



Evaluation of Efficacy of Faecal Microbiota Transplantation for Patients with Irritable Bowel Syndrome: A Scoping Review of Randomized Controlled Trials

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Abstract

Objective: This scoping review aims to summarize current RCT studies on FMT for IBS, exploring safety, efficacy, microbiota correlations, and suggesting future research directions.

Introduction: Several RCT studies have been conducted to evaluate the effect of FMT in IBS patients, where some show partial effectiveness, and others show minor differences compared to placebo. These inconsistencies, combined with ongoing safety concerns and uncertainty regarding microbiome-mediated mechanisms, prompted this scoping review. This review may stimulate further research and encourage larger, more comprehensive trials.

Methods: The review encompassed a comprehensive search across multiple databases, including MEDLINE, Embase, and Scopus. The initial search was conducted in 23 September 2023 using multiple search criteria and limiters (e.g., English language, published from 1 January 2018, and excluding animal studies). An updated search was conducted in 18 August 2026 using the same search strategy, with nine additional initial records.

Results: The search yielded 11 RCTs investigating FMT as a potential therapeutic intervention for IBS. The RCTs demonstrated heterogeneous results in symptom improvement compared to placebo. Notably, 57.1% of FMT-treated patients achieved a clinical response at week 12, accompanied by reductions in IBS-SSS scores. Mixed findings included limited long-term FMT effectiveness, transient symptom reduction, and instances where FMT did not significantly outperform placebo. Adverse events varied, ranging from mild and transient to infections, with consistent positive effects of FMT on gut microbiota diversity and composition noted across studies.

Conclusions: FMT shows promise for IBS treatment, yielding positive outcomes in symptom relief and microbiota changes. However, challenges in donor selection, placebo effects, and safety require further exploration. Future research should refine treatment protocols, examine microbial markers, and conduct large-scale trials to establish FMT's efficacy and safety in IBS.

Keywords: Faecal Microbiota Transplantation; Irritable Bowel Syndrome; Randomised Controlled Trials; Scoping Review; Therapeutic Outcome

Abbreviations: IBS: Irritable bowel syndrome; FMT: faecal microbiota transplantation; JBI: Joanna Briggs Institute; BMI: Basal mass index

Introduction

Background of irritable bowel syndrome

Irritable bowel syndrome (IBS) is a chronic functional gastrointestinal disease that affects more than 10% of the population and is considered as a massive economic burden on the healthcare system [1]. A case-control study emphasizes that

individuals with IBS are frequently insufficiently managed by the healthcare system [2]. The study highlights the significant impact of both Sense of Coherence and confidence, stressing the necessity to address these factors for improved productivity and quality of life in IBS patients [2]. IBS is classified into three main types: diarrhea-predominant (IBS-D), constipation-predominant

(IBS-C), and mixed IBS (IBS-M), each characterized by distinct patterns of bowel habits [3]. The aetiology of IBS has been found to be associated to various factors; these include intestinal permeability, gut immune function, motility, visceral sensation, brain-gut interactions, psychosocial status, and alterations in the gut microbiome [4]. The latter is also called dysbiosis, which is an imbalance of the distribution of microbiota in the gut [5]. Although dysbiosis does not have a clear definition [6], increased microbial diversity and specific gut microbiota have been associated with a lower likelihood of IBS [7,8].

Current treatments for IBS mainly involve dietary and pharmacological interventions, yet many patients experience incomplete symptom relief and recurrent episodes [4]. This lack of definitive treatment underscores the necessity for more comprehensive interventions to address the complexity of IBS. The American College of Gastroenterology guidelines currently recommend against the use of faecal microbiota transplantation (FMT) for IBS due to the inconsistent evidence of symptom relief [9]. This highlights the need for further research into its potential therapeutic role.

Faecal microbiota transplantation for IBS

Faecal microbiota transplantation is a potential treatment for IBS that involves the transfer of beneficial gut microbiota from a healthy donor to an IBS patient, with the objective of rectifying dysbiosis and potentially alleviating symptom [8,10]. FMT has demonstrated established efficacy in recurrent *Clostridioides difficile* infection and is being investigated in other conditions including inflammatory bowel disease [11]. However, the safety and efficacy of FMT as an IBS treatment are still under investigation, necessitating further exploration of the current literature on the subject. Although some treatments such as probiotics have been associated with strong efficacy on major symptoms of IBS, IBS patients are likely to relapse in less than two months period [12]. In comparison, FMT may provide longer-term symptom relief. However, FMT generally shows less overall improvement of IBS symptoms compared to probiotics [13]. In a systematic review involving an analysis of case reports and case series on IBS, around 50% of patients showed clinical improvement with FMT [14]. Despite this positive outcome in non-randomized studies, RCT results have been inconclusive and inconsistent [14]. Furthermore, there are concerns regarding the side effects associated with FMT. A randomized clinical trial reported that >80% of patients who received FMT experienced side effects, including symptoms such as diarrhea and bloating [14]. Notably, about half of the patients who received the placebo also exhibited similar outcomes, except for diarrhea [14].

