Novel Biome

Fecal Microbiota Transplantation | GMP Manufactured

LEVERAGING YEARS OF EXPERIENCE IN THE FMT SPACE TO PROVIDE HIGH-QUALITY FMT PRODUCTS THAT ARE SAFE, EFFECTIVE AND CONSISTENT

About Us

Our sole focus is to provide the best FMT products possible, utilizing highly screened donors, a GMP-certified microbiota lab, and stringent manufacturing standards under our Health Canada Drug Establishment License (DEL).

- Deep expertise in FMT manufacturing and the human microbiome
- Supporting clinical partners: MDs, NDs, NPs, PAs, and researchers
- Highly screened donor program and extensive testing
- Freeze-dried capsule, oral powder, enema and colonoscopy formats
- Health Canada DEL: GMP manufacturing and GLP-aligned laboratory practices

OUR CAPABILITIES

Specialized GMP Manufacturing



FMT Products



Donor Screening



FMT TREATMENT

Disclaimer: Novel Biome is a contract manufacturer of FMT products, providing high-quality FMT products to physicians. The information provided in this document should not be considered medical advice and is based on Novel Biome's understanding of their FMT products and past experience treating patients with FMT. Our hope is that this information helps as a starting point for physicians. If you have more questions, comments or concerns with these instructions, please email us at support@novelbiome.com.

Before We Start

Write down 3 patients you'd consider for FMT today.

Go with what you know right now. No names, no wrong answers.

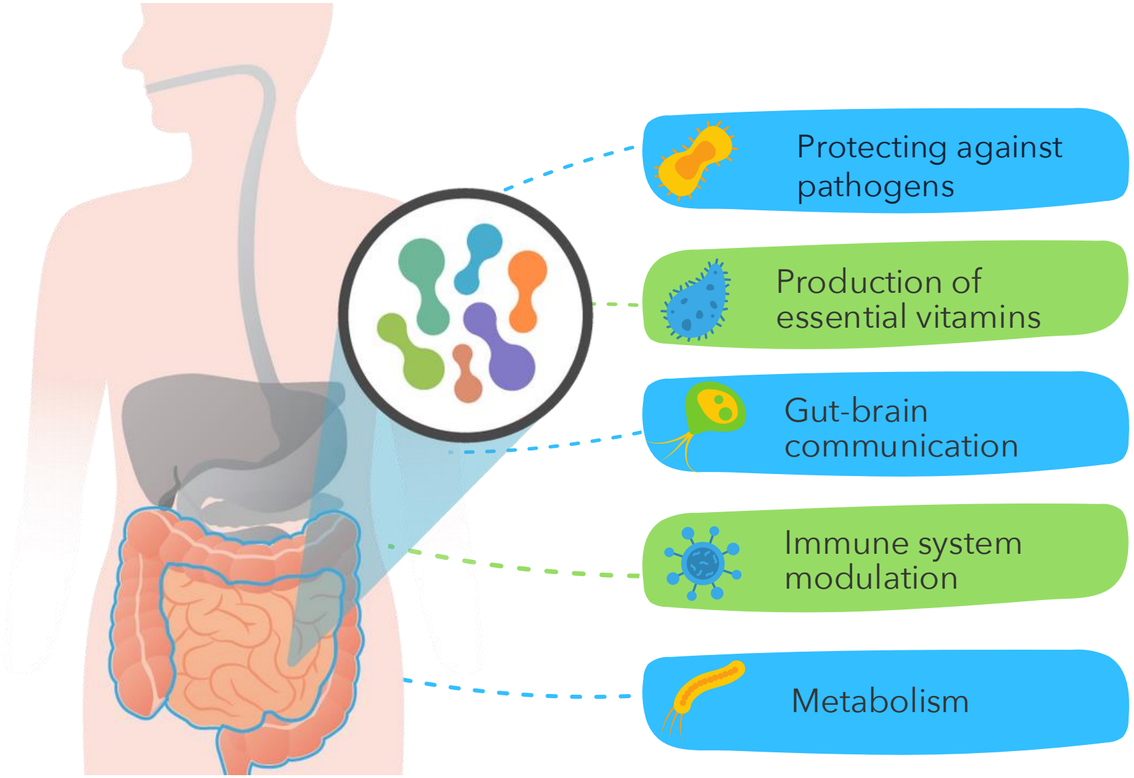
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Why focus treatment on the gut microbiome?

The microbiome is vital for many functions within the human body, such as:



