KAKASSA TOIVO PAREMMASTA HUOMISESTA

Perttu Arkkila, Gastroenterologian professori, HUS ja Helsingin yliopisto

Virallinen indikaatio ulosteensiirrolle

Toistuva tai muulle hoidolle refraktaarinen Clostridioides difficile-infektio on ainoa virallinen indikaatio ulosteensiirrolle.

FMT for rCDI
Statement: FMT is recommended as treatment option for both mild and severe rCDI. Its implementation in clinical practice is recommended.
Quality of evidence: high.
Strength of recommendation: strong.

FMT for refractory CDI
Statement: FMT can be considered as a treatment option for refractory CDI.
Quality of evidence: low.
Strength of recommendation: strong.

- **Other indications** The experts panel took into account other clinical indications for a possible use of FMT in the clinical practice, such as **IBD, IBS, metabolic disorders, paediatrics**, but for none of them emerged an evidence-based recommendation to use FMT except that in a context of research.

Cammarota G el al. Gut. 2017 Apr; 66(4): 569–580.

Ulosteensiirtoa käytetään rutiinihoitona Suomessa

- Yhtenäiset toimintatavat Suomessa
  - Toistuva Clostiridioides difficile infektio
  - Kokeellisena hoitona mm. IBS, resistentit bakteerikannat jne.
    - Yhteinen arvio gastroenterologin, infektiolääkärin ja mikrobiologin kanssa.
- Ulostepankkitoiminta aloitettu
  - Lahti, Turku, Tampere, muissa sairaaloissa vielä käynnistysvaiheessa
- Menossa useita monikeskustutkimuksia Suomessa

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Research paper

The use of Faecal Microbiota Transplantation (FMT) in Europe: A Europe-wide survey

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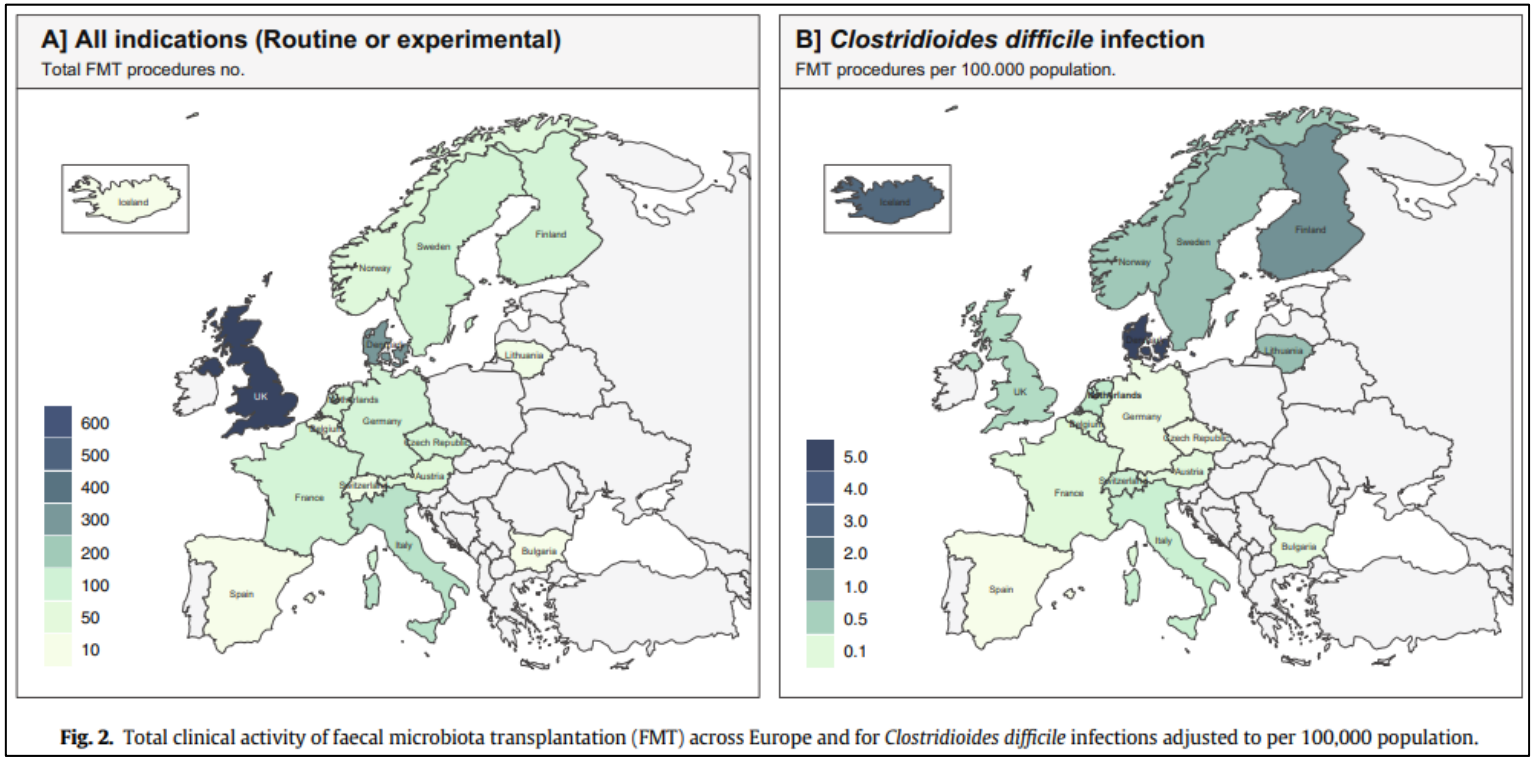

Fig. 2. Total clinical activity of faecal microbiota transplantation (FMT) across Europe and for *Clostridioides difficile* infections adjusted to per 100,000 population.

https://doi.org/10.1016/j.lanepe.2021.100181

Muut indikaatiot

- **Irritable bowel syndrome (IBS)**
- **Inflammatory bowel diesease (IBD)**
  - **Colitis ulcerosa**
  - **Morbus Crohn**
  - **Pouchitis**
- Neurologiset sairaalat
  - Autismi
  - Multiple scleroosi
  - Parkinsonin tauti
- Metabolinen oireyhtymä ja obesiteetti
- Graft versus host
- Multidrug resistant organisms
- Small intestinal bacterial overgrowth (SIBO)
- Krooninen väsymysoireyhtymä
- Reuma, spondylartropatia
- Insomnia, depressio
- Maksakirroosi, enkefalopatia, NAFLD

Diabetes Obes Metab. 2019 Mar;21(3):479-490.

WHAT HAS BEEN PUBLISHED ABOUT IBS

Study	size	FMT method	Follow-up	Results at 12 weeks	difference IBS-SSS score (BL vs. 12 wk)
Holster 2019	N = 17	Colonoscopy	26 wk	No difference	69
Johnsen 2018	N = 83		52 wk	FMT 65% , Placebo 43%	76
Lahtinen 2020	N = 55		52 wk	No difference (FMT 48%, Placebo 42%)	62
Aroniadis 2019	N = 48	FMT capsules	12 wk	No difference	57
Halkjær 2018	N = 52		26wk	FMT 36.4% , placebo 79.2%	56
Madsen 2021	N = 52		26wk	No difference	
El-Salhy 2020	N = 165	Gastroscopy	12 wk	FMT 83% Placebo 23.6%	147
Holvoet 2021	N = 62		52 wk	FMT 56%, Placebo 26%	

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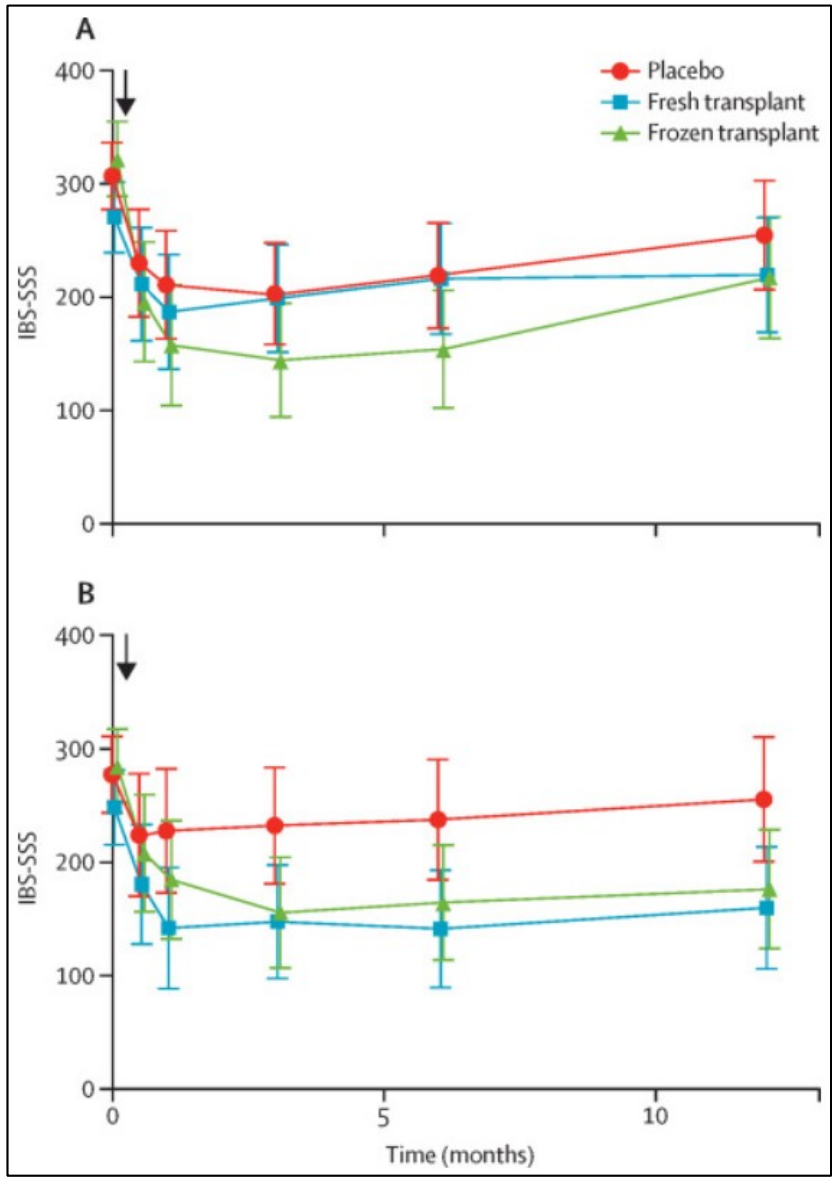
Volume 3, Issue 1, January 2018, Pages 17-24