Gaps and objectives of the scoping review

Considering the numerous recent clinical trials conducted on IBS, this study aims to address research gaps by conducting a comprehensive scoping review of the existing literature on FMT as an intervention for IBS. This review encompasses a summary

of current RCT studies, with a focus on assessing safety, efficacy, microbiota correlations, and proposing future research directions in this rapidly evolving field. The scoping review is conducted in the Western Sydney area under the supervision of the School of Medicine of Western Sydney University.

Review question

Primary outcome

What is the current evidence from RCT studies regarding the safety and efficacy of FMT as an intervention for IBS?

Secondary outcome

What correlations exist between microbiota changes and clinical outcomes in the context of FMT for IBS, and what are the potential future research directions in this evolving field?

Methods

Search strategy

The proposed scoping review aligns with the 2020 version of the Joanna Briggs Institute (JBI) methodology and adheres to the structured framework designed for scoping reviews [15]. The scoping review involved a comprehensive search across a range of prominent databases, including MEDLINE, Embase, and Scopus, aimed at identifying studies that assess the effectiveness of FMT in patients diagnosed with IBS. The study employed all three databases and utilized Boolean operators like “AND” and “OR” as well as truncation and a mix of index terms, including MESH terms, to capture the most relevant studies. A sample search strategy using Ovid MEDLINE, one of the primary databases, is provided for reference. In the appendix of this paper (see Appendix I), a sample of the search strategy is presented, illustrating the keywords and operators utilized in the systematic literature search.

The search incorporated a range of relevant terms related to IBS, encompassing synonymous terms such as “Irritable Colon” and “Mucous Colitides”. This initial search yielded results that were combined and further refined to focus specifically on FMT by incorporating keywords such as “Transplant,” “Faecal Microbiota,” and related terms such as “faecal microbiome” and “faecal flora.” To ensure the inclusion of recent and relevant evidence, a combination of index terms and synonyms was employed to refine the search results, specifically targeting randomized controlled trials, and controlled clinical trials. Key terms such as “randomized controlled trial,” “randomised,” “placebo,” and “drug therapy” were utilized. Filters and index terms were thoughtfully utilized for precise inclusion criteria. These measures excluded animal studies, ensuring a focus on human-based research. Additionally, filters were applied to limit the search to studies published from 1 January 2018 onwards to capture research with improved methodologies for donor selection and FMT administration. A language filter was also employed to exclude non-English studies, enhancing result accuracy by mitigating potential representation

issues in other languages. The search strategy was not further refined to include terms related to effectiveness and treatment outcomes. This decision was made considering that most randomized trials inherently focus on therapeutic outcomes. The same search strategy was adapted for the other two databases, with slight modifications made to align with each database's specifications, particularly in the context of narrowing the search to RCT studies.

Study Criteria

The scope of this research has been divided into various criteria which is divided into three sections, including criteria for the design of the studies based on guidelines for functional gastrointestinal disorders clinical trials [16], donors-based criteria as per the guidelines of the European Consensus [17]. Additionally, patient selection criteria have been defined to ensure the accurate diagnosis of IBS based on the ROME III or IV criteria, and to minimize potential inaccuracies related to other medical conditions that might be influenced by FMT [18]. Although the updated Rome V criteria were published in 2026, their introduction is not expected to substantially affect patient selection because most trials enrolled patients with moderate-to-severe IBS symptoms [19]. The three criteria sections are as follows:

Study Design Inclusion Criteria

- a) Articles published from 1 January 2018 onwards to ensure the review's currency.
- b) Priority given to randomized clinical trials.
- c) Studies included if they provided a clear description of participant allocation through randomization and employed appropriate blinding methods.
- d) Inclusion of both a placebo group and an FMT intervention group in the study design.
- e) Studies assessing symptomatic improvement as a clear intervention outcome.
- f) Inclusion of studies conducted in the English language.

Inclusion Criteria for Donor in studies:

- I. Donors should have no history of gastrointestinal disorders (e.g., IBS, IBD), chronic constipation, or metabolic issues affecting gut health.
- II. No history of neurological or psychiatric conditions.
- III. Basal mass index (BMI) should fall within the normal range ($18.5 \leq \text{BMI} \leq 30$).
- IV. Comprehensive blood and stool testing is required to screen for potential transmittable diseases.