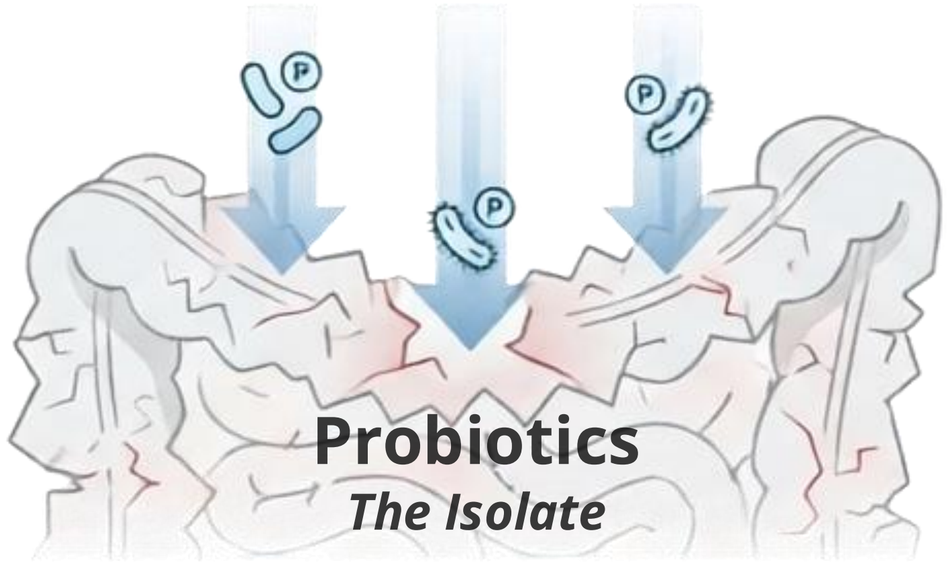
Symptoms associated with gut dysbiosis

- GI Issues/ Disturbances
- Bloating
- Chronic Constipation
- Abdominal Pain
- Leaky Gut
- Skin Issues (eczema, acne, psoriasis)
- Chronic Inflammation
- Fatigue
- Mood changes/ Issues
- Brain fog
- Sleep Issues

Ref: Wilson, B. C. et al. 2019, Hall, A. B., Tolonen, A. C. & Xavier, R. J. 2017, Odamaki, T. et al. 2016, PerezMuñoz, M. E. et al. 2017, The Human Microbiome Project Consortium. 2012,

Why FMT Isn't Just Another Probiotics?

FMT is an **ecosystem transplant**. It adds hundreds of species simultaneously, restoring the full ecological structure, including interactions between species.