- In this double-blind, randomised, placebo-controlled, parallel-group, single-centre study, we enrolled patients with IBS with diarrhoea or with diarrhoea and constipation (excluding dominating constipation) defined by the ROME III criteria, scored as moderate to severe according to the IBS severity scoring system (IBS-SSS; a score of ≥175).
- Eligible participants were aged 18–75 years and were recruited locally by general practitioners in northern Norway.
- We randomly assigned 90 participants (2:1) in blocks of six to active or placebo FMT.

Johnsen PH, Lancet Gastroenterol Hepatol. 2018 Jan;3(1):17-24.

Results



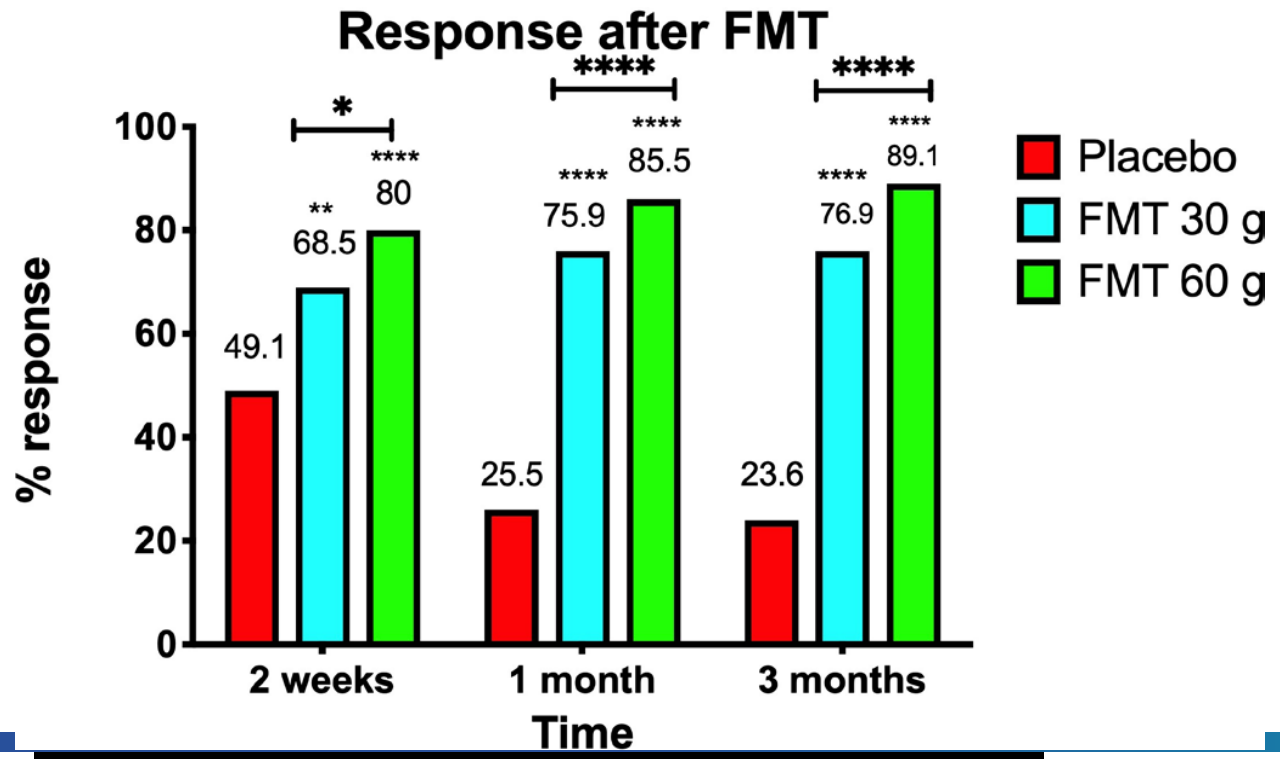
Interpretation

FMT induced significant symptom relief in patients with IBS. However, larger multicentre studies are needed to confirm the results.

Johnsen PH, Lancet Gastroenterol Hepatol. 2018 Jan;3(1):17-24.

Efficacy of faecal microbiota transplantation for patients with irritable bowel syndrome in a randomised, double-blind, placebo-controlled study

Magdy El-Salhy ,[1,2] Jan Gunnar Hatlebakk,[2] Odd Helge Gilja,[2] Anja Bråthen Kristoffersen,[3] Trygve Hausken[2]



Significance of this study

What is already known on this study?

- The intestinal bacterial profile of patients with irritable bowel syndrome (IBS) differs from that of healthy subjects.
- The low bacterial diversity (dysbiosis) in patients with IBS might contribute to the pathophysiology of IBS.
- Faecal microbiota transplantation (FMT) has been investigated in two previous double-blind, placebo-controlled studies. One of those studies found improvement of the IBS symptoms, whereas the other found no effect.

What are the new findings?

- FMT is an effective treatment for IBS that improves abdominal symptoms, fatigue and quality of life.
- The use of a superdonor is necessary for successful FMT.

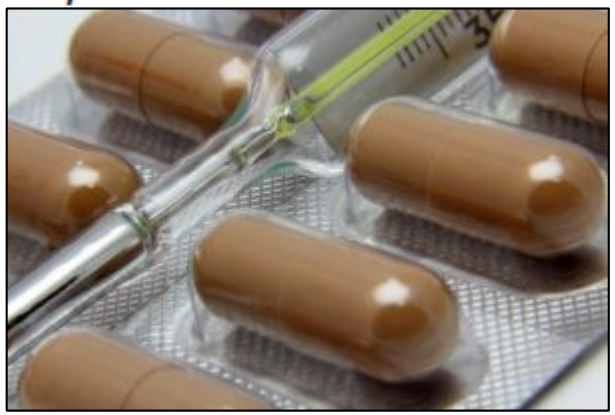
How might it impact on clinical practice in the foreseeable future?

- This study demonstrates the effectiveness of FMT in the treatment of IBS.
- The use of frozen faeces administered via a gastroscope makes FMT easy to perform in the clinic.

El-Salhy M, et al. Gut 2020;69:859–867.

Faecal microbiota transplantation alters gut microbiota in patients with irritable bowel syndrome: results from a randomised, double-blind placebo-controlled study

Sofie Ingdam Halkjær,[1] Alice Højer Christensen,[2] Bobby Zhao Sheng Lo,[1] Patrick Denis Browne,[3] Stig Günther,[2] Lars Hestbjerg Hansen,[3] Andreas Munk Petersen[1]



Halkjær SI, et al. Gut 2018;67:2107–2115.