V. No exposure to antibiotics, immunosuppressant therapy, or chemotherapy within the past 3 months.

VI. No history of or known exposure to infectious diseases like HIV, HBV, HCV, syphilis, or other transmissible infections.

VII. Absence of ongoing or recent systemic infections at the time of donation.

VIII. Avoidance of risky behaviors such as illegal drug use or engaging in high-risk sexual activity that could increase disease transmission risk.

Criteria for participants of the trials

Inclusion Criteria:

- a) Adults aged 18 to 75 years.
- b) Participants met IBS diagnostic criteria as per ROME III or ROME IV.

Studies with participants of concerning features suggesting organic diseases mimicking IBS were excluded:

- a. Unexplained weight loss.
- b. Evidence of gastrointestinal bleeding.
- c. Unexplained iron-deficiency anaemia.
- d. A family history of specific organic gastrointestinal diseases.

Positive results on specific diagnostic tests including:

- I. Complete blood cell count
- II. C-reactive protein
- III. Faecal calprotectin levels
- IV. Serologic testing for celiac disease
- V. Age-appropriate colorectal cancer screening

Study Navigation and Selection

The study utilized EndNote (version 20, released in 2020) as the primary tool for systematically collecting, managing, and organizing relevant evidence. Studies were imported from three databases, as mentioned in the search strategy section, including their titles, abstracts, and citations in the Vancouver style. The software was employed to group the studies based on their respective origin databases. Initial duplicates were removed using EndNote's automated features, followed by a manual check to eliminate any remaining duplicates. Screening of titles and abstracts was conducted to exclude studies that were deemed irrelevant. Lastly, full-text screening was performed to determine which studies would be considered for inclusion in the review (Figure 1).