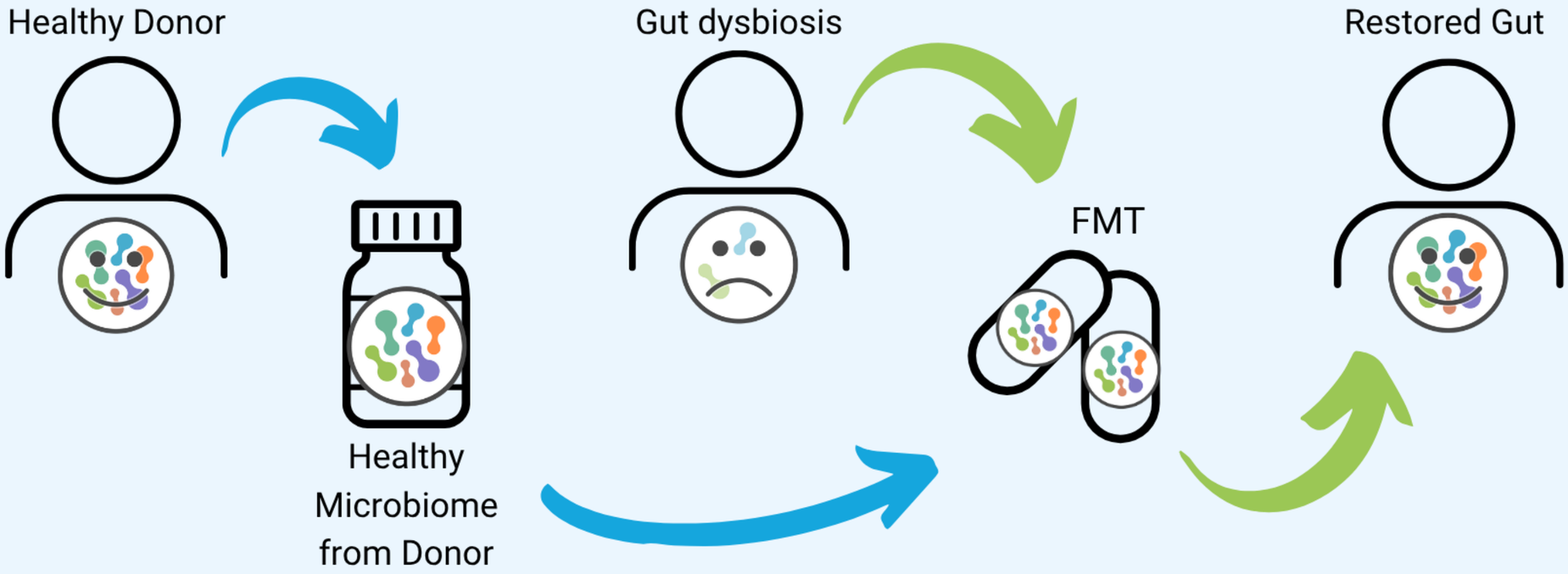


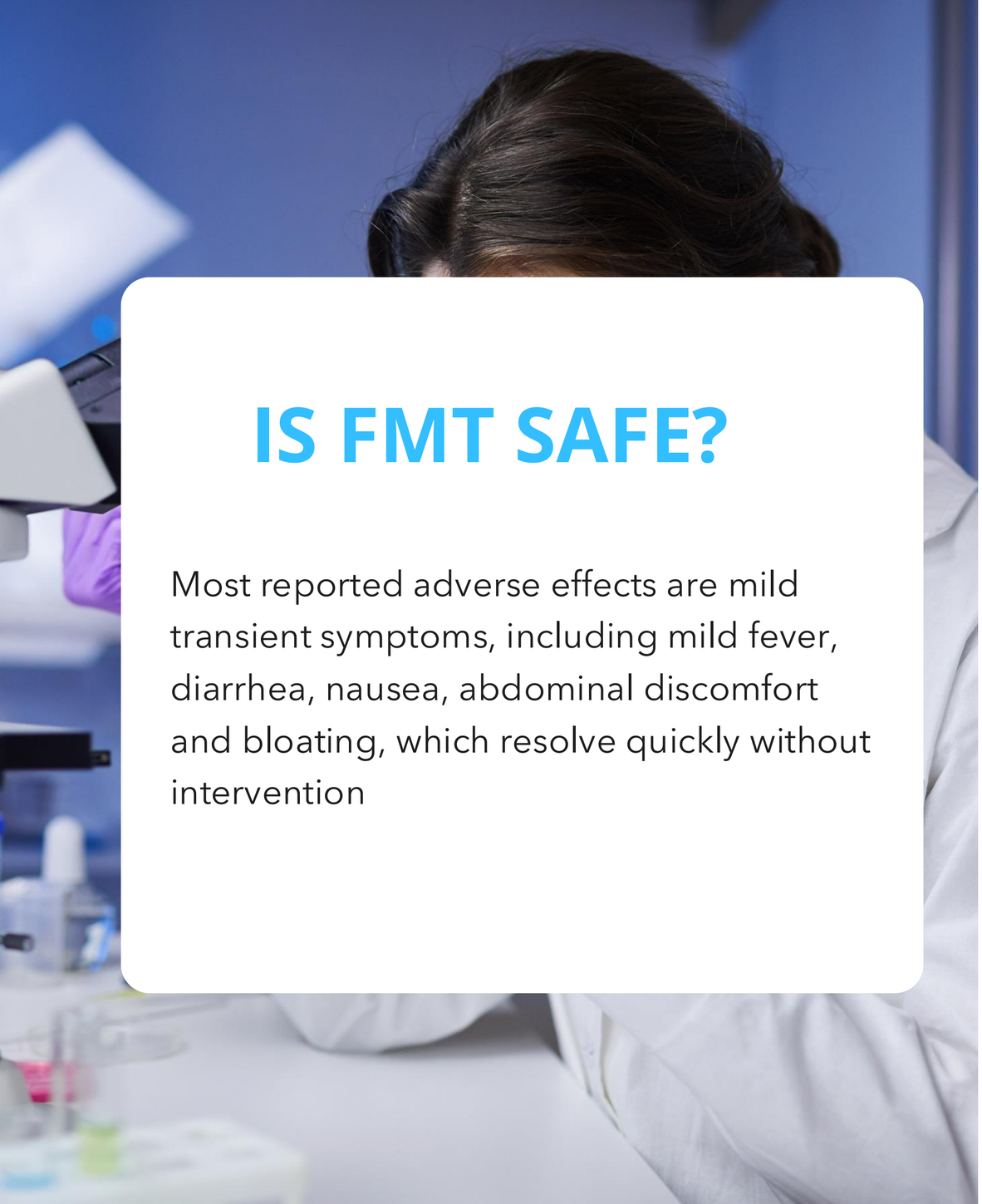
- Adds 1–3 select strains.
- **Transient**
- Cannot overcome established regime shifts

- Delivers a complete ecological structure.
- Actively competes for colonization space, displacing pathobionts.
- Provides full **engraftment**.

WHAT IS FECAL MICROBIOTA TRANSPLANTATION?

FMT helps to **re-educate** the recipient's gut microbiome, inducing the re-colonization of the gut and restoring microbial diversity to donor-like proportions





IS FMT SAFE?

Most reported adverse effects are mild transient symptoms, including mild fever, diarrhea, nausea, abdominal discomfort and bloating, which resolve quickly without intervention

WHAT ARE THE MOST CRITICAL SAFETY COMPONENTS FOR FMT?

Donor Screening

Donor screening is designed to minimize the risk of transmitting potentially infectious diseases or contagious traits from a donor(s) to a patient.

High-Quality Product Manufacturing

Incorporating pharmaceutical-grade laboratory spaces, equipment and production standards is critical to ensure the quality and safety of final FMT products.

DONOR SCREENING

Initial Donor screening: Use stringent health, wellness and family history screening criteria exceeding all published screening standards.

Blood, Urine and Stool screening: Initial and routine (every 90 days) screening of over 120 testing parameters, including parasites, viruses, fungi, and active infections.

Physical exam: All our donors undergo an in-person physical exam with an on-staff physician.

Day of Donation screening: Before each donation, donors complete a current health screening to check for any changes in their health.

Additional safety:

- All processed and manufactured stool is first held in quarantine for 90 days to ensure that all blood and stool screening passes our standards.
- We keep a portion of all manufactured samples. If an adverse reaction occurs, we can conduct further testing.