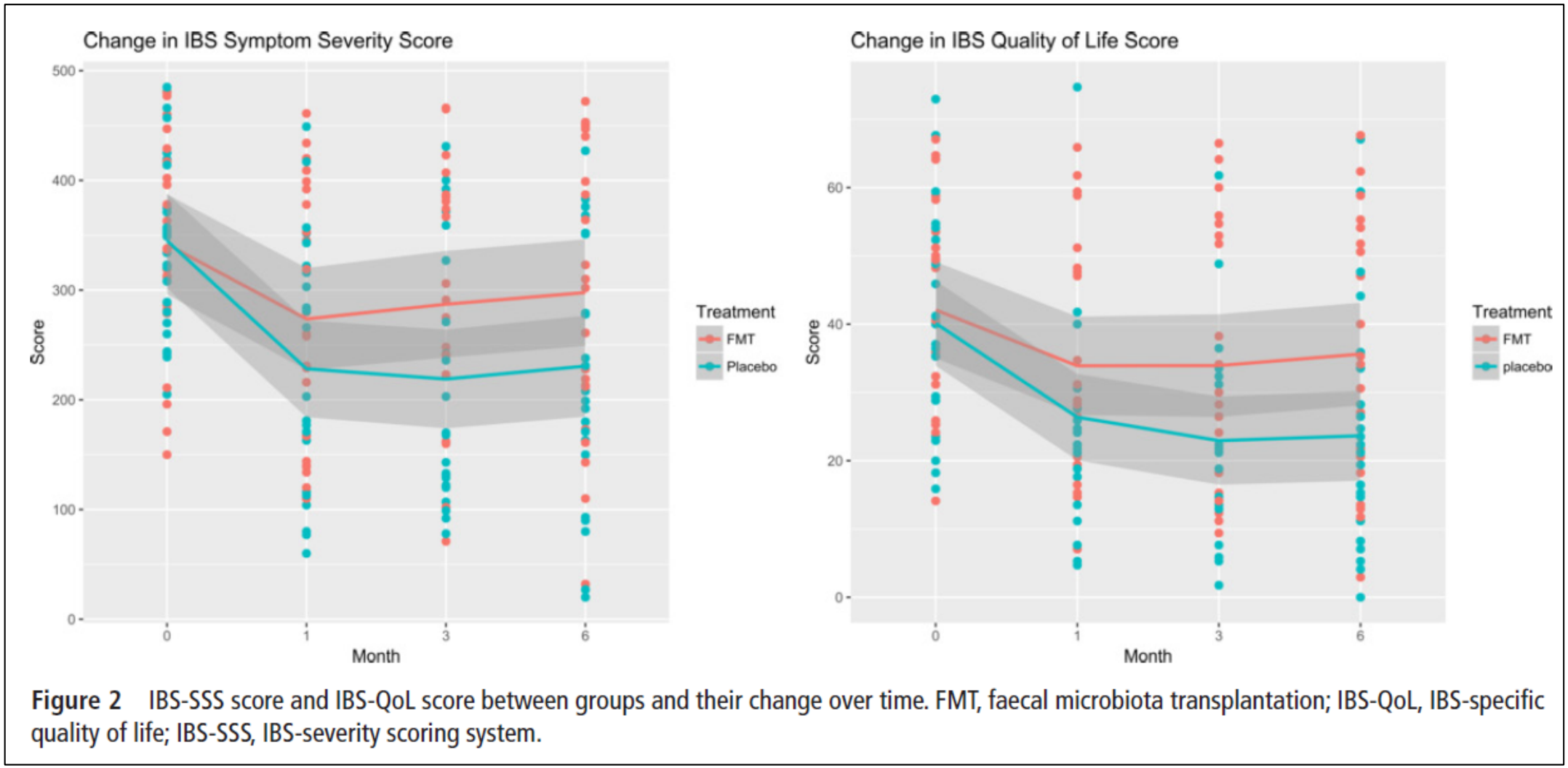


Figure 2 IBS-SSS score and IBS-QoL score between groups and their change over time. FMT, faecal microbiota transplantation; IBS-QoL, IBS-specific quality of life; IBS-SSS, IBS-severity scoring system.

Halkjær SI, et al. Gut 2018;67:2107–2115.

Received: 20 November 2019 | First decision: 14 December 2019 | Accepted: 29 March 2020

DOI: 10.1111/apt.15740

AP&T Alimentary Pharmacology & Therapeutics WILEY

Randomised clinical trial: faecal microbiota transplantation versus autologous placebo administered via colonoscopy in irritable bowel syndrome

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Conclusions: FMT provided only a transient relief of symptoms, although it induced a sustained alteration in the microbiota of IBS patients. Therefore, FMT delivered by a single infusion via colonoscopy cannot be recommended as a treatment for IBS in clinical practice.

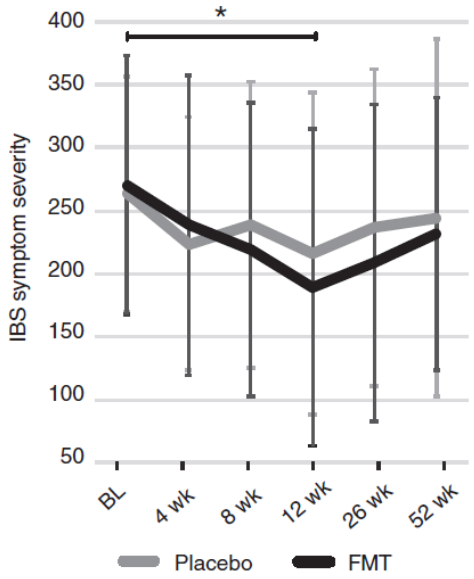
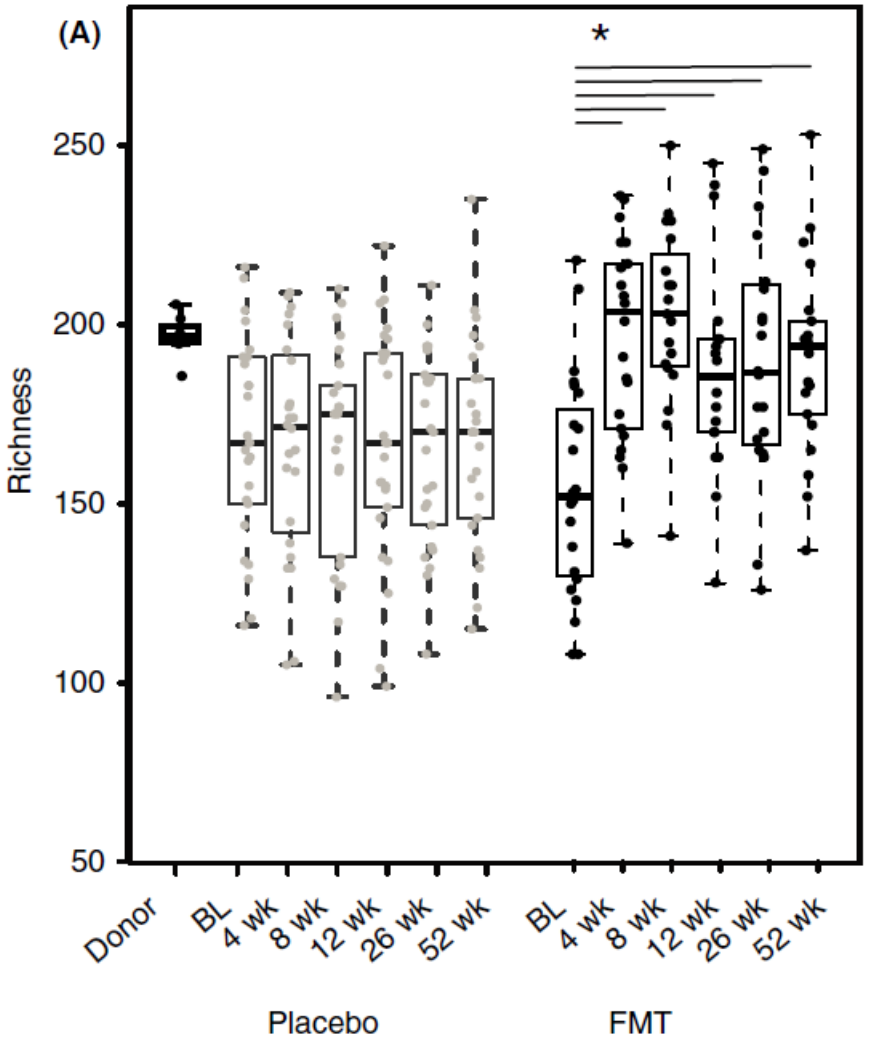


FIGURE 1 The IBS symptoms reduced significantly after FMT as compared to the baseline, but the reduction was not significant when compared with placebo. The IBS-symptom severity -score in the placebo group (grey line) and the FMT group (black line) through the 52-week follow-up period. Asterisk (*) indicates a significant decline in the IBS symptoms in the FMT group at 12 weeks when compared with the baseline (*t* test, $P = 0.01$)



The FMT treatment significantly increased the microbial richness, whereas the placebo group displayed no change.