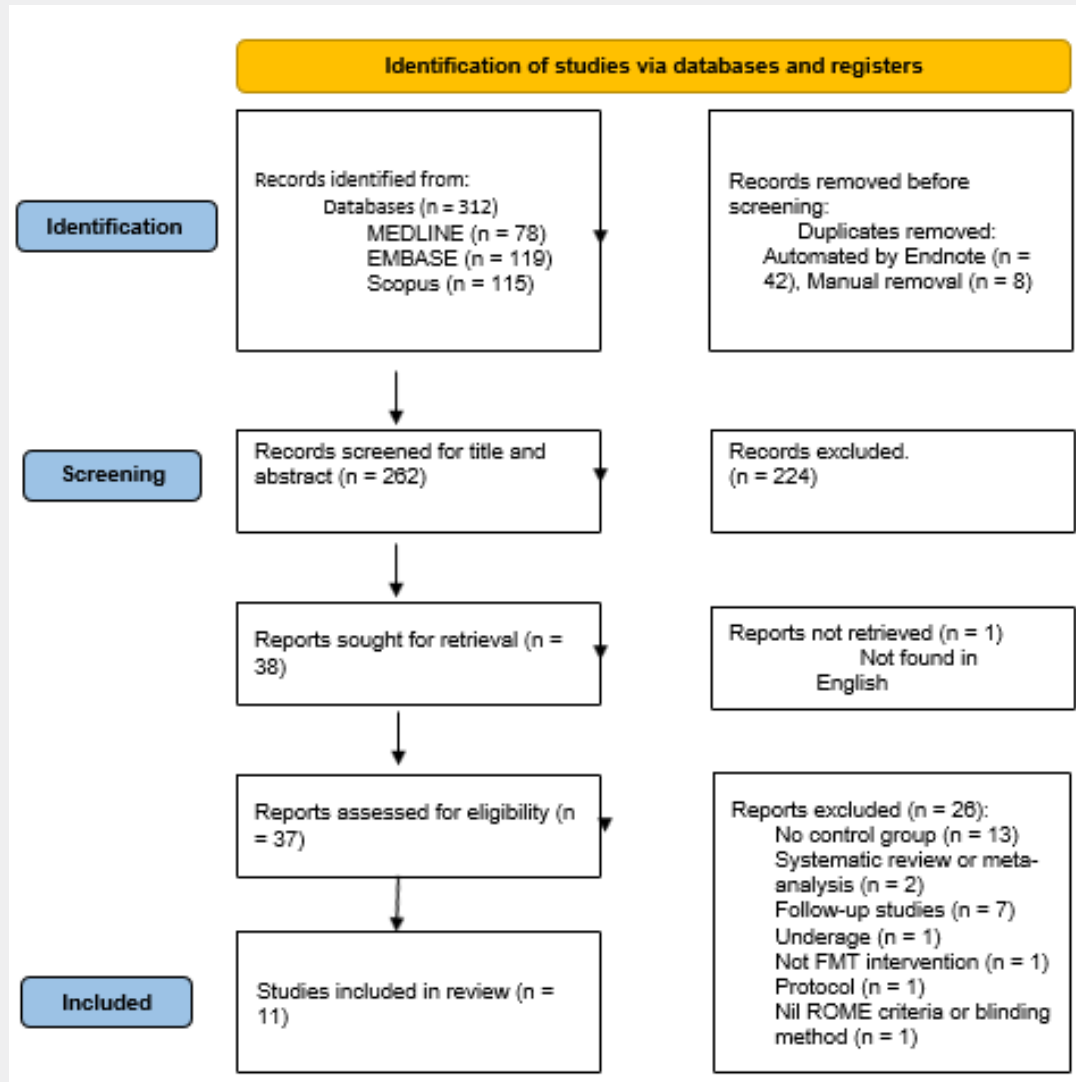


Figure 1: PRISMA flow diagram.

Data Extraction

JBIC data extraction methods were employed for the retrieval of data [15]. The information extracted from studies included elements such as the first author's name, publication year, study design, and primary and secondary outcomes. A detailed table presenting the extracted data can be found in the results section. It is noteworthy that the data extraction methods were adjusted as necessary from the JBI methodology to align with the specific needs of this review (Table 1 & Table 2).

Results

Characteristics of included RCT studies

Study Selection Flowchart and Data Extraction Tables: A PRISMA flowchart is shown below to summarise the selection of the studies [20].

Setting and Participant Characteristics: Most studies utilized web-based systems or randomized blocks organized by non-involved personnel, contributing to effective masking and blinding of researchers and participants [21-25, 28-31]. One study employed randomization to minimize selection bias but lacks details on the method used. Another study used computer software for randomization, with researchers blinded, but with no mention of external personnel involvement [27]. The participant numbers varied across studies, with the majority involving around 50 participants [22, 24, 25, 27-29, 31]. Two studies included fewer than 20 subjects while two studies had larger cohorts of 165 and 83 participants [21, 31]. The criteria for participation were well-defined, with all studies incorporating ROME III or IV as the inclusion criteria. Most studies concentrated on specific subtypes of IBS, particularly severe to moderate cases with some excluding IBS-C [24-26, 28, 29, 31].

Table 1: Representing Design and Features of RCT Studies.

n	Study Design	Aims	Participants and criteria	FMT Intervention				
				Groups	Measurements	FMT donor	Route of administration	Duration
El-Salhy M, Norway, 2020.21	RDBPCS	To clarify FMT's impact on IBS symptoms.	165 patients Criteria: Age: 18 - 85, ≥175 on IBS-SSS, ROME IV criteria	55 in placebo (Own faeces), 54 in 30g FMT, 55 in 60g FMT.	IBS-SSS, IBS-QoL, FAS, and others	One donor, athletic, regularly exercises, and healthy lifestyle	Gastroscopy to the distal duodenum	3 months post-procedural observations.
Halkjaer SI, Denmark, 2018.22	RDBPCS	To investigate FMT's effect on gut microbiota and clinical outcomes in IBS patients.	52 patients, Aged 18–60 years, IBS-SSS ≥175, ROME III criteria	26 in FMT and 26 in Placebo.	IBS-SSS and IBS-QoL. Keeping a daily diary of symptom, use of laxatives, and side effects.	Four donors, satisfactory selection criteria. Directed to maintain a healthy lifestyle and diet for the collection times.	Oral capsules	Observations of up to 6 months
Holster S, Sweden, Finland, and the Netherlands, 2019.23	Double-blind RCT	To explore FMT's effect on IBS symptoms, visceral sensitivity, and alteration of microbiota.	16 adults including all IBS subtypes, ROME III criteria	8 patients in allogenic group	GSRS-IBS, IBS-SSS, and VAS-scores.	2 Healthy donors selected with a satisfactory criterion	Colonoscopy	Observations of up to 6 months
				8 patients in autologous group				
Holvoet T, Belgium, 2020.24	RDBPCS	To determine the efficacy of FMT in patients with refractory IBS	62 patients, aged 18-75 years, with refractory IBS-D or IBS-M, ROME III criteria	43 in the FMT group 19 in the Placebo group	A daily symptom diary and IBS-QoL	Donors were two healthy adult males with sufficient donor characteristics	Gastroscopy to distal duodenum	Visits across 12 weeks. An assessment one-year post-procedure
Lahtinen P, Finland, 2020.25	RDBPCS	To investigate the efficacy of FMT compared to autologous placebo in treating IBS.	49 patients, aged 18-73 years, with refractory IBS-D or IBS-M, and ROME III confirmed diagnosis of IBS	23 in the FMT group and 26 in the placebo group.	IBS-SSS and IBS-QoL.	A single universal donor, young adult male who was in good general health and normal BMI, satisfactory for the donors' criteria	Colonoscopy	52 weeks including several follow ups
Lin H, China, 2021.26	Placebo-controlled RCT	Assessing FMT effectiveness and its impact on emotions in IBS-D patients with mild-modest anxiety and depression.	18 IBS-D patients with symptoms of anxiety and depression, age > 20 years, ROME III	Divided into FMT group and Control group (receiving blank capsules), each with 9 subjects	IBS-SSS and IBS-QoL. Hamilton Depression and Anxiety Rating Scale.	Healthy 36-year-old male, normal BMI and meets criteria	Oral capsules	Frequent follow-ups conducted over three months.

