



DOSSIER · SUBSTANCE

Gut Microbiome

The gut microbiome is not a substance but an ecosystem—and the focal point for more health promises than any other topic in recent years. This page distinguishes what has actually been tested in humans from what is merely inferred from associations.

10,854

STUDIES IN
TOTAL

2,980

IN HUMANS

424

OF WHICH
CONTROLLED

1,795

IN ANIMALS

522

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

The gut microbiome at a glance

ORIGIN:

The gut microbiome is a complex ecosystem comprising trillions of microorganisms in the human intestine that break down dietary fibre, produce short-chain fatty acids, interact with the immune system, and influence the intestinal barrier. It varies more widely between individuals than genetic material and serves as a central focus in health research, though methodological challenges—such as the absence of a 'healthy microbiome' reference standard—persist.

STATE OF RESEARCH:

10,854 evaluated publications · 424 controlled human studies · 2,556 observational studies · 2,087 review articles · 1,795 animal studies · 321 cell culture studies

CURRENT EVIDENCE:

- **Intestinal barrier function** A randomised pilot study (2023) involving 30 patients with IBS-D showed improved intestinal permeability (in 81.5% of participants) and positively affected quality of life and stool consistency. Limited by an open-label design and lack of long-term data.
- **Faecal microbiota transplantation (FMT)** A meta-analysis (2022) with 505 participants found no significant global symptom improvement in IBS following FMT, but subgroup analyses revealed efficacy with defined donors and colonoscopic administration. Heterogeneous protocols and lack of standardisation limit the validity of these findings.
- **Inflammatory processes:** A Phase 2 study (2025) involving 56 patients with alcoholic liver disease showed a trend towards improved gut barrier function markers with the postbiotic ReFerm®, though no significant microbiota changes were observed. Small sample size and lack of blinding limit the results; clinical effects remain to be investigated.
- **Systemic diseases (Parkinson's)** A randomised study (2025) with 30 Parkinson's patients showed motor improvements after FMT, associated with increased *Faecalibacterium* and *Roseburia*. Small sample size and lack of long-term data are limitations. Causal relationships between microbiome changes and clinical outcomes in humans remain to be confirmed.
- **Microbiome modulation (kefir)** A study (2025) involving 21 female footballers showed that kefir increased microbial diversity and the abundance of *Akkermansia muciniphila*, correlating with changes in athletic performance markers. Lack of blinding and dietary control are limitations; the relevance for non-athletes is not examined.

LIMITATIONS:

- Most studies are small and homogeneous, limiting generalisability. Long-term data are often lacking, and the heterogeneity of microbiota analysis methods (e.g., 16S rRNA vs. metagenomics) complicates comparisons.
- Causal relationships between microbiome changes and clinical outcomes frequently remain unclear, as much of the data derive from association studies or preclinical models. Effects in humans have not been confirmed. Direct comparisons between intervention strategies (e.g., probiotics vs. polyphenol-rich extracts) are lacking.
- Probiotic effects are strain-specific; general statements about 'probiotics' are not robust. Additionally, probiotic administration after antibiotics may delay the return to the original gut flora in some cases.

ASSESSMENT:

The gut microbiome is a highly individualised ecosystem with effects on the intestinal barrier, inflammation, and systemic diseases shown in studies. While FMT shows potential in specific contexts, the strongest evidence for clinical efficacy remains to be established. Probiotic effects are strain-specific and not generalisable.

1. Key Points

The human gut harbours trillions of microorganisms that break down dietary fibre, produce short-chain fatty acids, interact with the immune system, and influence the intestinal barrier. Their composition varies more between individuals than genetic material does.

This very diversity poses a methodological challenge in the field: there is no 'healthy microbiome' as a reference standard. Deviations from an average provide little meaningful insight on their own, and the term **dysbiosis** describes an observation rather than a diagnosis.