FMT vaikutus elämänlaatuun ja masennukseen

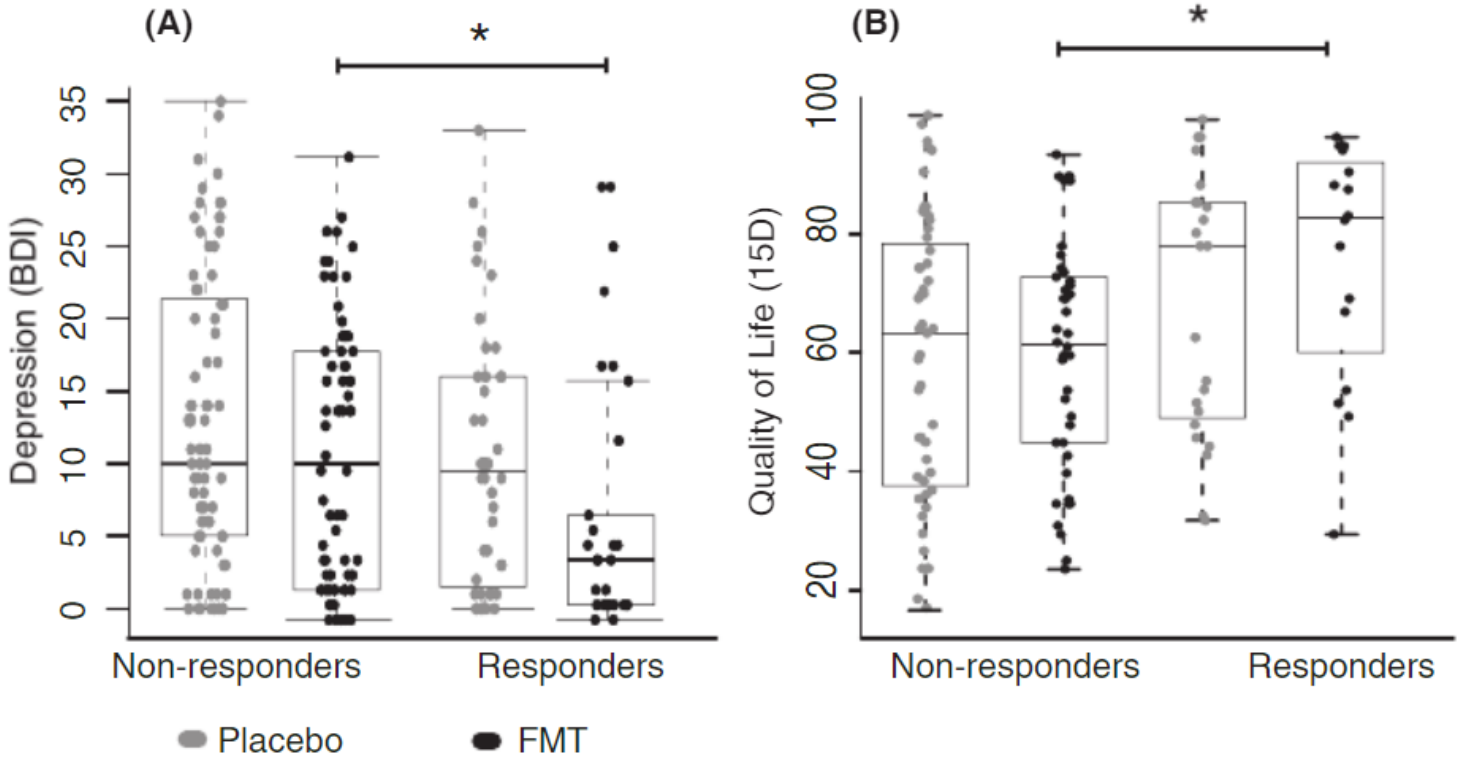
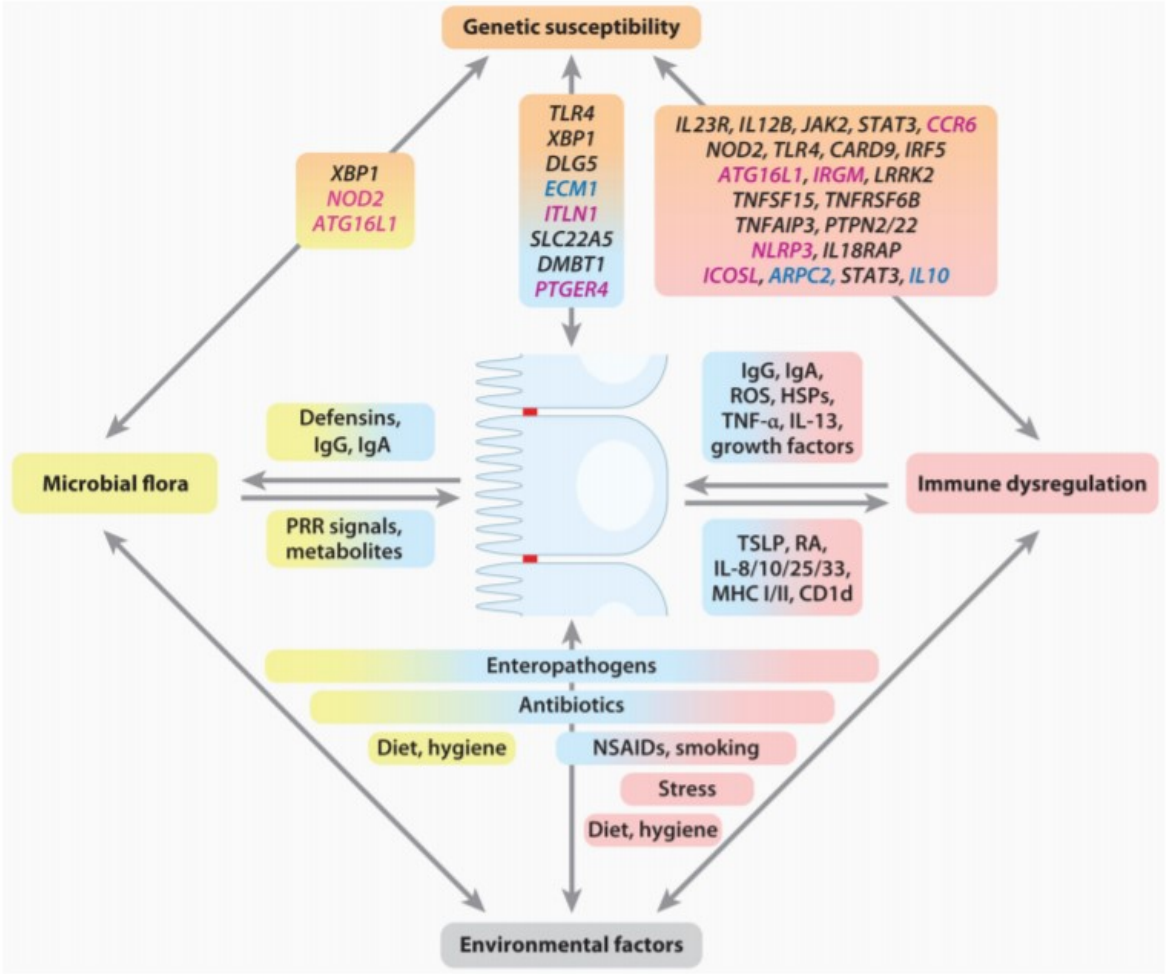


FIGURE 3 The responder status had a significant effect on the depression and quality of life measures. A, Depression scores (ANOVA, $P = 0.05$) and (B) general quality of life (15D) scores were significantly (ANOVA, $P = 0.05$) reduced in those FMT-treated patients who responded to the treatment

[redacted]ahtinen p. et al. Aliment Pharmacol Ther. 2020;51:1321–1331.

Etiology of inflammatory bowel disease (IBD)



Kaser et al. Annu Rev Immunol. 2010 ; 28: 573–621.

Table 1
Summary of 3 randomized controlled trials of fecal microbiota transplant in ulcerative colitis

Study	Mechanism of FMT	Frequency of FMT	Stool Source	FMT Preparation	Placebo Type	Bowel Lavage Before FMT	Medications Allowed During Study	Primary End Point Achieved
Moayyedi et al,[40] 2015	Retention enema	Once per week for 6 wk	6 Healthy donors (volunteer)	50 g of donor stool with 300 mL of commercial bottled drinking water	Water	No	Glucocorticoids Mesalamine Immunomodulators Anti-TNFs[a]	Yes
Rossen et al,[41] 2015	Nasoduodenal infusion	Two infusions 3 wk apart	15 healthy donors (patient directed or volunteer)	120 g of donor stool with 500 mL of normal saline	Autologous stool	Yes	Glucocorticoids Mesalamine Immunomodulators[b]	No
Paramsothy et al,[42] 2017	Colonoscopy, then enema	5 d/wk for 8 wk	Mixture of stool from 3–7 healthy donors organized into stool donor batches	37.5 g of stool with isotonic saline and then filtered to make a 150-mL infusion	Isotonic saline with brown food color and stool odor	Yes	Glucocorticoids Mesalamine Immunomodulators[c]	Yes

Abbreviation: TNF, tumor necrosis factor.

[a] On a stable dose for at least 12 weeks (4 weeks for steroids) and they still had active disease.

[b] Stable doses of mesalamine, thiopurines, and corticosteroids less than or equal to 10 mg daily permitted throughout the study; patients excluded if they were on anti-TNFs or methotrexate within 8 weeks or cyclosporine within 4 weeks.

[c] Oral mesalamine as long as the dose was stable for greater than or equal to 4 weeks, and thiopurines or methotrexate as long as the patients had been on these for at least 90 d and the dose was stable for at least 4 weeks. Prednisone at a dose of less than or equal to 20 mg daily permitted as long as the dose had been stable for at least 2 weeks, with a mandatory steroid taper of up to 2.5 mg/wk with the goal of being steroid free by week 8. Anti-TNF agents and calcineurin inhibitors were not allowed during the study and in the preceding 12 weeks. Rectal corticosteroids and mesalamine were also not allowed during the study and within 2 weeks before enrollment, and antibiotics and probiotics were not allowed within 4 weeks of enrollment.

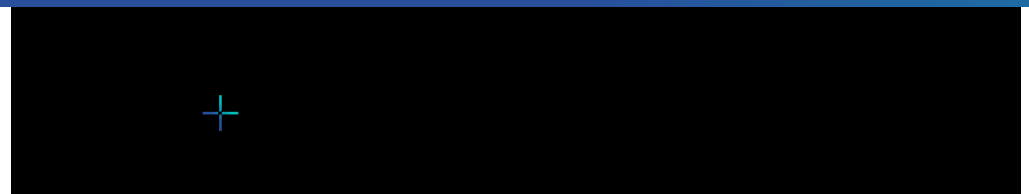
Multidonor intensive faecal microbiota transplantation for active ulcerative colitis: a randomised placebo-controlled trial

Sudarshan Paramsothy, Michael A Kamm, Nadeem O Kaakoush, Alissa J Walsh, Johan van den Bogaerde, Douglas Samuel, Rupert W L Leong, Susan Connor, Watson Ng, Ramesh Paramsothy, Wei Xuan, Enmoore Lin, Hazel M Mitchell, Thomas J Borody

	Faecal microbiota transplantation (n=41)	Placebo (n=40)	Risk ratio (95% CI)	p value
Primary outcome				
Steroid-free clinical remission and endoscopic remission or response*	11 (27%)	3 (8%)	3·6 (1·1–11·9)	0·021
Secondary outcomes				
Steroid-free clinical remission†	18 (44%)	8 (20%)	2·2 (1·1–4·5)	0·021
Steroid-free clinical response‡	22 (54%)	9 (23%)	2·4 (1·3–4·5)	0·004
Steroid-free endoscopic remission§	5 (12%)	3 (8%)	1·6 (0·4–6·4)	0·48
Steroid-free endoscopic response¶	13 (32%)	4 (10%)	3·2 (1·1–8·9)	0·016