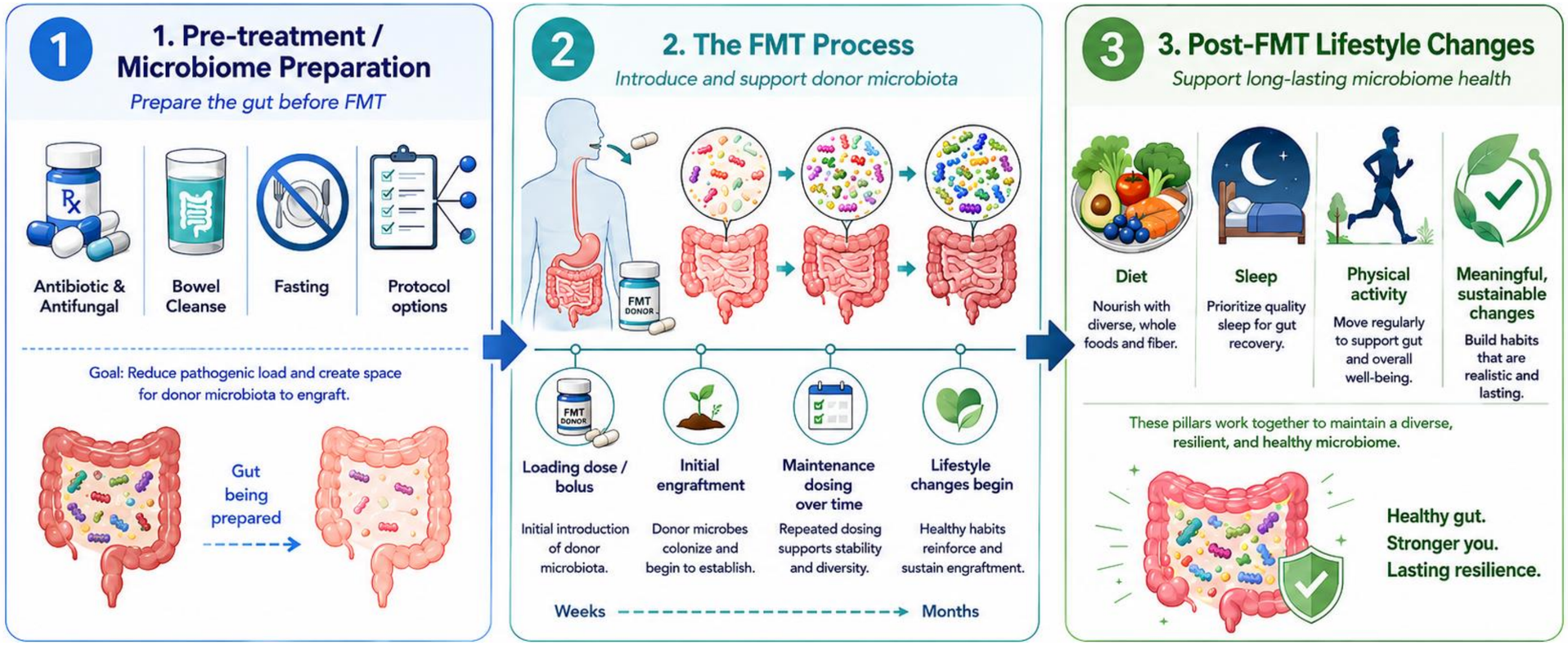
Standard initial medical and health screening	Novel Biome's initial screening
--	Vaginally born
--	Breastfed
Donor ages range from ≥18 and ≤60 years old	All donors under 30 years of age
General healthy diet	Confirmed diverse omnivorous diet
<3 months use of antibiotics, antifungals, antivirals, immune-suppressants, chemotherapy	Limited lifetime use of antibiotics (<5) and antifungals No lifetime use of antivirals, immune-suppressants, chemotherapy
--	Never smoked and lives in a non-smoking home (both tobacco and cannabis)
Only recent allergic reactions	No allergies
No travel of 6 months to tropical countries and high-risk areas of communicable disease/ infectious intestinal diseases	Review any travel for 12 months outside of home country
Inquire about 13 different infectious diseases	Inquire about 34 different infectious diseases
--	No treatment or diagnosis of: GI disorders, Autoimmune disease, metabolic disorders, neurodegenerative, neurodevelopmental, mood disorders, cancers or chronic pain
--	No sleep issues (e.g. insomnia, frequent waking, nightmares)

FMT TREATMENT

In general, FMT treatment

is often broken down into

3 phases:



PRE-TREATMENT

Antibiotics & antifungals

Typically 2 weeks of antibiotics & antifungals (antiparasitic as needed)

Helps prepare the gut microbiome by reducing species richness and dominant microbiota so the graft can take.

Shown to improve engraftment and outcomes post-FMT.

Bowel cleanse

Clear out as much fecal matter and "wash out" the system. More important for patients with constipation

I.E., Magnesium Citrate, Magnesium Oxide, MoviPrep, etc.

Fasting

On the day of the bowel cleanse and during the first day of FMT treatment, we suggest patients go on a water fast if possible

Supplement Review

Stop antimicrobials, probiotics and single-ingredient prebiotics 48 hours before FMT.

Reviewing a patient's supplements before starting FMT can help increase FMT success.

Other considerations

Mold: treat the active burden first. The goal is not zero: assess, reduce, stabilize. Urine mycotoxin testing is recommended.

Biofilms: can impair engraftment. Biocidin from one month before FMT, stopping 48 hours prior.

Liver support: add for die-off management.

FMT DOSING OPTIONS

FMT treatment consists of a loading dose and, if needed, a maintenance dose.

Loading Dose: takes place the day following a bowel cleanse. Loading doses are normally larger FMT doses given over 2-3 days.

OPTION 1 · STANDARD LOADING

15 capsules per day for 2 days
One bottle of 30 capsules, split over 2 days.

OPTION 2 · EXTENDED LOADING

10 capsules per day for 3 days
One bottle of 30 capsules, split over 3 days.

OPTION 3 · ENEMA

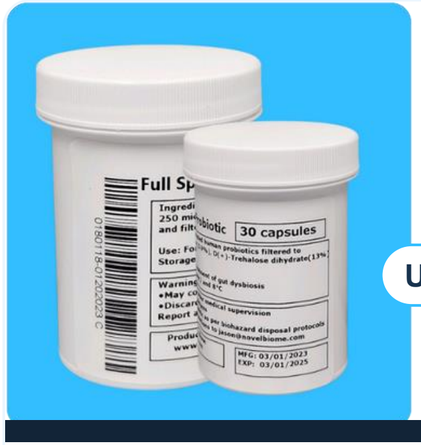
One enema per day for 2 days, or
1 enema, then begin maintenance on day 2.

Maintenance Dose: smaller doses over a period of days/weeks/months.

A good rule of thumb: the more chronic the condition, the longer the treatment

Full details in the clinical protocols

OUR FORMULATIONS



Capsules

UPPER DELIVERY

Double-encapsulated, enteric-coated FMT capsules with comparable efficacy to colonoscopy.

