

CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Fecal Microbiota Transplantation for Autism: Clinical Effectiveness, Cost- Effectiveness, and Guidelines

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Research Questions

1. What is the clinical effectiveness of fecal microbiota transplantation for the treatment of individuals with autism spectrum disorder?
2. What is the cost-effectiveness of fecal microbiota transplantation for the treatment of individuals with autism spectrum disorder?
3. What are the evidence-based guidelines regarding the use of fecal microbiota transplantation for the treatment of individuals with autism spectrum disorder?

Key Findings

No relevant literature was identified regarding fecal microbiota transplantation for the treatment of individuals with autism spectrum disorder.

Methods

A limited literature search was conducted by an information specialist on key resources including Medline and Embase via OVID, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were fecal microbiota transplantation and autism spectrum disorders. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and June 7, 2019. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Individuals (of any age) with autism spectrum disorder
Intervention	Fecal microbiota transplantation
Comparator	Q1-Q2: Dietary interventions; No treatment; Placebo; Usual care Q3: No comparator
Outcomes	Q1: Clinical effectiveness (e.g., change in autism severity scales [e.g., Childhood Autism Rating Scale, Social Responsiveness Scale, Aberrant Behavior Checklist], rates of adverse events) Q2: Cost-effectiveness Q3: Evidence-base guidelines
Study Designs	Health technology assessment, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations and evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

No relevant literature was identified regarding fecal microbiota transplantation for the treatment of individuals with autism spectrum disorder.

References of potential interest are provided in the appendix.

Overall Summary of Findings

No relevant literature was identified regarding fecal microbiota transplantation for the treatment of individuals with autism spectrum; therefore, no summary can be provided.

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

No literature identified.

Economic Evaluations

No literature identified.

Guidelines and Recommendations

No literature identified.

Appendix — Further Information

Previous CADTH Reports

1. Fecal microbiota transplantation (fecal transplant) for adults with inflammatory bowel disease. (*CADTH issues in emerging health technologies no.143*). Ottawa (ON): CADTH; 2015:
<https://www.cadth.ca/dv/ieht/fecal-microbiota-transplantation-fecal-transplant-adults-inflammatory-bowel-disease>. Accessed 2019 Jun 12.

Randomized Controlled Trials – *Ongoing Clinical Trials*

2. Children's Hospital Los Angeles. NCT03426826: The gut-brain study. ClinicalTrials.gov. Bethesda (MD): U.S. National Library of Medicine; 2019:
<https://clinicaltrials.gov/ct2/show/NCT03426826?term=fecal+microbiota&cond=Autism&rank=2>. Accessed 2019 Jun 12.
3. Finch Research and Development LLC. NCT03829878: Efficacy, safety, and tolerability study of oral Full-Spectrum Microbiota™ (CP101) in subjects with autism spectrum disorder and associated GI symptoms (SPROUT) (SPROUT). ClinicalTrials.gov. Bethesda (MD): U.S. National Library of Medicine; 2019.
<https://clinicaltrials.gov/ct2/show/NCT03829878?term=fecal+microbiota&cond=Autism&rank=3>. Accessed 2019 Jun 12.
4. Arizona State University. NCT03408886: Microbiota transfer therapy for adults with autism spectrum disorder (ASD) who have gastrointestinal disorders (MTT-ASD). ClinicalTrials.gov. Bethesda (MD): U.S. National Library of Medicine; 2018:
<https://clinicaltrials.gov/ct2/show/NCT03408886?term=fecal+microbiota&cond=Autism&rank=1>. Accessed 2019 Jun 12.

Non-Randomized Studies – *No Comparator*

5. Kang DW, Adams JB, Coleman DM, et al. Long-term benefit of microbiota transfer therapy on autism symptoms and gut microbiota. *Sci Rep*. 2019;9(1):5821.
[PubMed: PM30967657](https://pubmed.ncbi.nlm.nih.gov/30967657/)
6. Kang DW, Adams JB, Gregory AC, et al. Microbiota transfer therapy alters gut ecosystem and improves gastrointestinal and autism symptoms: an open-label study. *Microbiome*. 2017;5(1):10.
[PubMed: PM28122648](https://pubmed.ncbi.nlm.nih.gov/28122648/)

Review Articles

7. Kho ZY, Lal SK. The human gut microbiome - a potential controller of wellness and disease. *Front Microbiol*. 2018;9:1835.
[PubMed: PM30154767](https://pubmed.ncbi.nlm.nih.gov/30154767/)
8. Choi HH, Cho YS. Fecal microbiota transplantation: current applications, effectiveness, and future perspectives. *Clin Endosc*. 2016;49(3):257-265.
[PubMed: PM26956193](https://pubmed.ncbi.nlm.nih.gov/26956193/)

9. Evrensel A, Ceylan ME. Fecal microbiota transplantation and its usage in neuropsychiatric disorders. *Clin Psychopharmacol Neurosci*. 2016;14(3):231-237.
[PubMed: PM27489376](#)

Additional References

10. Arizona State University. Autism symptoms reduced nearly 50 percent two years after fecal transplant. Science Daily; 2019:
<https://www.sciencedaily.com/releases/2019/04/190409093725.htm>. Accessed 2019 Jun 12.
11. Campion D, Ponzo P, Alessandria C, Saracco GM, Balzola F. The role of microbiota in autism spectrum disorders. *Minerva Gastroenterol Dietol*. 2018;64(4):333-350.
[PubMed: PM29600698](#)
12. Shi YC, Yang YS. Fecal microbiota transplantation: current status and challenges in China. *JGH Open*. 2018;2(4):114-116.
[PubMed: PM30483574](#)
13. Urbonas V, Cervinskiene J. Fecal transplantation and its role in autism spectrum disorders. Presented at the 31st International Workshop on Helicobacter and Microbiota in Inflammation and Cancer; September 2018; Kaunas, LT.
<https://onlinelibrary.wiley.com/doi/full/10.1111/hel.12525>. Accessed 2019 Jun 12.
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16. Siebenhaar A, Rosien U. Fecal microbiome transfer. *Internist Prax*. 2016;56(2):269-277.