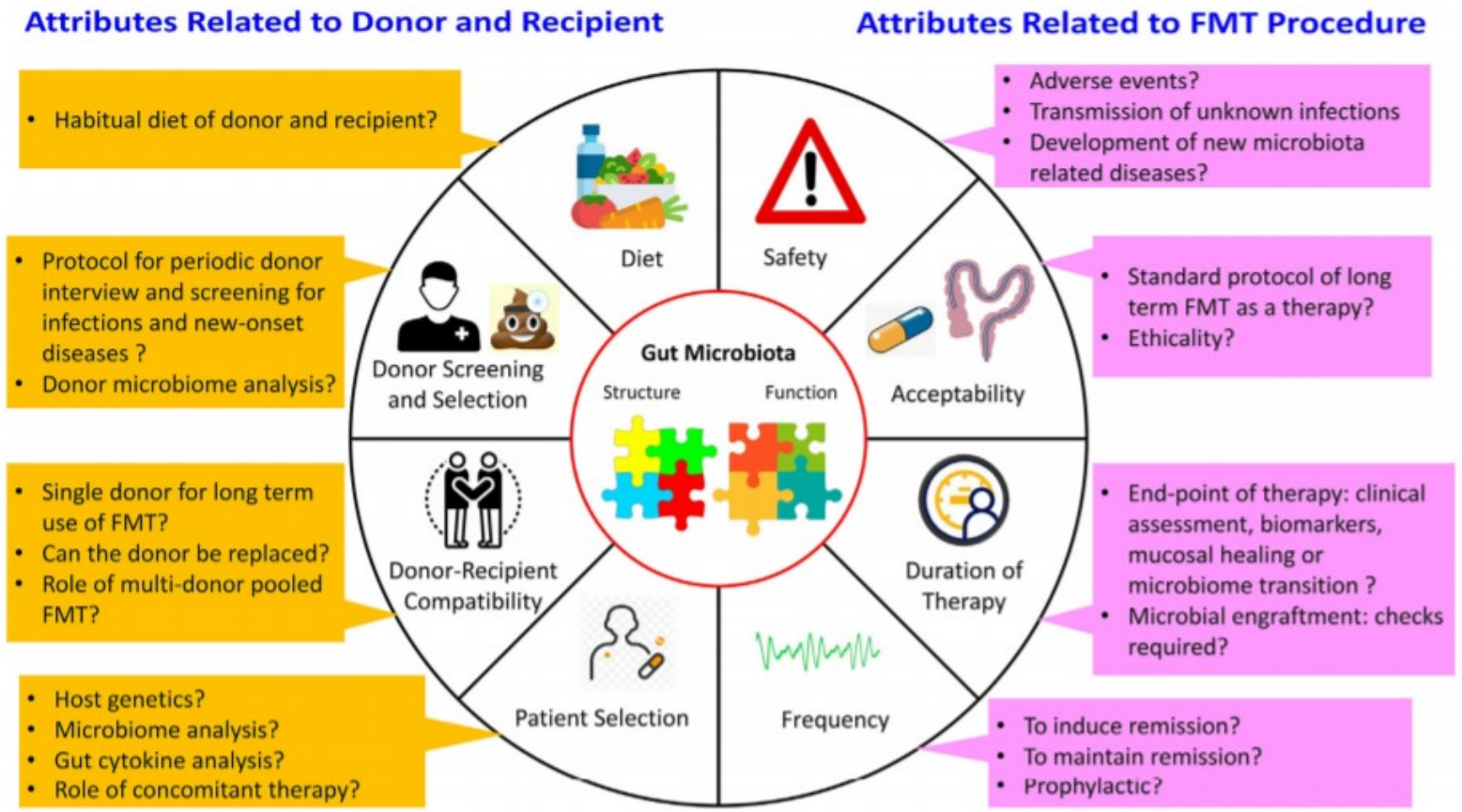
*Total Mayo score ≤2, with all subscores ≤1, and ≥1 point reduction from baseline in endoscopy subscore. †Combined Mayo subscores of ≤1 for rectal bleeding plus stool frequency. ‡Decrease of ≥3 points or ≥50% reduction from baseline (or both) in combined Mayo subscores for rectal bleeding plus stool frequency. §Mayo endoscopy subscore 0. ¶Mayo endoscopy subscore ≤1, with ≥1 point reduction from baseline.

Table 2: **Primary and secondary outcomes at week 8**



***Lancet* 2017; 389: 1218–28**

Unsettled issues for long term use of FMT as a therapy in ulcerative colitis

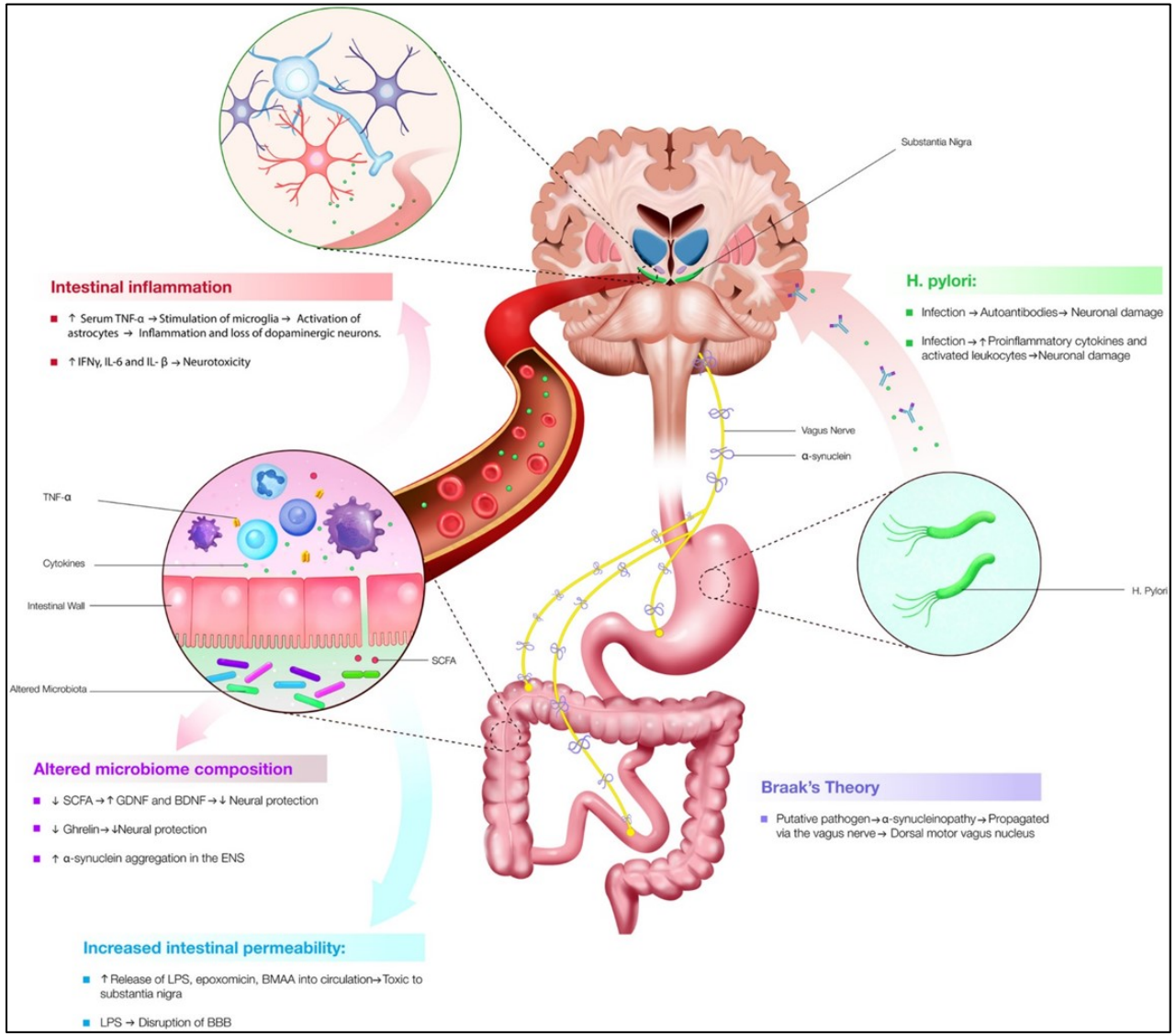


Singh A et al., Long term management of ulcerative colitis with Faecal Microbiota Transplantation, Medicine in Microecology, https://doi.org/10.1016/j.medmic.2020.100026