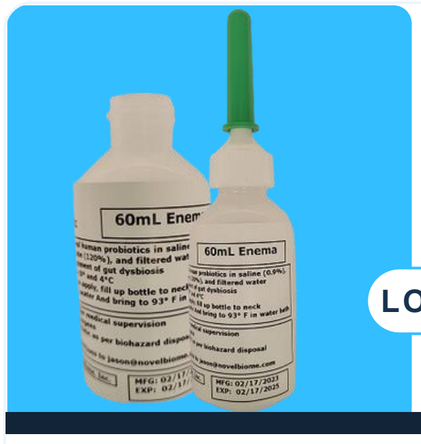


Oral Powder

UPPER DELIVERY

Aimed at patients who can not swallow capsules and must be mixed with a liquid. Third-party validated as substantially colorless, odorless and tasteless.

U.S. Patent No. 12,064,451



Enema & Colonoscopy

LOWER DELIVERY

This product can be used for both lower delivery (colonoscopy or enema) or upper delivery (nasogastric/nasoduodenal tube). This formulation requires reconstitution

POST-FMT: LIFESTYLE CHANGES

Encouraging patients to make lifestyle changes after FMT can help enhance the survival and composition of the new gut microbiota.



Diet

Diet diversity is key. We recommend at least 50 different foods a week! Diet accounts for ~57% of gut microbiota alterations.



Physical activity

Positively impacts the composition and diversity of the gut. Research suggests moderate-intensity aerobic exercise is more effective.



Sleep

Consistent sleep routines and limiting screens before bed. Align sleep with natural light-dark cycles.



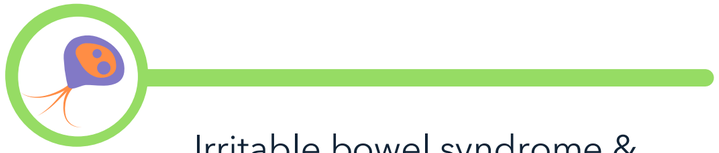
Environmental toxins

Remove any harmful sources within your environment, such as mold, pesticides and heavy metals.

THE RESEARCH

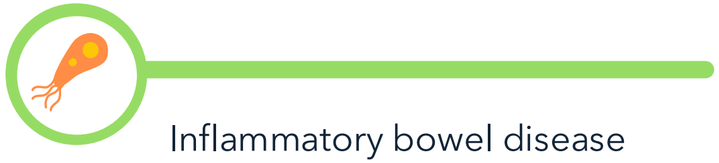
THE GUT MICROBIOME AND FMT IN DIFFERENT CONDITIONS

Where Has FMT Been Evaluated ?



Irritable bowel syndrome &

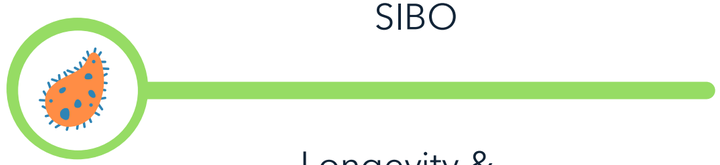
SIBO



Inflammatory bowel disease

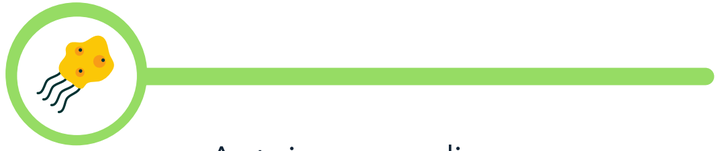


Autism Spectrum Disorder



Longevity &

Health Span optimization



Autoimmune diseases



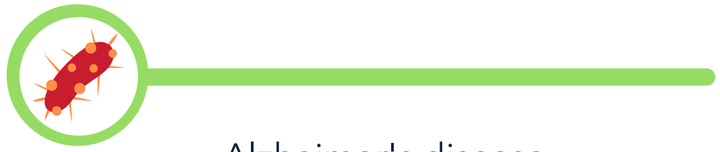
Post-antibiotic recovery



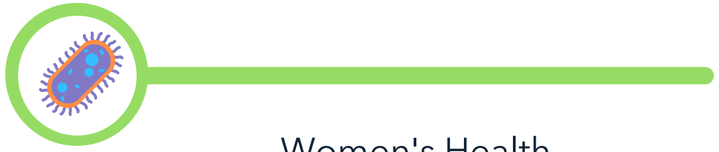
Parkinson's Disease



Multiple Sclerosis



Alzheimer's disease

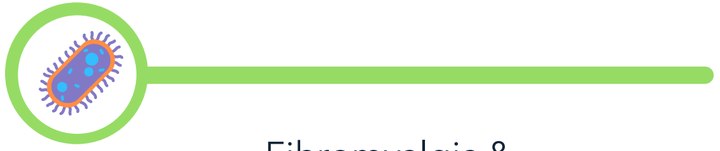


Women's Health



Recurrent infections:

C.diff, UTI

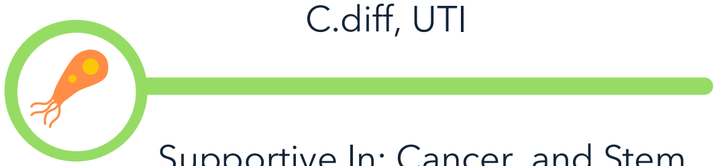


Fibromyalgia &

Chronic fatigue

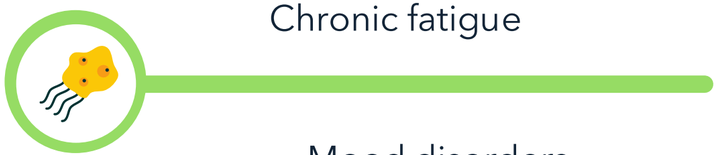


Metabolic conditions



Supportive In: Cancer, and Stem

Cells



Mood disorders

Ref: Choi, H. H. & Cho, Y. S. 2016, Xu, M. Q. 2015, Allegretti, J. R. et al. 2019, Rinott, E. et al. 2021, Brandt, L. J. & Aroniadis, O. C. 2013.