2. What the Studies Show in Detail

The key human studies and most important reviews—organised by application area, including population, duration, preparation, outcome measures, and results, exactly as reported in the original publications. Numbers are included only where the study provides them.

Distribution of **controlled human studies** by application area—numbers are not additive, as a single study may be assigned to multiple areas:

APPLICATION AREA	CONTROLLED STUDIES
Gut and microbiome	422
Inflammatory processes	177
Safety and tolerability	162
Immune system	135

APPLICATION AREA	CONTROLLED STUDIES
Metabolism	134
Cognition and mental health	82
Fatigue and stress	74
Oncology	40

Gut Microbiome and Intestinal Barrier Function

In a randomised, placebo-controlled pilot study (2023) involving 30 patients with diarrhoea-predominant irritable bowel syndrome (IBS-D) and confirmed intestinal hyperpermeability (measured via radionuclide tracer), a multi-strain probiotic (preparation: 2 capsules/day; exact strains not specified in the abstract) was administered for 30 days. The primary endpoint was the change in intestinal permeability. The study showed an improvement in 81.5% of participants (n=27, Full Analysis Set), with 37% showing normalisation of permeability. Mean permeability decreased significantly (baseline minus day 30: 3.4; 95% CI: 1.7–5.2). Secondary outcomes included improvements in IBS-QoL total scores (day 30 minus baseline: 8.0; 95% CI: 3.0–12.9) and stool consistency (Bristol Stool Scale). The study did not isolate the effects of individual probiotic strains. Limitations included the lack of blinding and the lack of long-term follow-up ¹¹.

A meta-analysis (2022) of 7 randomised controlled trials (RCTs) with 9 cohorts and 505 participants examined the efficacy of faecal microbiota transplantation (FMT) in IBS. The primary endpoint was global symptom improvement at 12 weeks (short-term) and 12 months (long-term). No significant difference was found between FMT and placebo (RR 0.63; 95% CI: 0.39–1.00 and RR 0.88; 95% CI: 0.53–1.45, respectively). Subgroup analyses revealed significant short-term symptom improvement in studies with low risk of bias (RR 0.53; 95% CI: 0.35–0.81), defined donors (RR 0.31; 95% CI: 0.14–0.72), and FMT via colonoscopy (RR 0.66; 95% CI: 0.47–0.92). Limitations included heterogeneity in FMT protocols (donor selection, route of administration) and the lack of standardisation in microbiota analyses ¹⁰.

In a randomised, controlled study (2025) involving 21 professional female footballers (aged 18–29 years), the impact of daily consumption of 200 mL kefir over 28 days on microbiota composition (16S rRNA sequencing) and athletic performance (30–15 Intermittent Fitness Test) was investigated. The kefir group showed a significant increase in microbial diversity (Shannon and Chao1 indices) and abundance of *Akkermansia muciniphila* and *Faecalibacterium prausnitzii*. These bacteria correlated positively with VO_2max ($\text{mL}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$) and end speed (km/h) in this cohort. Limitations included the small sample size, lack of blinding, and the absence of standardised dietary control ¹³.

A randomised, double-blind study (2025) involving 72 patients with Parkinson's disease examined the combined effects of propionic and butyric acid (SCFAs) and the prebiotic 2'-fucosyllactose over 6 months. Primary endpoints were motor (UPDRS-III) and non-motor symptoms. The study showed clinically relevant improvements in motor function (reduction in levodopa dosage) and laboratory-measured modulation of peripheral immune responses (e.g., mitochondrial respiration in immune cells) for the combination. In gut organoids (preclinical), the microbiota altered inflammation- and barrier-associated gene expression patterns. The design did not allow isolation of the effects of propionic or butyric acid alone. Limitations included the absence of a placebo group without the SCFA/prebiotic combination and the lack of a separate SCFA-only arm ¹⁵.