Neurological indications

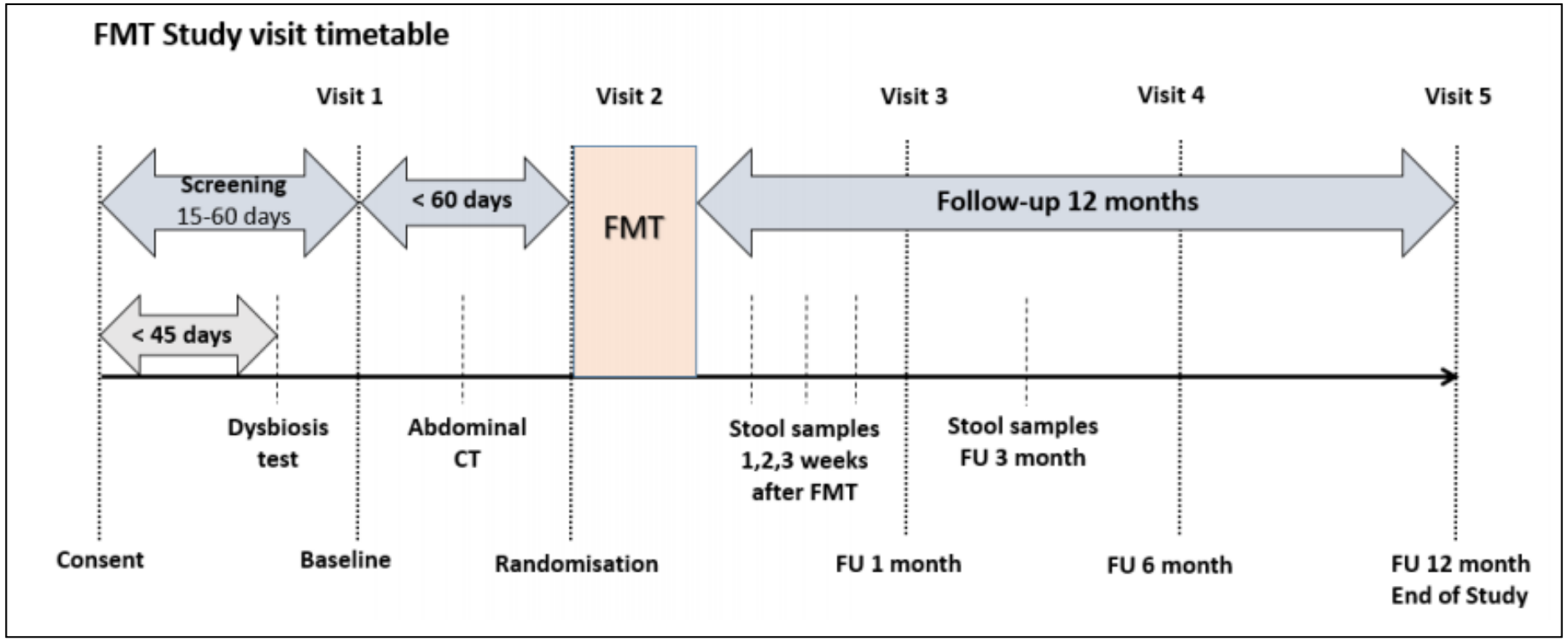
- Autism
- Multiple sclerosis
- Parkinson disease

Implications of the Gut Microbiome in Parkinson's Disease



Elfil et al., 2020, Mov Disord, 35: 921-933

FMT in the treatment of Parkinson disease



The importance of the microbiota-gut-brain axis (MGBA) in PD has grown rapidly. In the gut, alpha-synuclein (asyn) pathology, inflammation, altered gut microbiota (GMB), and reduced intestinal cholinergic innervation have been described.

RESEARCH Kang et al. Microbiome (2017) 5:10 Open Access

Microbiota Transfer Therapy alters gut ecosystem and improves gastrointestinal and autism symptoms: an open-label study

Dae-Wook Kang[1†], James B. Adams[2†], Ann C. Gregory[3,15†], Thomas Borody[4], Lauren Chittick[5,15], Alessio Fasano[6], Alexander Khoruts[7,8,9], Elizabeth Geis[2], Juan Maldonado[1], Sharon McDonough-Means[10], Elena L. Pollard[2], Simon Roux[5,15], Michael J. Sadowsky[8,11], Karen Schwarzberg Lipson[12], Matthew B. Sullivan[3,5,15,16*], J. Gregory Caporaso[12,13*] and Rosa Krajmalnik-Brown[1,14*]

18 children with ASD (ages 7–16 years) who were diagnosed by the Autism Diagnostic Interview-Revised (ADI-R) and had moderate to severe gastrointestinal problems.

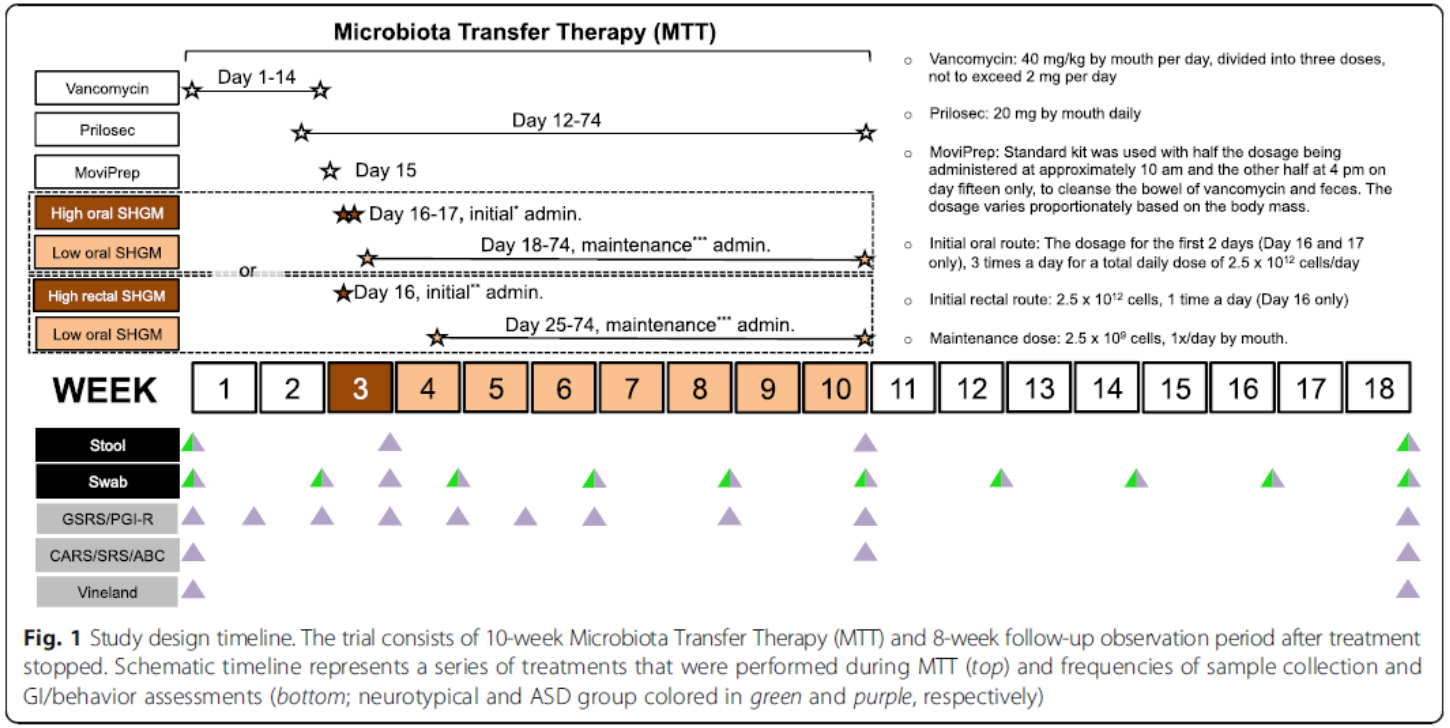


Fig. 1 Study design timeline. The trial consists of 10-week Microbiota Transfer Therapy (MTT) and 8-week follow-up observation period after treatment stopped. Schematic timeline represents a series of treatments that were performed during MTT (*top*) and frequencies of sample collection and GI/behavior assessments (*bottom*; neurotypical and ASD group colored in *green* and *purple*, respectively)

Conclusions: This exploratory, extended-duration treatment protocol thus appears to be a promising approach to alter the gut microbiome and virome and improve GI and behavioral symptoms of ASD. Improvements in GI symptoms, ASD symptoms, and the microbiome all persisted for at least 8 weeks after treatment ended, suggesting a long-term impact.

RESEARCH ARTICLE

Fecal microbiota transplantation for the improvement of metabolism in obesity: The FMT-TRIM double-blind placebo-controlled pilot trial

Elaine W. Yu[1,2]*, Liu Gao[1], Petr Stastka[1], Michael C. Cheney[1], Jasmin Mahabamunuge[3], Mariam Torres Soto[3], Christopher B. Ford[4], Jessica A. Bryant[4], Matthew R. Henn[4], Elizabeth L. Hohmann[2,3]

- FMT-TRIM was a 12-week double-blind randomized placebo-controlled pilot trial of oral FMT capsules.
- They randomized 24 adults with obesity and mild–moderate insulin resistance to weekly healthy lean donor FMT versus placebo capsules for 6 weeks.
- The primary outcome, assessed by intention to treat, was change in insulin sensitivity between 0 and 6 weeks as measured by hyperinsulinemic euglycemic clamps.
- Additional metabolic parameters were evaluated, including HbA1c, body weight, body composition by dualenergy X-ray absorptiometry, and resting energy expenditure by indirect calorimetry.

PLoS Med 17(3): e1003051. https://doi.org/ 10.1371/journal.pmed.1003051

Table 2. Metabolic parameters in FMT and placebo groups throughout the 12-week study.