What outcomes are reported after FMT?

Research shows that a thriving microbiome can support better well-being and can lead to improvements such as:

Microbial diversity restored

With reduced pathogenic overgrowth.

GI dysfunction reduced

Bloating, constipation, diarrhea, abdominal pain.

Gut barrier function improved

Reduced intestinal permeability.

Inflammation reduced

Both inflammatory markers and gut and systemic inflammation.

Gut–brain function improved

Neurotransmitters, hormones, cognitive function, fatigue

Improved Quality of Life

Mood, cognition and fatigue, alongside improved quality of life.



IRRITABLE BOWEL SYNDROME

PROTOCOL AVAILABLE

The Gut Microbiome in IBS



Altered gut microbiota composition and significantly reduced microbial diversity which plays a role in symptoms.



Gut-brain communication appears to be impacted and altered levels of microbial metabolites may play a role.



IBS patients are more likely to present with small intestinal bacterial overgrowth (SIBO)

FMT is shown to:

Studies show positive outcomes with response rates of over 50%.

Induce changes in the gut microbiome with shifting in gut microbial composition and diversity.

Significant reductions of IBS symptoms, fatigue and improved quality of life.

Ref: El-Salhy, Gilji, Hatlebakk 2023, Wang et al., 2023, Halkjær et al., 2023, Yau et al., 2023, El-Salhy and Hatelbakk 2024, Rodrigues et al., 2023, Körner and Lorentz 2023

Note: Results of studies are inconclusive and contradictory across the research

SMALL INTESTINAL BACTERIAL OVERGROWTH

PROTOCOL AVAILABLE

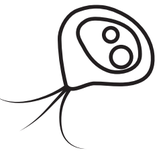
The Gut Microbiome in SIBO



Dysbiosis and impaired intestinal motility allow bacteria to overpopulate the small intestine, driving gas, bloating, and nutrient malabsorption



Up to 78% of IBS patients present with concurrent SIBO confirmed by hydrogen or methane breath testing



Recurrent SIBO after antibiotic treatment is common (<40%). Addressing root-cause dysbiosis is a critical adjunct.

FMT is shown to:

Studies show positive outcomes with response rates of over 50%.

Achieve greater than 50% symptom improvement sustained over 1-3 years post-treatment

Restores microbial balance as adjunctive therapy alongside Rifaximin

Ref: Ghoshal et al. 2017, Gu, L. et al. 2017, Wang, L. et al. 2024, XU, F. et al. 2021.

Note: Results of studies are inconclusive and contradictory across the research

INFLAMMATORY BOWEL DISEASE (IBD)

PROTOCOL AVAILABLE

The Gut Microbiome in IBD



Gut dysbiosis is thought to be the key regulator in IBD development.



The gut microbiome in IBD patients is characterized by reduced species richness and diversity.



Severity of IBD is related to increased pathogenic bacteria and decreased beneficial anti-inflammatory bacteria

FMT is shown to:

A modest remission rate of around 30-45%. Response is higher in patients with ulcerative colitis (3X more likely to achieve remission)

FMT capsules using multiple donors are effective and may enhance long-term treatment strategies.

Cycles of immune response may affect FMT outcomes, and longer treatment may be required to achieve longer remission windows.

Ref: Boicean, A. et al. 2023, Pandey, H. et al. 2024, Arora, U. et al. 2024, Aldars-García, L. et al. 2021, Anderson, J. L. et al. 2012, Tan, P. et al. 2020, Paramsothy, S. et al. 2019, Borody, T. J. et al. et al. 1989, Borody, T. J. et al. 2003, Mocanu, V. et al. 2021.

Note: Results of studies are inconclusive and contradictory across the research

AUTISM SPECTRUM DISORDER

PROTOCOL AVAILABLE

The Gut Microbiome in ASD



Children with ASD are 3 times more likely to experience GI symptoms than their peers.



Gut microbiome development is impaired in children with ASD.



The gut microbiota of children with ASD significantly differs.

FMT is shown to:

- Improved GI symptoms by over 50% across studies.
- Decrease in ASD-related behaviors with increased improvements over time.
- Improved gut microbiota diversity and maturity of the gut, similar to that of age-matched peers.
- Altered gut-brain connection.

Ref: Kang, D.-W. et al. 2017 , Kang, D.-W. et al. 2019, Li, N. et al. 2021, Qureshi, F. et al. 2020 , Kang, D.-W. et al. 2020

Note: Results of studies are inconclusive and contradictory across the research

LONGEVITY & HEALTH SPAN OPTIMIZATION

PROTOCOL AVAILABLE

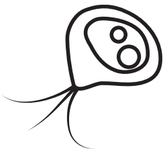
The Gut Microbiome in Aging



There is a decrease in diversity and functionality in the gut microbiome during aging.



Decrease beneficial bacteria (e.g., Actinobacteria, Bifidobacteria, Lactobacillus), and increase pro-inflammatory taxa in aging.



Evidence suggests that an imbalance in the gut microbiome could contribute to immunity, inflammation, frailty, neurodegenerative diseases, and cognitive function.