Tarek M, Norway, 2022.27	RDBPCS	To evaluate the efficacy and safety of FMT in patients with IBS and to compare its effects with placebo and autologous conditioned serum treatment.	43 Patients, aged 18–65 years, > 175 IBS-SSS score, ROME III	ACHIM, 30 g of donor-FMT or placebo (30 g of own), at a ratio of 1:1:1	IBS-SSS and SF-NDI	Healthy first-grade donors that are related to the subject. All donors have been screened to a sufficient criterion.	Gastrosco- py to the descending part of the duodenum	Follow ups of up to 24 weeks post-procedure.
Singh P, USA, 2022.28	RDBPCS	Compare engraftment after FMT in IBS-D with or without antibiotics and placebo. Evaluate IBS-SSS, IBS-QoL, and GIS changes.	44 patients aged 18 and 80, with IBS-D according to the ROME III criteria	FMT alone (11 subjects), R-FMT (11), CM-FMT after (10), placebo glycerol with brown colouring (12)	IBS-SSS and IBS-QoL	Six donors of healthy lifestyle and sufficient donor criteria	Oral capsules	10 weeks follow up
Yau YK, Hong Kong, 2023.29	RDBPCS	Evaluation of the safety and efficacy of FMT for the treatment of IBS-D and investigation of changes in the gut microbiota	56 patients, age > 18, with IBS-D, ROME III	Allocation of 1:1 ratio to either FMT or placebo	IBS-SSS and IBS-QoL	Two healthy donors, unrelated to the participants, with satisfactory criteria	Gastroscopy to the distal duodenum	Visits across 12 weeks.
Johnsen PH, Norway, 2018.30	RDBPCS	Investigation of the efficacy and safety of FMT for patients with moderate-to-severe IBS	83 Subjects, aged 18-75, with IBS-SSS of ≥175, ROME III criteria	FMT group: 55, Placebo (own faeces) group: 28	IBS-SSS and questionnaires assessing fatigue and quality of life.	Two healthy donors with satisfactory criteria	To the caecum via endoscope.	Assessments and follow ups of up to 12 months after FMT
Aroniadis OC, USA, 2019.31	Double blinded, randomised, placebo-controlled crossover trial	Examine if FMT for IBS-D improves symptoms compared to a placebo.	48 participants, aged 18–65, IBS-D of IBS-SSS > 175, ROME III criteria	Assigned in a 1:1 ratio in either FMT group or placebo group (placebo capsules contained a brown pigment)	IBS-SSS and IBS-QoL	Four donors who were sufficiently screened and selected	Oral capsules	24 Weeks, cross-over of two 12-week with several follow ups.

Table 2: Representing Primary and Secondary Outcomes of RCT Studies.

