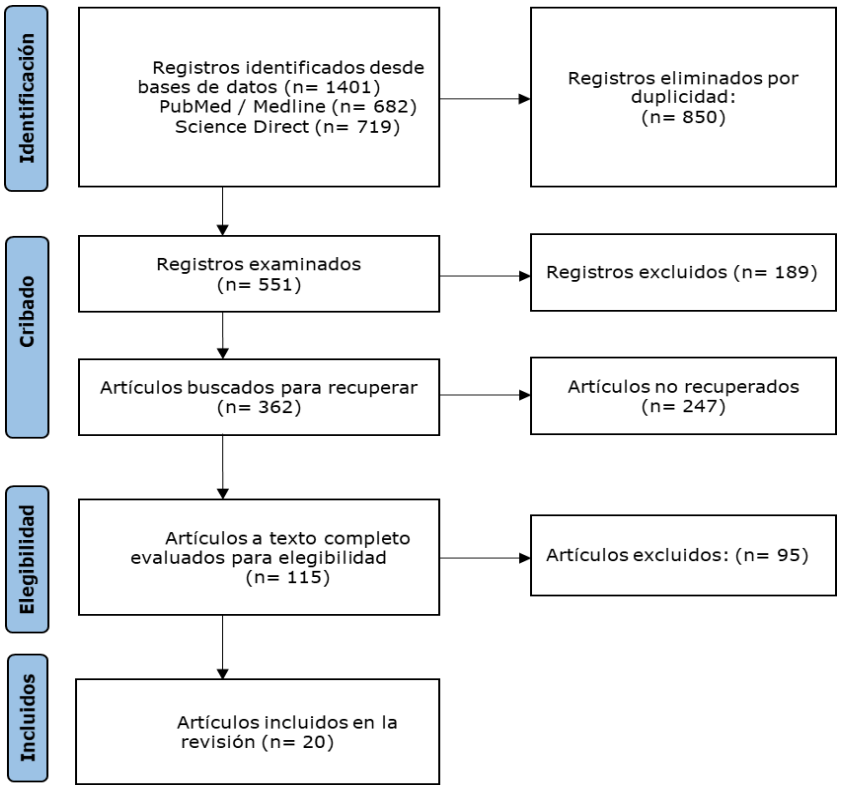

Fig. 1 Article selection diagram.

For data extraction and analysis, a matrix was designed to collect key variables from each study: author, publication year, country, methodological design, sample size and characteristics, pathologies addressed, clinical outcomes, and procedure safety. Information was integrated into a qualitative synthesis enabling comparison of findings and identification of common patterns. No meta-analysis was performed due to heterogeneity in designs and outcomes, though a critical narrative analysis highlighted strengths and limitations of available evidence.

DEVELOPMENT

The gut microbiota helps maintain human homeostasis, playing a crucial role in immune regulation, vitamin synthesis, intestinal defense, and peristaltic movement. In recent years, fecal microbiota transplantation (FMT) has become a major topic in the global medical community, gaining popularity among gastroenterologists, pediatricians, and pediatric gastroenterologists. The rising prevalence of *Clostridium difficile* infection (CDI) as a nosocomial disease in many countries has been a key driver for implementing FMT in recurrent or relapsing cases unresponsive to conventional therapies. This approach has demonstrated efficacy in both adults and children, including favorable cost-benefit ratios.[8]

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Fecal transplants are safe and effective for recurrent *Clostridium difficile* infection (CDI) in children, according to a clinical report published by the American Academy of Pediatrics (AAP).[9] In a report reviewing evidence supporting FMT, the AAP confirmed it as a viable treatment option for children with severe or recurrent CDI.[10] CDI is a bacterium carried asymptomatically in the digestive systems of up to 5 % of people. Approximately half of healthy infants under one year harbor CDI in their stool without symptoms. Often, the bacterium produces a toxin causing diarrhea, abdominal cramps, and colitis (intestinal inflammation).[11]

Transmission occurs when a child touches a contaminated surface and then puts fingers in their mouth. A 2020 study showed that one or two FMT cycles prevented CDI recurrence in children 87 % of the time. Researchers defined CDI eradication as absence of recurrence for at least two months post-FMT and noted pediatric success rates comparable to those in adults.[9]

Little is known about changes in antimicrobial resistance (AMR) genes and potential pathogen load in pediatric FMT recipients. However, FMT for CDI in children reduces AMR genes and potential pathogens while altering microbiota composition and function.[12] FMT is an effective therapy for recurrent CDI in pediatric patients. For recurrent CDI, FMT appears safe and effective.[13]

In recent years, there has been a notable increase in studies on the implications of gut microbiota (GM) in children with autism spectrum disorder (ASD),[14] a heterogeneous group of neurodevelopmental disorders characterized by impaired social communication and restricted, repetitive sensorimotor behaviors. Many children with ASD present gastrointestinal symptoms—diarrhea, loose stools, abdominal pain, and constipation—potentially linked to gut microbiome alterations.[15] Scientific evidence on this emerging alternative therapy remains limited. However, it appears promising not only for its primary outcome—alleviating gastrointestinal symptoms—but also for its secondary therapeutic effect of improving autistic behavioral symptoms.[16]