Gut Microbiome and Inflammatory Processes

A systematic review (2023) summarises observational studies on the role of the intestinal barrier in chronic inflammatory diseases. Dysfunctions of the epithelial barrier (e.g., reduced tight junction proteins) lead to a 'leaky gut', facilitating the translocation of bacterial endotoxins (e.g., LPS) and pro-inflammatory cytokines. This association has been observed in metabolic dysfunction-associated steatohepatitis (MASH), primary sclerosing cholangitis, and extraintestinal conditions such as rheumatoid arthritis. In preclinical models, translocated endotoxins activate CD14 receptors in the liver, suggesting a potential pathway; this effect has not been investigated in human studies, and the relevance for humans remains unclear. A limitation is the lack of causal evidence in human interventional studies, as data are predominantly derived from animal models or association studies.

In a randomised, controlled phase-2 study (2025) involving 56 patients with advanced alcoholic liver disease, the postbiotic ReFerm® (n=28) was tested against a standard diet (Fresubin®, n=28) over 24 weeks. The primary endpoint was a $\geq 10\%$ reduction in the fibrosis marker $\alpha\text{-SMA}$ in liver biopsies. This was achieved in 29% of the ReFerm® group vs. 14% of the control group (OR=2.40; 95% CI: 0.63–9.16; p=0.200). Secondary outcomes showed a trend towards improved gut barrier function but no significant changes in microbiota composition. The study provides preliminary evidence for a potential effect on liver fibrosis markers, though clinical outcomes such as disease progression or symptoms were not assessed. Limitations included the small sample size, lack of blinding, and the absence of specific microbiota taxa identified as biomarkers.

At the taxa level, *Proteobacteria* and *Escherichia-Shigella* were increased, while *Firmicutes*, *Faecalibacterium*, and *Prevotella* 9 were reduced in the observational sarcopenia studies included. Limitations included heterogeneity across studies (different definitions of sarcopenia, age groups) and the lack of interventional data to establish causality ⁹.

HYPOTHESIS The observed microbiota changes in sarcopenia and liver fibrosis suggest a shared pathomechanism: impaired gut barrier function enables translocation of endotoxins, triggering systemic inflammatory processes.

Gut Microbiome and Systemic Diseases

A randomised, double-blind study (2025) involving 131 patients with bipolar disorder (BD) or schizophrenia-spectrum disorder (SSD) examined the effects of the multi-strain probiotic Ecologic BARRIER over 3 months. Primary endpoints were psychiatric symptoms (Brief Psychiatric Rating Scale) and cognitive function (Brief Assessment of Cognition in Schizophrenia). Limitations included the short intervention duration and the lack of analysis of specific microbiota taxa.

In a randomised, controlled study (2025) involving 30 patients with mild-to-moderate Parkinson's disease (Hoehn-Yahr stages I-III), fresh FMT via colonoscopy was tested against placebo (saline solution). The FMT group showed improvements in UPDRS-III scores (group×time effect: B=-8.80; 95% CI: -13.79 to -3.81) and quality of life (PAC-QOL: B=-29.67; 95% CI: -45.35 to -13.98). Metagenomic analyses revealed an increase in *Faecalibacterium* and *Roseburia*, while *Escherichia-Shigella* decreased. Limitations included the small sample size and the lack of long-term follow-up ¹².

A review (2022) summarises preclinical and clinical data on the role of gut dysbiosis (GD) in neuropsychiatric disorders among various microbiota-related interventions. GD is associated with overstimulation of the hypothalamic-pituitary-adrenal (HPA) axis and the neuroimmune system, linked to increased pro-inflammatory cytokines, oxidative stress, and mitochondrial dysfunction. In schizophrenia and depression, reduced abundances of *Faecalibacterium* and *Roseburia* and elevated *Proteobacteria* levels were observed. A limitation is the lack of RCTs demonstrating a causal link between microbiota modulation and clinical outcomes in these disorders ²¹.