Characteristic	Placebo group			FMT group			Difference between FMT and placebo groups in change from baseline (95% CI)	
	Baseline	6 weeks	12 weeks	Baseline	6 weeks	12 weeks	Baseline to 6 weeks	Baseline to 12 weeks
Weight (kg)	111 ± 20	111 ± 20	111 ± 19	110 ± 26	114 ± 26	111 ± 27	−0.2 (−2.4, 2.0)	0.2 (−2.0, 2.4)
Lean mass (kg)	58 ± 12	58 ± 12	58 ± 11	60 ± 15	62 ± 15	61 ± 16	−0.4 (−2.1, 1.4)	−0.1 (−1.9, 1.6)
Fat mass (kg)	53 ± 10	53 ± 10	52 ± 10	49 ± 13	51 ± 14	50 ± 14	1.1 (−0.7, 3.0)	1.2 (−0.6, 3.0)
VAT volume (cm^3)	998 ± 319	991 ± 285	976 ± 308	1048 ± 368	1107 ± 423	982 ± 358	19 (−76, 115)	−52 (−147, 42)
Fasting glucose (mmol/l)	4.8 + 0.4	4.8 + 0.4	5.1 + 0.6	5.0 + 0.7	4.8 + 0.7	5.1 + 0.6	0.02 (−0.3, 0.4)	−0.1 (−0.4, 0.3)
HbA1c (%)	5.5 ± 0.3	5.5 ± 0.3	5.5 ± 0.3	5.6 ± 0.2	5.5 ± 0.4	5.4 ± 0.4	−0.1 (−0.2, 0.1)	**−0.1 (−0.3, −0.01)**
HOMA-IR	3.5 ± 1.9	3.4 ± 1.3	4.8 ± 1.7	3.5 ± 1.4	3.9 ± 1.4	4.7 ± 2.0	0.3 (−0.6, 1.3)	−0.02 (−0.9, 0.9)
Total cholesterol (mmol/l)	5.1 ± 0.6	5.1 ± 1.1	5.2 ± 0.7	5.5 ± 0.6	5.2 ± 0.8	5.2 ± 1.0	−0.3 (−0.8, 0.2)	−0.3 (−0.8, 0.2)
HDL (mmol/l)	1.2 ± 0.3	1.1 ± 0.3	1.1 ± 0.4	1.3 ± 0.4	1.3 ± 0.5	1.3 ± 0.3	0.04 (−0.1, 0.2)	0.08 (−0.1, 0.2)
LDL (mmol/l)	3.3 ± 0.6	3.3 ± 1.2	3.2 ± 0.7	3.3 ± 0.8	3.0 ± 0.9	2.9 ± 0.9	−0.2 (−0.6, 0.2)	−0.2 (−0.6, 0.2)
Triglycerides (mmol/l)	1.3 [1.1, 1.8]	1.2 [1.1, 2.0]	1.4 [1.0, 2.7]	1.7 [1.1, 2.2]	1.9 [1.2, 2.3]	1.5 [1.3, 2.1]	−0.4 (−1.4, 0.5)	−0.8 (−1.7, 0.1)
CRP (mg/l)	3.5 [2.3, 7.3]	3.0 [1.7, 5.0]	4.6 [2.5, 6.8]	2.9 [1.7, 5.6]	3.5 [1.9, 5.0]	2.9 [2.0, 4.1]	**1.8 (0.3, 3.3)**	−0.1 (−1.6, 1.3)
REE (kcal/day)*	1,503 ± 218	1,536 ± 241	n/a	1,588 ± 305	1,705 ± 351	n/a	8.4 (−97, 114)	n/a
Caloric intake (kcal/day)	1,939 ± 463	2,006 ± 693	1,689 ± 760	2,121 ± 729	2,236 ± 949	2,331 ± 822	−50 (−603, 502)	389 (−155, 932)

Yu EW et al. PLoS Med 17(3): e1003051. 2020.

Fecal microbiota transplantation for the improvement of metabolism in obesity

Conclusions Weekly administration of FMT capsules in adults with obesity results in gut microbiota engraftment in most recipients for at least 12 weeks. Despite engraftment, we did not observe clinically significant metabolic effects during the study

- Future studies should evaluate pre-selection of donors and recipients, and consider microbiome and lifestyle modifications concurrently

Yu EW et al. PLoS Med 17(3): e1003051. 2020.

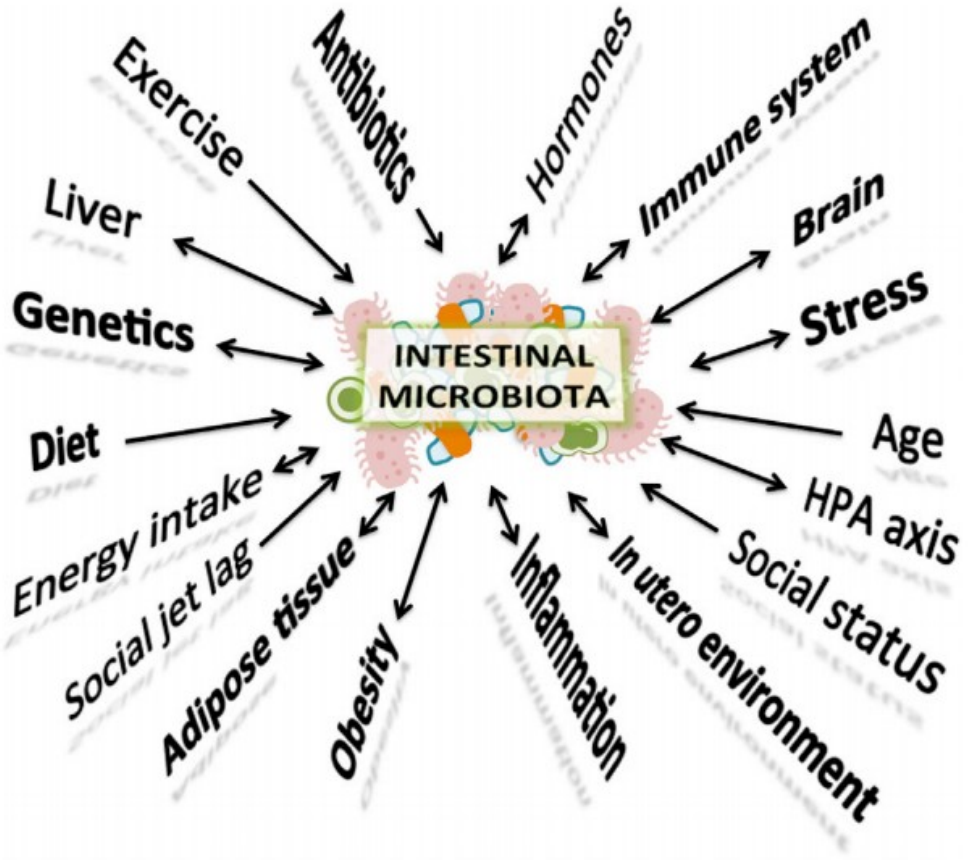
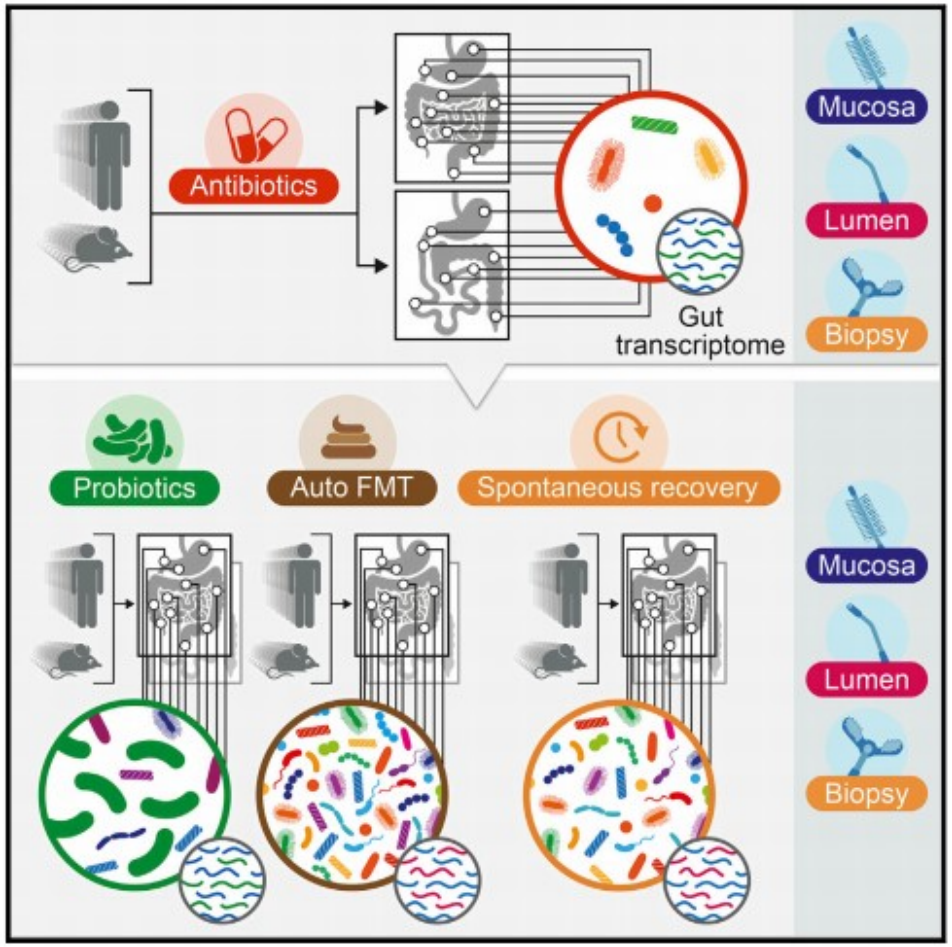


Figure 1. Environmental Factors and the Bidirectional Interaction with Host Organ Systems Shape the Intestinal Microbiome
Studies over the past decade have revealed that many environmental factors, including diet, antibiotic exposure, energy intake (EI), and exercise, can dramatically influence the intestinal microbiome (both membership and functional capacity). In addition to environment, further research has revealed a bidirectional interaction between host organ systems and the intestinal microbiome in shaping host metabolic outcomes.