First Author, Country Setting, and Year	Groups	Primary Outcome	Secondary Outcomes		
		Effectiveness on IBS symptoms	Side effects	Change in microbiota	Quality of life
El-Salhy M, Norway, 2020.21	55 in placebo (Own faeces), 54 in 30g FMT, 55 in 60g FMT.	> 50% of the FMT group showed significant improvements in abdominal symptoms, fatigue, and quality of life regardless of the IBS subtype.	Mild intermittent abdominal pain, diarrhea, or constipation occurred in the first 2 days after FMT.	Higher concentrations of Alistipes spp. and Lactobacillus spp. were inversely correlated with the IBS-SSS score.	Included in primary outcomes
Halkjaer SI, Denmark, 2018.22	26 in FMT and 26 in Placebo.	All groups showed improvements in IBS-SSS scores. However, more significant improvements were seen in the placebo group.	70% of all participants experienced side effects, including: abdominal pain, bloating, nausea, and headache	FMT increased microbiota diversity which was similar to donors' biodiversity.	Placebo group showed greater improvements in IBS-QoL scores than FMT group
Holster S, Sweden, Finland, and the Netherlands, 2019.23	8 in allogenic group 8 in autologous group	FMT group showed a significant decrease in GSRS-IBS scores compared to baseline scores. Both groups showed a decrease in IBS-SSS scores.	Side effects were observed in Most patients but were higher in the placebo group. No serious adverse events.	No change in microbiota diversity was observed.	IBS-QoL scores increased significantly in the allogenic group.
Holvoet T, Belgium, 2020.24	43 in the FMT group 19 in the Placebo group	Relief from general IBS symptoms achieved at 3 months post FMT in 56% of patients compared to 26% in the placebo group.	No mention of side effects	The microbial diversity of donors was considerably higher than that of IBS patients at baseline.	The FMT group had a significantly higher mean improvement in the IBS-related quality of life.
Lahtinen P, Finland, 2020.25	23 in the FMT group 26 in the placebo group.	The FMT group had a temporary improvement in IBS-SSS at 12 weeks, but the improvement did not last throughout the 52-week follow-up.	35% experienced mild, transient adverse events post-FMT, with similar occurrences in FMT and placebo groups.	In FMT-treated patients, the microbial composition shifted to mirror that of the donor, and stool water content markedly decreased compared to baseline.	Both groups showed significant 12-week improvement, transiently.
Lin H, China, 2021.26	9 in FMT group and 9 in control group	FMT significantly reduced IBS-SSS scores by approximately 57% compared to the control.	No mention of side effects	FMT led to favourable shifts in gut microbiota, enhancing beneficial genera and improving faecal consistency.	Compared to placebo, FMT treatment led to a significant decrease in anxiety and depression symptoms, alongside an improvement in IBS-QoL scores.
Tarek M, Norway, 2022.27	43 Patients, divided, at a ratio of 1:1:1 in ACHIM, 30 g of donor-FMT or placebo (30 g of own),	The IBS-SSS scores reduced by about 30% in all groups.	Mild gastrointestinal symptoms with similar occurrence across all three subgroups. No serious adverse events	Significant gut microbiota profile changes observed in active treatment groups compared to no changes in the placebo group	The SF-NDI score showed a slight reduction, with similar decreases across all groups.
Singh P, USA, 2022.28	FMT alone (11 subjects), R-FMT (11), CM-FMT (10), placebo glycerol with brown colouring (12)	IBS-SSS scores slightly decreased in all; FMT-alone group had the least significant reduction.	~15% of adverse events across all groups including 3 infections of oral and genitourinary origins No serious adverse events	The FMT-alone group exhibited more bacterial engraftment, but it wasn't significant for effective relief compared to other groups.	Improvements in IBS-QoL score were seen in all groups with no differences.

Yau YK, Hong Kong, 2023.29	56 patients allocated in a 1:1 ratio to either FMT or placebo	FMT recipients showed significant IBS-SSS score reduction and symptom improvement at week 12, compared to less prominent changes in the placebo group.	Adverse events, unrelated to interventions, were experienced by 20 subjects at similar rates in both groups. No serious adverse events	FMT recipients had distinct microbiota changes, including increased <i>Lawsonibacter</i> , <i>Ruminococcus bicirculans</i> , <i>Odoribacter</i> , and decreased <i>Ruminococcus gnavus</i> , <i>Streptococcus mitis</i> .	There was no significant difference in IBS-QoL and GAD-7 score between the groups at week 12
Johnsen PH, Norway, 2018.30	FMT group: 55, Placebo group: 28	A >75-point reduction in IBS-SSS score occurred in about half of the active treatment group versus approximately one-third of the placebo group at 12 months.	One serious post-FMT adverse event requiring admission, involving nausea and vertigo. Mild symptoms occurred in both groups. No long-term effects	Not included in this study	FMT significantly enhanced IBS-QoL scores in moderate to severe IBS-D patients compared to placebo at 6 and 12 months. (Secondary end point study) ³⁰
Aroniadis OC, USA, 2019.31	48 subjects divided in a 1:1 ratio in either FMT group or placebo group	There was no significant difference in IBS-SSS at 12 weeks between the groups. Placebo first followed by FMT capsules continued to improve between 12 weeks and 24 weeks, compared to the FMT-first group who plateaued.	Adverse events related to the intervention did not differ between groups, with infrequent severe events, and no recorded FMT-related life-threatening events.	Microbiota analysis revealed no significant enrichment of specific bacterial genera in responders, but a notable increase in similarity between patient and donor microbiomes occurred after FMT.	Both groups showed improvement from baseline to week 12 in IBS-QoL