FMT is shown to:

Young-donor FMT may reduce age-related symptoms and improve overall health

Restores microbial equilibrium, reduces inflammation, improves immune health and supports mucosal healing

Shown to mitigate age-related cognitive decline and reduce signs of frailty, and to work to complement other therapies

Ref: Li, H., Ni, J. & Qing, H. 2021, Novelle, M. G. et al. 2025, Xie, J. et al. 2025, Kong, F. et al. 2019, Tikunov, A. Y. et al. 2023, Cerna, C. et al. 2025

Note: Results of studies are inconclusive and contradictory across the research

SUPPORTIVE

POST-LYME SYNDROME

PROTOCOL AVAILABLE

The Gut Microbiome in Lyme



10-20% of Lyme disease patients develop PTLDS after antibiotic therapy, with persistent fatigue, neurological symptoms, and gut dysbiosis



Prolonged antibiotic (and antimicrobial) courses deplete microbial diversity



PTLDS shows a distinct microbiome signature compared to healthy controls

FMT is shown to:

Restore microbiome diversity following antibiotic dysbiosis

Reduce C. difficile overgrowth risk and leaky gut commonly elevated after extended antibiotic treatment

Support gut-immune axis modulation as an emerging adjunct in complex post-Lyme management

Ref: Morrissette et al., 2020, Johns Hopkins Lyme Research Center, Körner and Lorentz 2023

Note: Direct FMT-PTLDS clinical trials are limited; evidence is mechanistic and case-based

AUTOIMMUNE DISEASE

PROTOCOL AVAILABLE

RA & SLE

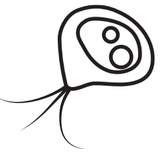
The Gut Microbiome in Autoimmune Disease



Shared dysbiosis signature across autoimmune diseases



Key Features: TH17/Treg imbalance, Leaky gut, microbial translocation, molecular mimicry



Microbial diversity decreases with increased pro-inflammatory levels, reduced Butyrate producers, and increased intestinal permeability.

FMT is shown to:

Overall: Microbial reconstitution, SCFA restoration, Reset immune signalling and secondary bile acid restoration

Improved disease activity scores, reduction in medications, improved disability scores

Improvement in immune markers showing proof of concept of immune modulation

Ref: Giloteaux et al., 2016, Nagy-Szakal et al., 2017, Kenyon, Cole, Izadi 2019, El-Salhy 2023, Salonen et al., 2023, .

Note: Results of studies are in their early stages and are limited at this time.

SUPPORTIVE

ONCOLOGY

PROTOCOL AVAILABLE

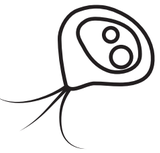
The Gut Microbiome in Cancer



Gut dysbiosis is thought to play a key role in the development and progression of some cancers.



Gut dysbiosis can contribute to carcinogenesis by promoting inflammation and DNA damage and altering immune responses.



Some microbial species might influence the tumor microenvironment, which is essential for cancer cell survival and metastasis.

FMT is shown to:

FMT has been shown to overcome resistance to immune checkpoint inhibitors and enhance responses to immunotherapy.

FMT has been shown to reduce gastrointestinal toxicities, reduce side effects of cancer treatments and enhance post-treatment recovery

FMT has been shown to reduce graft-versus-host complications following hematopoietic cell transplant and to manage symptoms by reducing inflammation and improving outcomes.

Ref: Baruch, E. N. et al. 2021, Davar, D. et al. 2021, Van Dingenen, L. et al. 2023, Brusnic, O. et al. 2024, Wardill, H. R. et al. 2019, Habibi, S. & Rashidi, A. 2023,.

Note: clinical trials are limited

SUPPORTIVE

STEM CELLS

The Gut Microbiome with Stem Cells



Lower gut diversity can increase susceptibility to complications



Gut dysbiosis can impact the efficacy and negative outcomes of stem cell therapies by:

- impaired immune responses
- increased susceptibility to infections
- increased systemic inflammation

Combined Therapeutic Potential:

FMT can reduce complications and help with Graft-versus-Host Disease and the impacts of Multidrug-Resistant Organisms

FMT can enhance stem cell treatment by correcting dysbiosis and modulating systemic immunity.

FMT can optimize the environment for stem cells by increasing protective metabolites and improving immune regulation to enhance engagement.

Ref: Bilinski, J. et al. 2016, Nørgaard, J. et al. 2023, Innes, A. J. et al. 2021, Van Lier, Y. F. et al. 2020, Habibi, S. & Rashḋi, A. 2023, Wardill, H. R. et al. 2019, Zhang, X. et al. 2023, Khosravi, A. et al. 2014, Margiana, R. et al. 2022, Segal, J. P. et al. 2020, Kakihana, K. et al. 2016, Tavoukjian, V. 2019, Woodworth, M. H. et al. 2019.

Note: Study results are in the early stages and limited at this time.

PARKINSON'S DISEASE

PROTOCOL AVAILABLE

The Gut Microbiome in PD



Gut microbiota composition differs in people with PD.



In 80% of PD cases, colonic inflammation precedes motor symptoms by several years.



Alterations in the gut microbiome and colonic inflammation may be associated with PD predisposition and progression.

FMT is shown to:

Preliminary studies show improvements in both motor and non-motor symptoms.

FMT capsules reduce constipation and increase the diversity of the microbiome

FMT capsules reduce constipation and increase the diversity of the microbiome

Ref: DuPont, H. L. et al. 2023, Guseo A. 2012, Huang, H. et al. 2019, Segal, A. et al 2021.

Note: Results of studies are in their early stages and are limited at this time.