Maruvada p et al. Cell Host & Microbe 22, November 8, 2017

Post-Antibiotic Gut Mucosal Microbiome Reconstitution Is Impaired by Probiotics and Improved by Autologous FMT



Highlights

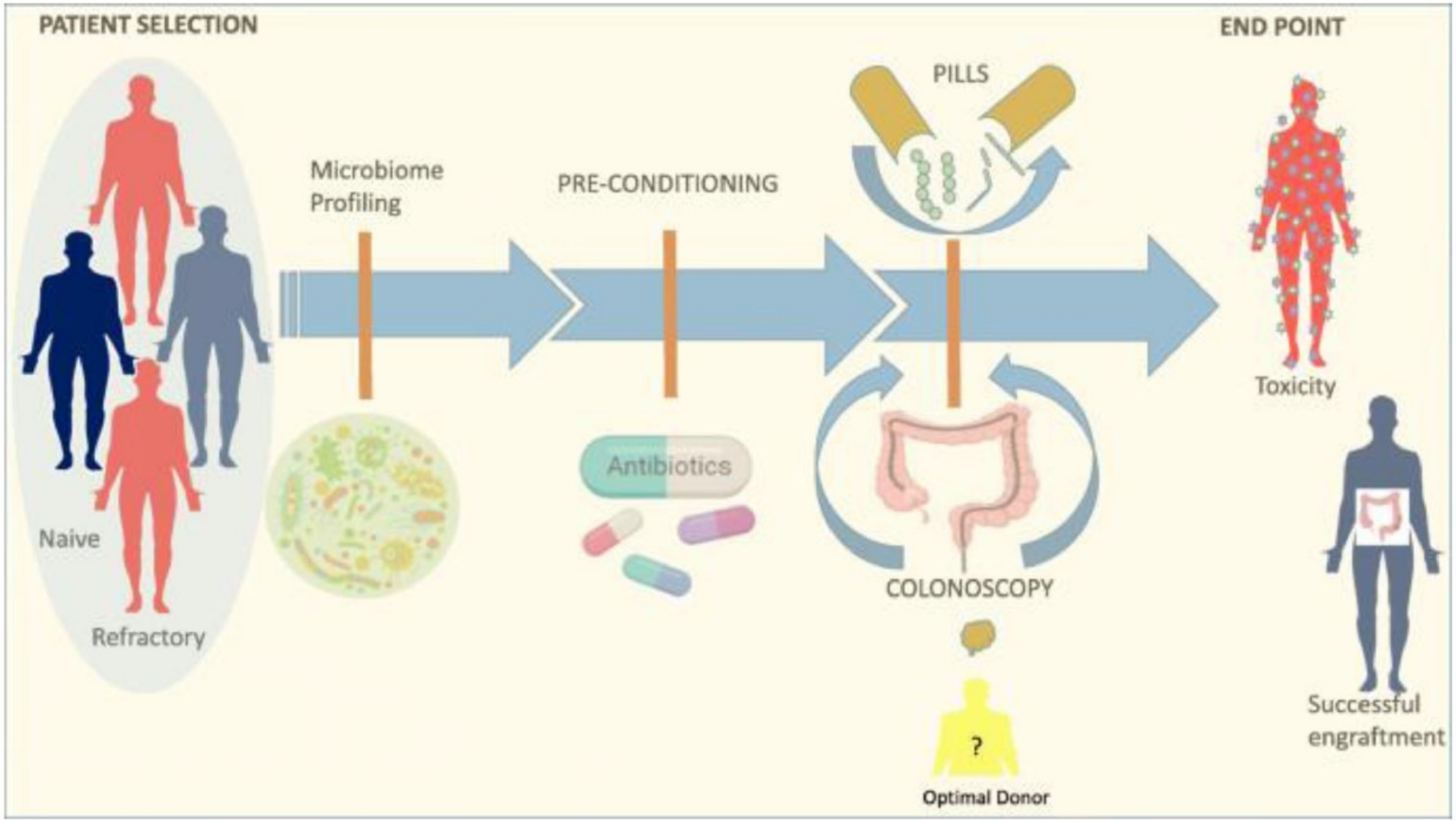
- Murine gut mucosal probiotic colonization is only mildly enhanced by antibiotics
- Human gut mucosal probiotic colonization is significantly enhanced by antibiotics
- Post antibiotics, probiotics delay gut microbiome and transcriptome reconstitution
- In contrast, aFMT restores mucosal microbiome and gut transcriptome reconstitution

In Brief

Probiotics perturb rather than aid in microbiota recovery back to baseline after antibiotic treatment in humans.

Suez et al., Cell 2018, 174, 1406–1423

Gut microbiome modulation via fecal microbiota transplant to augment immunotherapy in patients with melanoma or other cancers



FMT is a proven method of modulating the gut microbiota and is currently being investigated in multiple clinical trials in the setting of immunotherapy to either enhance response or treat toxicity

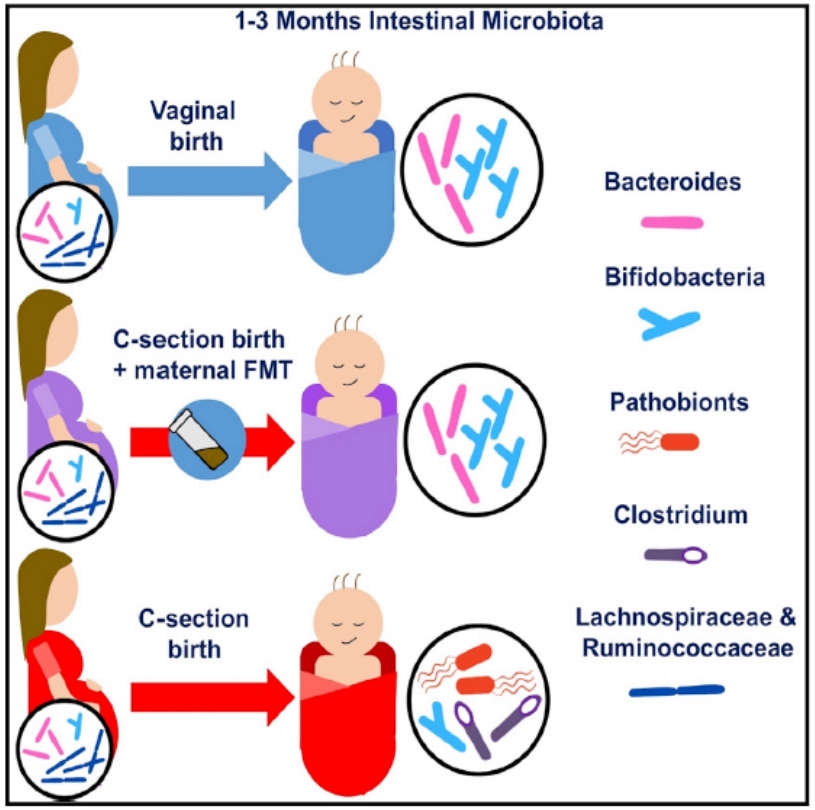
JL McQuade et al Curr Oncol Rep. 2020 Jun 24;22(7):74. doi: 10.1007/s11912-020-00913-y

Cell

Article

Maternal Fecal Microbiota Transplantation in Cesarean-Born Infants Rapidly Restores Normal Gut Microbial Development: A Proof-of-Concept Study

Graphical Abstract



Authors

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In Brief

A proof-of-concept safety study shows that oral fecal transplantation can shift the microbiome composition of infants who are born via cesarean section to a profile that is more similar to those born via vaginal delivery.

rpela K., Helve O., Kolho K-L., Saisto T., Skogberg K., Dikareva E., Stefanovic V., Salonen A., Andersson , de Vos W. Maternal Fecal Microbiota Transplantation in Cesarean-Born Infants Rapidly Restores ormal Gut Microbial Development: A Proof-of-Concept. Cell, 2020. DOI: 10.1016/j.cell.2020.08.047

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Letter to the Editor

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SAGE

Stool for fecal microbiota transplantation should be classified as a transplant product and not as a drug

Josbert J Keller[1,2], Maria JGT Vehreschild[3], Christian L Hvas[4], Simon MD Jørgensen[4], Jouzas Kupciskas[5], Alexander Link[6], Chris JJ Mulder[7], Simon D Goldenberg[8], Ramesh Arasaradnam[9], Harry Sokol[10,11,12], Antonio Gasbarrini[13], Christoph Hoegenauer[14], Elizabeth M Terveer[15,2], Ed J Kuijper[16,2] and Perttu Arkkila[17]; On behalf of the UEG working group of the Standards and Guidelines initiative *Stool banking for FMT*

Lopuksi

- Ulosteensiirrosta voi tulla hoitomuoto myös uusiin indikaatioihin
- Todennäköisesti tarvitaan tarkkaan valittu siirre sopiville potilaille
- Tarvitaan hyviä kontrolloituja tutkimuksia!
  - Ulosteensiirtotutkimuksen kautta opimme sairauksien etiologiasta ja taudinkulusta
- Ulosteensiirto pitää luokitella kudossiirteeksi eikä lääkkeeksi