Overall Picture

The available studies indicate that modulation of the gut microbiome—whether through probiotics, prebiotics, FMT, or SCFAs—is associated with improvements in intestinal barrier function and inflammatory parameters. Evidence points particularly to the reduction of endotoxins (e.g., LPS) and stabilisation of tight junction proteins, suggesting a shared mechanism in preclinical models of liver disease, IBS, and neurodegenerative disorders. However, direct comparisons between different intervention strategies and long-term clinical data on sustainability are often lacking.

Significant gaps remain in the standardisation of microbiota analyses (e.g., 16S rRNA vs. metagenomics) and the definition of 'healthy' donor microbiota for FMT. Furthermore, most studies are conducted in small, homogeneous populations, limiting generalisability.

Methodology of the evidence base

The included studies predominantly feature controlled designs (including some randomised controlled trials) with intervention durations ranging from 4 weeks (e.g., kefir study ¹³) to 24 months (e.g., FMT in melanoma ⁸). Typical endpoints include changes in microbiota diversity (α/β -diversity), clinical scores (e.g., UPDRS-III, IBS-SSS), and biomarkers (e.g., zonulin, SCFAs). Common weaknesses include the absence of placebo-controlled groups in some studies (e.g., ¹¹), short follow-up periods (usually <6 months), and heterogeneity in microbiota analysis methods. Additionally, dose-response relationships are rarely investigated, and most studies lack detailed taxa-specific evaluations (e.g., only at the phylum level).

What the case of probiotics teaches us

Probiotics are widely assumed to be beneficial—particularly when used alongside antibiotics. However, THIS VERY APPLICATION HAS BEEN CALLED INTO QUESTION in controlled studies: recovery of the original gut flora may even be delayed by probiotic administration.

This is not an argument against probiotics as a whole. It does, however, demonstrate that effects are STRAIN-SPECIFIC

: what holds true for one strain in a given indication does not apply to 'probiotics' as a group. Products without specified strains and quantities cannot be linked to any study.

3. How Robust the Research Is

The number of controlled studies is high but spans a wide range of interventions: dietary changes, dietary fibre and prebiotic fibres, individual bacterial strains, combination products—and **faecal microbiota transplantation (FMT)**, in which the gut flora of a healthy donor is transferred.

Faecal microbiota transplantation is the best-supported intervention and, at the same time, the most revealing: it demonstrates that altering the gut flora can have clinical effects. However, this does not imply anything about over-the-counter products—the transfer of an entire microbial community is fundamentally different from administering individual strains.

4. What Is Often Claimed—and What the Data Show

STATEMENT	EVIDENCE
'The gut is the root of all disease'	Links between the microbiome and numerous diseases are well established. Whether the alteration is a cause or consequence remains unclear in most cases
Gut-brain axis	An active field with robust mechanisms demonstrated in animal trials and initial controlled human studies. Too early for therapeutic conclusions.
Consumer microbiome testing	The composition varies significantly depending on diet, time of day, and sampling. A single finding hardly justifies a recommendation for action.

STATEMENT	EVIDENCE
Faecal microbiota transplantation	The most well-documented intervention—but a medical procedure with its own risks, not a nutritional supplement concept.

5. The Most Robust Studies

Ranked by evidential strength, not by prominence. The full evaluation includes significantly more studies; these are the most reliable.

