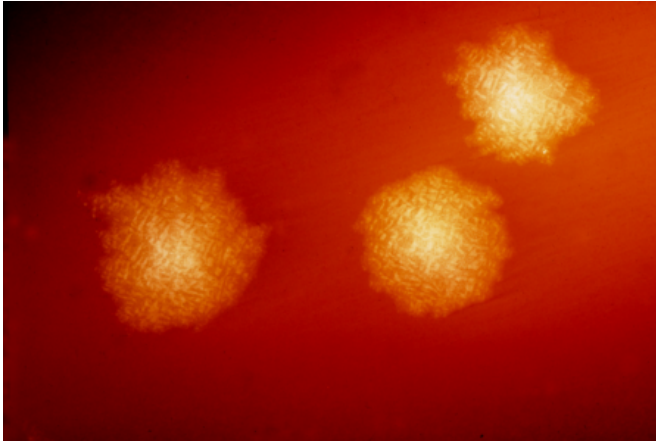


# Single fecal transplant no more effective than standard of care in treating *C. diff*

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This photograph depicts *Clostridium difficile* colonies after 48hrs growth on a blood agar plate; Magnified 4.8X. *C. difficile*, an anaerobic gram-positive rod, is the most frequently identified cause of antibiotic-associated diarrhea (AAD). It accounts for approximately 15-25% of all episodes of AAD. Credit: CDC

Researchers at the University Health Network have found that when treating recurrent *Clostridium difficile* infection (RCDI), a single fecal transplantation delivered by enema is no more effective than the existing standard of care for RCDI, administration of oral vancomycin taper. The findings were published recently in the journal *Clinical Infectious Diseases*.

Over the last decade, FT has re-emerged as a promising treatment for RCDI with recent studies showing it to be highly effective. In an effort to measure the true effectiveness of FT, the UHN team launched a phase 2/3, single centre, open-label trial, where study participants experiencing an acute episode of RCDI were randomly assigned to receive either 14 days of oral vancomycin therapy followed by a single FT of fresh donor stool via enema, or a six week taper of oral vancomycin only.

After analyzing the results of the first 30 patients, the team terminated the study since they found no significant difference between the treatments. In fact, a futility analysis showed that should the study have been completed, it is highly unlikely that FT would show benefit over oral vancomycin taper. This is the first study of its kind to compare FT to the current standard of care for RCDI.

"These findings are quite interesting and show that we have a lot to learn as to how well fecal transplantation works compared to the standard of care before it becomes a mainstream treatment," says Dr. Susy Hota, Medical Director, Infection Prevention and Control Program, University Health Network. "More research is needed into the many factors that influence the effectiveness of FT, such as donor and patient selection, FT manufacturing, how it is delivered to the patient, the number of times FT needs to be given, and any other variables that could improve outcomes."

*Clostridium difficile* (*C. diff*) is a bacterium that causes mild to severe diarrhea and other intestinal symptoms. It is the most frequent cause of infectious diarrhea in hospitals and long-term care facilities in Canada. One in four patients with *C. diff* infection go on to have repeated episodes of infection that can be challenging to cure.

Most cases of *C. diff* infection occur in patients who are taking antibiotics. Antibiotics can destroy a person's normal bacteria found in the gut, allowing *C. diff* bacteria to multiply and cause damage to the intestines.

FT, also known as a stool transplant, is the process of transplanting fecal bacteria from a healthy individual into a recipient with a disease presumed to be caused by the disruption of the microbiota - natural bacteria - of the gut. The goal of FT is to restore the gut's microbiota by introduction of healthy bacterial flora through a stool infusion. Over the last few years, FT has become increasingly

popular for treating recurrent CDI.

Today's results, however, indicate that more research needs to be done to determine whether this treatment is actually more effective than the standard of care, and specifically, how to obtain the best results from FT. The study also highlights that there is also much to learn about the long-term implications of FT.

"In light of our results, I would caution a blanket approach of FT to treat RCDI," says Dr. Hota. "The FT field is still evolving and, given as yet undefined long-term effects of manipulating the gut's microbiota, it should be approached with caution."

In an effort to provide more data about the long term health effects of FT, Dr. Hota, co-lead Dr. Susan Poutanen and colleagues at UHN, Sinai Health System and the University of Toronto founded the Microbiota Therapeutics Outcomes Program (MTO). A multi-disciplinary, collaborative research program, the MTO is conducting studies to measure [long term health](#) outcomes from FT when it is used to treat *C. diff* and several other health conditions.

Provided by University Health Network

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