Bacteriotherapy targeting gut microbiota composition via FMT seems a promising tool for addressing both gastrointestinal disorders and associated behavioral traits. An open-label Phase I clinical trial was conducted in 18 children aged 6–17 years. The protocol included a two-week antibiotic course, bowel cleansing, followed by lower-dose daily maintenance for 7–8 weeks. Significant shifts were observed in *Bifidobacterium*, *Prevotella*, and *Desulfovibrio* abundance, correlating with improved gastrointestinal symptoms and 25 % gains in language, social interaction, repetitive behaviors, hyperactivity, and irritability—effects sustained for eight weeks.[1]

More research is needed. While contemporary scientific evidence and experimental studies suggest FMT may benefit this population, results remain inconclusive. Future therapies for gastrointestinal disorders in ASD may also yield secondary behavioral improvements. Given current research trends in neurological disorders, FMT is likely to become a relevant area of investigation in coming years.[16]

Immunocompromised (IC) patients have a higher risk of refractory diarrhea. FMT is a safe and effective treatment for infectious diarrhea primarily caused by loss of microbial colonization. However, concerns exist that IC patients may be more prone to FMT-associated infectious complications, and few reports describe FMT in immunocompromised children.

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For refractory diarrhea in IC children with damaged microbiota, FMT is safe and effective and establishes a distinct microbial profile. The study has limitations. Despite initial successful FMT use in IC children, mechanisms, donor selection, optimal dosing, and timing for successful transplantation require clarification. Thus, high-quality, prospective, randomized, controlled trials with larger samples are needed in pediatric diseases.[17]

Asperger syndrome is a chronic neurodevelopmental disorder characterized by social and communication difficulties despite normal cognitive and language function. A case study first reported clinical improvement in an adult with Asperger syndrome and comorbid irritable bowel syndrome with chronic diarrhea following fecal microbiota transplantation (FMT). After three FMT rounds, significant improvements in both gastrointestinal and psychological symptoms were observed, associated with changes in gut microbiota structure and serum metabolites. This suggests microbiota-derived metabolites may influence distant organs like the nervous system, reducing mental symptoms—though study limitations and the need for further clinical and experimental research are acknowledged. Collectively, FMT emerges as a novel therapeutic option for Asperger patients, offering new perspectives on gut-brain integration.[18]

Clostridium difficile infection (CDI), increasingly seen in community settings, remains primarily treated with antibiotics—yet antimicrobial exposure disrupting gut microbiota is the main CDI risk factor. CDI is the leading cause of diarrhea in hospitalized patients.[19] Over the past decade, it has become an epidemic marked by increased frequency, severity, and recurrence—possibly due to aging populations, inappropriate antibiotic and proton-pump inhibitor use, emergence of hypervirulent strains, and poor healthcare worker adherence to biosafety protocols. CDI can be classified as mild, moderate, severe, or fulminant based on digestive damage and systemic manifestations. Dysbiosis or loss of gut microbiota diversity appears central to CDI pathogenesis and recurrence. First-line antibiotics include metronidazole and vancomycin.

However, recent years have seen increased therapeutic failures due to comorbidities, ongoing antibiotic needs for other infections, and resistant strains.[20] In a systematic review, FMT showed similar responses and adverse effects in immunocompetent and immunocompromised recipients, with placebo-controlled trials reporting no serious adverse events or transmitted infections. Adverse event risk is estimated at 0–28 %. Within two weeks post-procedure, one-third of patients may experience transient bowel changes and/or flatulence, typically self-resolving.

FMT has proven highly effective for CDI. The primary goal should be resolving CDI without compromising the microbiota. Recent CDI and FMT reports, along with expert consensus, suggest FMT as first-line treatment for adults and children regardless of severity. Most serious complications relate to procedural techniques rather than FMT itself. Expert experience and literature indicate adverse effects are minimal, short-lived, self-limiting, and easily managed. However, two recent cases of severe infections caused by multidrug-resistant bacteria highlight the critical need for rigorous donor screening. Experts call for future randomized trials to confirm FMT as initial CDI therapy.[19,20]

CONCLUSIONS

FMT has shown encouraging results in various digestive pathologies by promoting intestinal microbiota recovery, although it lacks official WHO validation as a standard treatment. International studies highlight its efficacy in *Clostridium difficile* infection—especially in antibiotic-resistant cases—and in immunocompromised patients with refractory diarrhea, where safety and significant clinical improvement have been demonstrated. These findings offer hope

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for broader application, but underscore the need for prospective, randomized, controlled trials with larger samples—particularly in pediatrics—to confirm effectiveness and establish FMT as a consolidated therapeutic option in digestive and preventive medicine.

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