

About Fecal Transplantation

Crohn's and Colitis Canada Position on Fecal Transplantation:

Fecal transplantation is a promising and exciting area of research that may lead to an alternative treatment option for ulcerative colitis (UC) and potentially Crohn's disease. Crohn's and Colitis Canada understands the eagerness and impatience of some patients; however, **Crohn's and Colitis Canada urges patients not to perform fecal transplantation themselves, or to accept a fecal transplant, outside of a research ethics board-approved clinical trial and to wait for scientific evidence as there are significant safety concerns including risk of serious infection.** This is still a new area of study, the effects of this treatment are still being investigated and the longer-term effects of fecal transplants remain unknown.

Background:

There are approximately 233,000 Canadians living with Inflammatory Bowel Disease (IBD). Nearly half of them, 104,000, live with ulcerative colitis (UC) and 129,000 live with Crohn's disease (CD).¹ CD is a chronic inflammatory condition of the gastrointestinal tract and UC is the chronic inflammation of the large intestine and rectum. Current treatment choices are limited. Crohn's and Colitis Canada invests in IBD research to foster advancements in treatments, and ultimately, finding cures for Crohn's disease and ulcerative colitis.

In 2013, Crohn's and Colitis Canada provided a substantive research grant to study the effectiveness and safety of fecal transplantation in persons living with UC. A team of researchers from McMaster University is administering a randomized controlled trial to evaluate the effectiveness of fecal transplants in ulcerative colitis. This study is expected to yield published results in 2014. Other teams of researchers across Canada are also investigating the role of fecal transplantation in the management of IBD.

Fecal transplantation is the process of inserting stool from a healthy donor into a recipient to restore the normal microbiome (microorganisms that live in our body) in a recipient's large bowel. The treatment is still in clinical testing and has not been endorsed by Health Canada for the treatment of IBD. Fecal transplantation has shown promising results; however, researchers are still learning about its effects and risks. Early testing has shown that multiple treatments may be required and subsequent treatments may be necessary in the future in the management of IBD.¹¹ Treatments are carried out by a colonoscope¹¹¹ (placing a scope in the colon), by fecal enema, or by a nasoduodenal tube¹¹ (inserting a tube through the nose into the bowel). Researchers are also investigating the development of a pill where needed bacteria are extracted from the stool and packed into a gelatin capsule.^{v,vi} However, this is an ongoing development that has yet to been proven as an effective and safe treatment approved by Health Canada.

Recommendations for People Living with IBD:

Although fecal transplants have been used successfully to treat recurrent infections with a bacteria called Clostridium difficile, the same level of success has not been observed with UC and further study is needed.^{vii} In one case it was reported that UC symptoms worsened in a patient receiving fecal transplantation for recurrent C. difficile infection.^{viii} Clinical trials are still underway to better understand the efficacy and safety of fecal transplantation for the treatment of Crohn's disease or ulcerative colitis.

For this reason, Crohn's and Colitis Canada **urges patients who are not participating in a research ethics-approved clinical trial setting not to perform fecal transplantation themselves, or to accept a fecal transplant outside of ethically approved clinical trial and to wait for scientific evidence as there is significant safety concerns and risk of serious infection.**

Many do-it-yourself videos and information on fecal transplantation can be easily found on the internet. However, the treatment needs to be carried out in a medical environment under the direction of a medical specialist. Potential healthy donors must be screened for bacterial, viral or parasitic infections to ensure that dangerous micro-organisms are not introduced to the person receiving the treatment. Self-treatment with unscreened stool poses the risk of transmission of serious disease (e.g. hepatitis, HIV, intestinal parasites). Even family members may be harboring some infections that do not appear harmful to them but may cause problems in transmission, so that relying on spousal, child, sibling or close friend stool donation carries unknown risks as well. People living with UC are urged to consult with their gastrointestinal specialist or family practitioner to seek medical advice on this or other treatments that are still in the research phase or that have not been approved by Health Canada for the treatment of UC.

More information can be found on The American Gastroenterological Association site: <u>http://fmt.gastro.org/</u>

ⁱⁱⁱ Lund-Tonnesen S, Berstad A, Schreiner A et al. (1998). Clostridium-difficile-associated diarrhea treated with homologous feces. *Tidsskr nor* Laegeforen 118 (7): 1027–1030.

^{iv} Persky SE, Brandt LJ (2000). Treatment of recurrent Clostridium-difficile-associated Diarrhea by Administration of Donated Stool Directly through a Colonoscope. *Am J Gastroenterol* 95 (11): 3283–3285.

^v Infectious Diseases Society of America (2013, October 4). Fecal transplant pill knocks out recurrent C. diff infection. *ScienceDaily*. Retrieved December 16, 2013, from <u>http://www.sciencedaily.com/releases/2013/10/131004105253.htm</u>

^{vi} The Canadian Press (2013, October 3). 'Poop' pills can treat C. difficile, Calgary doctor says. CBC News. Retrieved December 16, 2013, from http://www.cbc.ca/news/canada/calgary/poop-pills-can-treat-c-difficile-calgary-doctor-says-1.1895079

^{vii} Van Nood E, Vrieze A, Nieuwdorp M, Fuentes S, Zoentendal G, de Vos WMK, J.J. Duodenal infusion of donor feces for Recurrent Clostridium difficile. *New England Journal of Medicine*. 2013;368(5):407-415.

viii De Leon LM, Watson JB, Kelly CR. Transient Flare of Ulcerative Colitis after Fecal Microbiota Transplantation for Recurrent Clostridium Difficile Infection. *Clin Gastroenterol Hepatol*. 2013;11:1036-1038.

ⁱ The Crohn's and Colitis Foundation of Canada (2012). The Impact of Inflammatory Bowel Disease in Canada 2012: Final Report and Recommendations. *Ccfc.ca*. Retrieved 10 December, 2013, from http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf

ⁱⁱ Borody TJ, Campbell J. (2011, December) Fecal Microbiota Transplantation: Current Status and Future Directions. *Expert Review of Gastroenterology and Hepatology*; 5(6): 653-655.