Abbreviations for tables 1 & 2: RDBPCS: Randomized, Double-Blind, Placebo-Controlled Study, IBS-QoL: IBS-Specific Quality of Life, IBS-SSS, IBS Severity Symptom Scale, FMT: Faecal Microbiota Transplantation, IBS: Irritable Bowel Syndrome, IBS-M: Mixed, IBS-D: IBS Diarrhea Predominant, BMI: Basal Mass Index, FAS: Fatigue Assessment Scale, GSRS-IBS: gastrointestinal symptom rating scale, SF-NDI: Short form of Nepean Dyspepsia Index, ACHIM: anaerobically cultivated human intestinal microbiota, CM-FMT: Ciprofloxacin and Metronidazole, R-FMT: Rifaximin.

Donor Characteristics and FMT Administration

Donor criteria of the included studies was sufficient for inclusion in review, except that some studies deviated slightly regarding BMI criteria [28, 29]. One study reported using a super donor for FMT [21]. Treatment methods varied, including gastroscopy [19, 22, 25, 27] colonoscopy [21, 23, 28] and oral capsules for transplant delivery [22, 26, 28, 31]. Placebo methods varied across studies, with some using the patient's own feces [21, 23-25, 27, 29, 30] others employing faeces-free capsules [24, 26, 29] and one study not specifying the placebo type [22].

Outcomes in Symptomatic Relief

The RCT results were heterogeneous, with some trials demonstrating clinically significant symptom improvement while others reported no superiority over placebo. One study demonstrated positive results, with 57.1% of FMT-treated patients achieving a clinical response at week 12, accompanied by a notable reduction in IBS-SSS scores.²⁹ Two RCTs provided evidence of the benefits of FMT on mental health, showing significant improvements in anxiety and depression symptoms, along with notable reductions in IBS-SSS scores [26, 27]. In another study, approximately 50% of the FMT group exhibited significant improvements in abdominal symptoms, fatigue, and quality of life, surpassing lower rates in the placebo group [21]. Additionally, a trial reported that the allogenic FMT group experienced a significant decrease in GSRS-IBS scores and increased quality-of-life scores compared to the placebo group [23]. Johnsen et al. reported significant improvement in symptoms in the FMT group, with follow up extending up to 12 months [30].

On the other hand, mixed findings were reported across several RCTs. One article showed limited long-term effectiveness of FMT and emphasized the importance of donor selection, while another reported a transient reduction in IBS-SSS following FMT [25]. Two studies found no significant differences among subgroups, indicating that FMT did not significantly improve clinical outcomes compared to placebo [27, 28]. Another RCT reported a significant enhancement in IBS-QoL at six months and reported a notable decrease in IBS-SSS scores post-FMT, but symptom reduction was more prominent in the placebo [22]. Negative outcomes were reported in another trial, indicating that FMT did not lead to more remarkable improvement in symptoms or clinical response compared to the placebo group [31]. Furthermore, no significant differences were observed in primary and secondary outcomes, including quality of life, anxiety, depression, and fatigue.³¹

Adverse Events

In the initial days following FMT, mild intermittent abdominal pain, diarrhea, or constipation was reported, indicating a temporary discomfort [21]. Conversely, a substantial 70% of all participants in another study experienced side effects, including abdominal pain, bloating, nausea, and headache [22]. Side effects were observed in most patients in a separate study, with a higher incidence in the placebo group [23]. Notably, two studies did not explicitly mention side effects [24, 26]. Further investigation into adverse events revealed that one study reported 35% of participants experiencing mild, transient adverse events post-FMT, with similar occurrences in both the FMT and placebo groups [25]. Another study noted mild gastrointestinal

symptoms with comparable frequency across all three subgroups, highlighting the relatively consistent occurrence of mild side effects [27]. Additionally, approximately 15% of adverse events were reported across all groups in a different study, including three infections of oral and genitourinary origins; however, no serious adverse events were recorded [28]. In contrast, adverse events unrelated to interventions occurred at similar rates in both groups in another study, with no serious adverse events reported [29].

One study reported that adverse events related to the intervention did not differ between groups, with infrequent severe events and no recorded FMT-related life-threatening events [31]. Another study identified a serious post-FMT adverse event requiring admission, involving nausea and vertigo; however, mild symptoms occurred in both groups, and no long-term effects were observed [30]. No other serious adverse events were observed in any of the other trials.