Controlled Human Trials

- ¹ Endotoxins and Non-Alcoholic Fatty Liver Disease (2021)
- ² Probiotic supplementation during antibiotic treatment is unjustified in maintaining the gut microbiome diversity: a systematic review and meta-analysis (2023)
- ³ Inulin-type fructans and 2'-fucosyllactose alter both microbial composition and appear to alleviate stress-induced mood state in a working population (2023)
- ⁴ Sarcopenia in cirrhosis: Prospects for therapy targeted to gut microbiota (2023)
- ⁵ Does the microbiota boost immunotherapy? A meta-analysis explores faecal microbiota transplantation and immune checkpoint inhibitors (2025)
- ⁶ Guidance for Faecal Microbiota Transplantation Trials in Ulcerative Colitis: The Second ROME Consensus Conference (2025)
- ⁷ Consecutive faecal microbiota transplantation for metabolic dysfunction-associated steatotic liver disease: a randomised controlled trial (2025)
- ⁸ Improved survival in advanced melanoma patients treated with faecal microbiota transplantation using healthy donor stool in combination with anti-PD1 (2025)
- ⁹ Gut microbiota in patients with sarcopenia: a systematic review and meta-analysis (2025)
- ¹⁰ Faecal microbiota transplantation in irritable bowel syndrome: A meta-analysis of randomised controlled trials (2022)
- Probiotic Formulation for Patients with Bipolar or Schizophrenia Spectrum Disorder: A Double-Blind, Randomised, Placebo-Controlled Trial (2025)
- ¹¹ Effect of a Multistrain Probiotic on Intestinal Permeability in Patients with Diarrhoea-Predominant Irritable Bowel Syndrome: A Pilot Study (2023)
- ¹² Colonoscopic Faecal Microbiota Transplantation for Mild-to-Moderate Parkinson's Disease: A Randomised Controlled Trial (2025)
- ¹³ Effects of Kefir Consumption on Gut Microbiota and Athletic Performance in Professional Female Football Players: A Randomised Controlled Trial (2025)
- ¹⁴ Effect of Antioxidants on the Gut Microbiome Profile and Brain Functions: A Review of Randomised Controlled Trial Studies (2025)
- ¹⁵ Supplementation with short-chain fatty acids and a prebiotic improves clinical outcome in Parkinson's disease: a randomised, double-blind, prospective study (2025)
- The postbiotic ReFerm® versus standard nutritional support in advanced alcohol-related liver disease (GALA-POSTBIO): a randomised controlled phase 2 trial (2025)
- A systematic review and meta-analysis of clinical trials on the effects of glutamine supplementation on gut permeability in adults (2024)
- ¹⁶ Faecal microbiota transplantation plus immune checkpoint inhibitor rechallenge in patients with advanced non-small cell lung cancer: a single-arm exploratory study (2025)
- ¹⁷ *Akkermansia muciniphila* in neurological disorders: mechanisms and therapeutic potential via the gut-brain axis (2025)
- ¹⁸ Gut microbiota and metabolic responses to a 12-week caloric restriction combined with strength and HIIT training in patients with obesity: a randomised trial (2024)
- A randomised controlled trial of the effects of galacto-oligosaccharides on the gut-brain axis in young females (2025)
- ¹⁹ Faecal microbiota transplant to eradicate gastrointestinal carriage of antibiotic-resistant organisms (FERARO): a feasibility randomised controlled trial (2025)
- ²⁰ Effects of short-chain fatty acid-producing probiotic metabolites on symptom relief and intestinal barrier function in patients with irritable bowel syndrome (2025)

6. Summary

Evidence confirms that modulation of the gut microbiome—through probiotics, prebiotics, faecal microbiota transplantation (FMT), or short-chain fatty acids—is associated with improvements in intestinal barrier function, inflammatory parameters, and systemic diseases. The most robust data pertain to reductions in endotoxins (e.g., LPS) and the stabilisation of tight junction proteins, suggesting shared mechanisms in liver disease, irritable bowel syndrome, and neurodegenerative disorders. FMT demonstrates the strongest evidence as a medical intervention but is not a nutritional supplement concept and carries risks. Probiotics exert strain-specific effects, and their outcomes cannot be generalised.

HYPOTHESIS The observed microbiota alterations in sarcopenia and liver fibrosis suggest a common pathomechanism: a compromised intestinal barrier enables the translocation of endotoxins, triggering systemic inflammatory processes. Additionally, the gut-brain axis may play a role in neuropsychiatric diseases, with preclinical data pointing to mechanisms such as HPA axis overstimulation and neuroinflammatory processes. However, direct human interventional studies that could confirm these hypotheses are still pending.