MULTIPLE SCLEROSIS

PROTOCOL AVAILABLE

The Gut Microbiome in MS



Gut microbiota composition, metabolic profile (butyrate + indolepropionate) and diversity separate MS patients from healthy controls with near-perfect accuracy



Decrease in short-chain fatty acid-producing bacteria in MS patients.



Evidence suggests that an imbalance in the gut microbiome could contribute to the inflammation and damage experienced by individuals with MS.

FMT is shown to:

Appears to be safe, well tolerated in those with MS.

Provide sustained and durable impact on the gut microbiome composition and clinical features of MS for over 50 weeks.

Provides positive changes in MS clinical features, including improvements in gait, walking and balance measures.

Note: Results of studies are in their early stages and are limited at this time.

Ref: Makkawi, S. et al., 2018, Al, K. F. et al. 2022, Engen, P. A. et al. 2020.

ALZHEIMER'S DISEASE

PROTOCOL AVAILABLE

The Gut Microbiome in AD



Gut microbiota composition and diversity is different in those with AD.



AD patients show reduced gut microbiome richness and diversity.



Dysfunction in the gut-brain axis is a possible risk factor for neurodegenerative disorders like Alzheimer's disease.

FMT is shown to:

Case studies report rapid improvements in AD symptoms, including mood and cognitive function.

FMT capsules are well tolerated and increase microbiome diversity.

In a small pilot study, FMT was shown to maintain and improve cognitive function in people with mild cognitive impairment.

Note: Results of studies are in their early stages and are limited at this time.

Ref: Jin, J. et al. 2023, Nassar, S. T. et al. 2022, Sun, J. et al. 2019, Hazan, S. 2020, Park, S-H. et al. 2022.

FIBROMYALGIA

PROTOCOL AVAILABLE

The Gut Microbiome in Fibromyalgia



Studies consistently show altered gut microbial composition and increased gut permeability (“leaky gut”)



Gut-Brain axis, leading to altered neurotransmitter production and neuroimmune activation, potentially driving symptoms



Potential link between SIBO, intestinal permeability, and fibromyalgia

FMT is shown to:

Shown to alleviate pain and reduce overall symptom severity, including sleep, quality of life, anxiety and depression measures

Response rate of ~59% with improvement up to 12 months post-treatment

Neurotransmitter changes in serotonin and GABA (increase) and glutamate (decrease) indicate alterations in the gut-brain axis.

Ref Waterman, A. et al. 2025, Cai, W. et al. 2025, Martín Pérez, S. E. et al. 2025, Minerbi, A., Thurm, T. et al. 2017, Fang, H. et al. 2024, Slim, M., Calandre, E. P. & Rico-Villademoros, F. 2015,

Note: Results of studies are in their early stages and are limited at this time.

CHRONIC FATIGUE SYNDROME

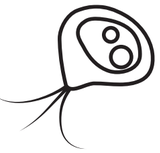
The Gut Microbiome in CFS



Associated with an imbalance in the gut microbiome.



Gastrointestinal symptoms are commonly reported, including IBS.



Bacterial diversity decreases with increased pro-inflammatory and decreased anti-inflammatory species.

FMT is shown to:

70% response rate, with improved symptoms and 58% reporting complete long-term symptom resolution.

Multiple FMTs seem to provide better results, while a single FMT showed no change.

FMT was reported to yield greater improvements than dietary and lifestyle changes.

Ref: Giloteaux et al., 2016, Nagy-Szakal et al., 2017, Kenyon, Cole, Izadi 2019, El-Salhy 2023, Salonen et al., 2023, .

Note: Results of studies are in their early stages and are limited at this time.

CLOSTRIDIUM DIFFICILE INFECTIONS

Clostridium difficile (C.diff)



The leading cause of antibiotic-associated diarrhea.



Increasing rates of infection, increased health care burden and rising disease severity and mortality.



Traditionally treated with antibiotics, but recurrence rates are high.

FMT is shown to:

Success rates of over 90% and more effective than traditional treatments.

Favorable safety profiles, higher rates of overall survival, and shorter hospital stays.

Superior long-term efficacy compared to other medical treatments in recurrent cDiff.

Ref: Allegretti, J. R.et al. 2019, Cammarota, G. et al. 2015, Kao, D. et al. 2017, Lee, C. H. et al. 2016, Lee, C. H. et al. 2019, van Nood, E. et al. 2013

ATTENTION-DEFICIT/ HYPERACTIVITY DISORDER

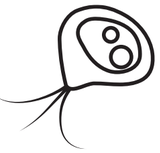
The Gut Microbiome in ADHD



Gut microbiota composition is different in those with ADHD.



Dysbiosis in the gut microbiome is suggested to impact the gut-brain axis, contributing to ADHD symptoms.



Studies have shown that diet may play a large role in gut dysfunction and ADHD symptoms.

FMT is shown to:

Improvements in attention and hyperactivity symptoms post-FMT.

Improved gut microbiota diversity.

Altered gut-brain connection.

Ref: Wang et al., 2019, Bull-Larsen and Mohajeri 2019, Mathee et al., 2020, Bundgaard-Nielsen et al., 2023, Kwak et al., 2023, Caputi et al., 2024

Note: Results of studies are in their early stages and are limited at this time.

QUESTIONS

ONLINE RESOURCES:

- Research-based blogs
- Treatment journey downloads
- Clinical trial database
- Research protocol database
- White papers and protocols
- YouTube videos



Scan to book an introductory call with our clinical team.

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THANK YOU

Thinking back to the patients you selected at the start of the talk, have these patients changed? Do you have more in mind?

Let's Connect

Discuss Your Patient Cases and Practical Applications in Your Practice.

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