Microbiome Changes

FMT demonstrated consistent positive effects on gut microbiota across the RCT studies, with increased diversity and a shift towards donor resemblance reported in various investigations [22, 25, 26]. Additionally, specific microbial changes, such as increased concentrations of *Alistipes* spp. and *Lactobacillus* spp., were inversely correlated with IBS-SSS scores in one study, while another study highlighted distinct changes in the FMT-alone group, indicating potential variations in bacterial engraftment efficacy. Furthermore, a shared observation across studies emphasized the higher baseline microbial diversity of donors compared to IBS patients [24, 25].

Discussion

Therapeutic Outcomes

The effectiveness of FMT in treating IBS varies across studies, with notable positive outcomes observed in several trials. For instance, a clinical response rate of 57.1% at week 12, coupled with a significant reduction in IBS-SSS scores, suggests a substantial improvement in symptoms among FMT-treated patients compared to the placebo group [29]. Moreover, mental health benefits, evidenced by improvements in anxiety and depression symptoms alongside reduced IBS-SSS scores, were consistent across two RCTs [26, 27]. Additionally, approximately 50% of the FMT group reported significant improvements in abdominal symptoms, fatigue, and quality of life, surpassing the placebo group [21]. Notably, a trial focusing on allogenic FMT highlighted a decrease in GSRS-IBS scores and increased quality-of-life scores, reinforcing the potential of FMT as a promising IBS treatment [23]. In contrast, studies with mixed or neutral findings underscored the limitations of FMT, emphasizing the importance of donor selection [24], and the transient nature of some therapeutic effects [25]. Donor-related factors may contribute to treatment response and warrant further investigation [21]. The role of

placebos, particularly the use of empty capsules as a control, raises questions about the psychological and physiological effects on IBS symptoms. The observed improvements in the placebo group in certain studies underscore the need to explore the psychological factors influencing symptom perception [31].

Safety of FMT

The safety profile of FMT in IBS patients varies across studies. Reports of adverse events, including mild gastrointestinal symptoms and infections, highlight the need for a comprehensive assessment of safety. Although most adverse events were mild and transient, further investigation is warranted to differentiate true side effects from placebo effects. Studies reporting no serious adverse events suggest that FMT in IBS is generally well-tolerated. However, the occurrence of serious adverse events requiring admission, such as nausea and vertigo, necessitates careful consideration of safety measures [30]. Despite donor screening, FMT carries a potential risk of transmitting infectious organisms, including multidrug-resistant organisms [32]. The Food and Drug Administration has issued safety alerts regarding infections associated with FMT, especially when considering FMT for non-life-threatening conditions such as IBS [32].

Microbiota associations

Microbiota changes associated with FMT demonstrate a consistent pattern of increased diversity and a shift towards donor resemblance [22, 25, 26]. Specific microbial changes, including elevated concentrations of *Alistipes* spp. and *Lactobacillus* spp., were inversely correlated with IBS-SSS scores, suggesting potential microbial markers for symptomatic relief [21]. The observation that FMT recipients had distinct microbiota changes, such as increased *Lawsonibacter* and *Ruminococcin bicirculans*, adds complexity to the understanding of bacterial engraftment efficacy [29]. Furthermore, a shared observation across studies emphasized the higher baseline microbial diversity of donors compared to IBS patients [21, 24, 25].

Limitations

Despite the promising findings, several limitations should be acknowledged. The included studies had small sample sizes and considerable methodological heterogeneity. Although most studies used similar patient selection criteria, they differed in FMT administration methods, donor selection and preparation, microbiome analysis techniques, and outcome assessment. These differences may affect the interpretation and comparability of the findings and warrant cautious generalization. In addition, title/abstract and full-text screening were conducted by a single reviewer, which can represent a potential limitation of the study selection process.

Future Recommendations

The necessity for additional investigation persists on several fronts within the context of FMT for IBS. Firstly, there is a need

to explore the potential impact of bowel preparation on FMT efficacy. Second, the placebo effect on IBS symptoms warrants thorough examination, considering observed improvements in the placebo group across select studies. To address uncertainty regarding efficacy in FMT's symptomatic relief effects for IBS, the recommendation stands for the implementation of larger controlled trials. Lastly, randomized trials focusing on the correlation between successful active FMT treatment and sustained long-term outcomes are pivotal to improve the understanding of FMT's efficacy in addressing IBS symptoms.

Conclusions

In conclusion, FMT may be a promising therapeutic option for IBS with several RCTs studies demonstrating positive outcomes in symptom relief and microbiota changes. Nonetheless, other RCTs showed unfavorable outcomes and mixed findings compared to the control groups. Other challenges related to donor selection, placebo effects, and safety considerations necessitate further exploration. Future research should focus on refining treatment protocols, investigating microbial markers, and conducting large-scale trials to establish the efficacy and safety of FMT in the context of IBS.

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