Future studies must address three key gaps: 1) standardisation of microbiota analyses (e.g., uniform methods such as metagenomics) and definition of a 'healthy' donor microbiota for FMT; 2) direct comparisons between different intervention strategies (e.g., probiotics vs. polyphenol-rich extracts) with dose-response relationships; and 3) long-term data on the sustainability of effects in larger, diverse populations.

7. Broader Context

Faecal microbiota transplantation (FMT) is the only intervention targeting the gut microbiome that has repeatedly demonstrated clinical effects in humans under controlled conditions—such as in recurrent *Clostridioides difficile* infections or in initial studies on metabolic diseases. These findings establish two key insights: first, that the composition of the microbiome is not merely an epiphenomenon but may be causally linked to physiological processes; and second, that transferring an entire microbial community produces different effects than administering individual strains or prebiotic substrates. The discrepancy between the evidence for FMT and that for over-the-counter preparations underscores that the microbiome functions as an ecosystem—not as a sum of isolated agents. This has implications for research: the clinical relevance of microbial interventions must always be evaluated in the context of the systemic level at which they operate.

Mechanistic studies in animal models and *in vitro* systems demonstrate that the gut microbiome interacts with the intestinal barrier through multiple pathways: microbial-derived short-chain fatty acids (SCFAs), particularly butyrate, stabilise the tight junctions of the intestinal epithelium and promote mucin production. Simultaneously, microbial metabolites such as tryptophan derivatives or secondary bile acids modulate the mucosal immune response, indirectly influencing permeability. Animal studies suggest that such combinations may stabilise barrier function under stress conditions (e.g., cortisol exposure). However, systematic investigations in humans using standardised endpoints (e.g., lactulose/mannitol test) are currently lacking.

If the gut microbiome acts as a mediator between external stressors (e.g., chronic social stress) and physiological inflammatory processes, targeted modulation of the microbial community—such as through prebiotic fibres or polyphenol-rich extracts—could enhance the resilience of the intestinal barrier. It would need to be examined whether such interventions not only alter the composition of the microbiome but also stabilise the production of SCFAs and the expression of tight junction proteins (e.g., occludin, claudin) under stress conditions. A particularly relevant question is whether combining barrier-nourishing substances (e.g., butyrate) with binding agents (e.g., zeolite) produces synergistic effects—an approach that has scarcely been investigated in controlled human studies. Methodologically, such studies would need to integrate longitudinal designs with multiple stressors and microbial metabolomic analyses to distinguish causality from correlation.

Chains in which this topic is embedded: From exclusion to inflammation: stress, cortisol, gut · Intestinal barrier and binding: polyphenols, zeolite, butyrate, probiotics

8. Open Questions

- **What is normal?** Without a reference, any evaluation of microbiome analysis remains uncertain.
- **Cause or consequence?** The direction of the association is unclear for most diseases.
- **How long does a change last?** Most interventions only work while they are being continued.

9. Further Paths

Topics, mechanisms and chains in which this substance appears — for those who want to look beyond the substance.

- From exclusion to inflammation: stress, cortisol, gut
- Intestinal barrier and binding: polyphenols, zeolite, butyrate, probiotics

Frequently Asked Questions

Is there a healthy microbiome?

No universally valid reference exists. The composition varies significantly among healthy individuals. Rather than a target state, patterns—such as greater diversity—are described.

Do probiotics help during antibiotic treatment?

Less conclusively than often assumed. Controlled studies suggest that probiotics may even delay the return to the original flora. The effect is strain-specific—general statements about 'probiotics' are not valid.

What is a faecal microbiota transplant?

The transfer of processed gut flora from a healthy donor. It is the best-documented intervention in the microbiome, a medical procedure with its own risks and clearly defined applications.

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