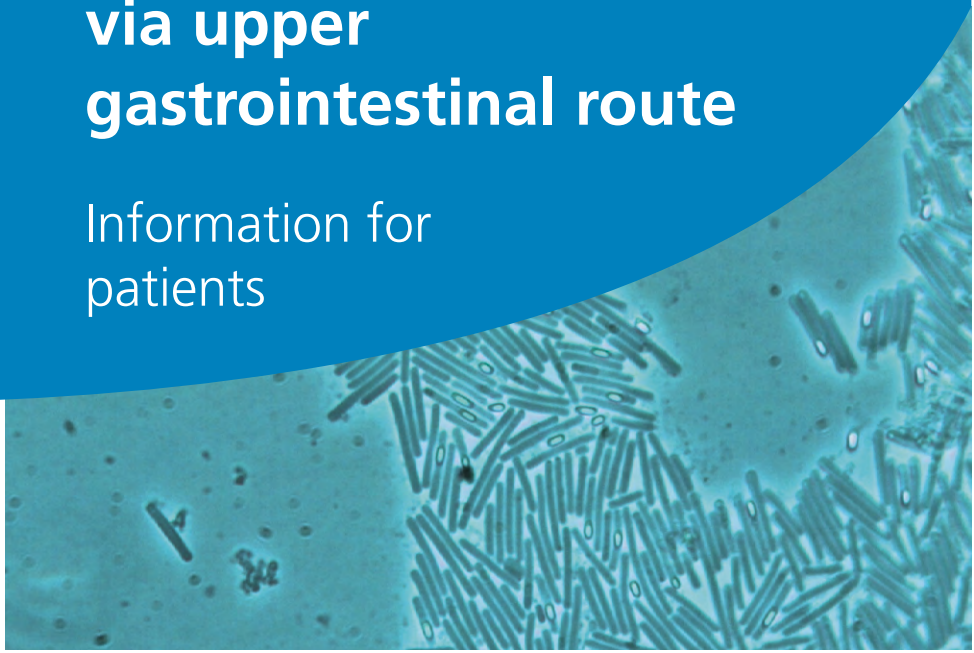
NHS
The Leeds Teaching Hospitals
NHS Trust

Faecal microbiota transplantation (FMT) to treat *Clostridioides difficile infection* (CDI)

via upper gastrointestinal route

Information for patients



Medicines Management
and Pharmacy Services

Faecal microbiota transplantation

You have been identified as potentially benefiting from a faecal microbiota transplant (FMT), also known as stool transplantation.

The purpose of this information leaflet is to offer you some background about this treatment and to highlight its risks and benefits before you decide whether you feel that it is suitable for you. Please take time to read the following information and feel free to ask for more details if you have any questions.

What is *Clostridiodes difficile (C. difficile)*?

C. difficile bacteria live in the bowel (also known as the gut). In a healthy person, *C. difficile* bacteria can live amongst the normal bacteria in the gut and do not cause disease. If the normal bacteria are reduced, for example by the use of antibiotics to treat other infections, then the numbers of *C. difficile* bacteria can increase and produce toxins which cause disease. *C. difficile* can cause diarrhoea, fever, loss of appetite, nausea and abdominal pain; and in severe cases be life-threatening.

What is FMT?

Faecal Microbiota Transplant (FMT) is the transfer of a processed mixture of liquid faeces from a healthy and thoroughly screened donor to the gut of an individual (recipient) for the treatment of a specific disease. It has been shown to be very effective in treating cases of recurrent *C.difficile* which have not responded to specific antibiotic therapy. "Good" bacteria from the donor faeces restore the balance of bacteria in the gut of the recipient, this keeps *C. difficile* growth in check or eradicates it altogether from the gut of the recipient, and prevents recurrence of *C. difficile* diarrhoea.

Who are the faecal donors?

Faecal donors are anonymous, healthy adults, between the ages of 18 and 50 years, who have not taken antibiotics in the last 3 months and have had no recent change in bowel habit. They undergo an extensive medical history and lifestyle assessment and are screened for gut infections (including presence of multi-drug resistant bacteria in the faeces) and for infections that can be transmitted by bodily fluids (usually blood), including Hepatitis A, B, C, E, HIV and syphilis. Donors and their donated faeces are also screened for SARS-Cov-2 (COVID-19). Only those negative for these infections will be allowed to be donors.

The FMT you will receive is obtained directly from the University of Birmingham Microbiome Treatment Centre who undertake this donor screening and storage of the processed liquid stool.

What's involved in FMT treatment?

You will be given antibiotic tablets to treat your *C. difficile* for at least four days prior to being given the FMT. The antibiotics should be stopped the night before the FMT.

You will receive a tablet of omeprazole on the morning of treatment to reduce the amount of stomach acid that could potentially kill the bacteria being given in the FMT.

A medicine called domperidone will also be given to promote stomach emptying into the small intestine. A tube (known as a nasogastric tube) is passed through the nose into the stomach and, once the correct position of the tube in the stomach

has been confirmed, FMT is administered down the tube by trained staff. You will not be able to smell or taste the FMT. The tube is then flushed with sterile water and removed after one hour.

Will FMT work for me?

There is increasing evidence that FMT can be used to treat illnesses related to major changes and loss of the normal gut bacteria. FMT is currently recommended and licensed for the treatment of *C. difficile* infection that does not respond to antibiotics or is recurrent. Although, there is no guarantee that FMT will alleviate or completely cure your condition, success rates are high and FMT is only offered in *C. difficile* when other available treatments have already failed.

The symptoms of *C. difficile* infection are stopped in around 91% of patients who receive FMT treatment, compared to only 30–40% of patients who receive antibiotic treatment. Patients usually see improvement in their diarrhoea within 24–72 hours after the FMT.

What are the risks of treatment?

FMT is sometimes associated with mild self-limiting gastro-intestinal symptoms in the days following FMT (such as transient nausea, bloating, flatulence, belching and constipation). Patients with coexisting inflammatory bowel disease may experience a flare of symptoms

There is a low, but possible, risk of transmission of a pathogen (an organism, e.g., bacteria or virus, which can cause illness) from the donor FMT to the recipient. The risk is low as donors,

and their faeces, are thoroughly screened for common infections spread by blood and faeces and restricted from donating if any are detected. One pathogen which both you and the donor stool will be screened for is Helicobacter pylori. If you test negative for this pathogen in your stool then we would aim to give you negative stool. If this is not possible, you would be offered Helicobacter pylori positive stool which would have a risk of transmission therefore of this bacteria. After receipt of FMT, we would test you for this bacteria six weeks later and offer you treatment to eradicate it if positive. There may also be unrecognised 'pathogens' (organisms which can cause illness) in the FMT, which could subsequently cause illness in the recipient.

There are some additional risks related to the procedure itself. For example, if FMT is delivered by a nasogastric tube there is a very small risk of perforation from placement of the nasogastric tube. There is also a risk of the nasogastric tube being incorrectly inserted into the lungs. Delivery of FMT into the lungs would cause a serious infection. Steps are taken to ensure correct placement of the tube into the stomach according to hospital guidelines, and the position of the tube will always be checked before it is used to deliver the FMT.

You will be able to discuss any risks associated with having FMT with your doctor when they ask your permission (consent) for the procedure.

What will happen after FMT treatment?

FMT is a relatively new treatment and it is therefore important to understand if the treatment works. In addition to any routine clinical follow up you may have, your doctor will complete a FMT specific questionnaire about your progress at seven days (this data will be sent to the University of Birmingham Microbiome Treatment Centre as part of their routine follow up for FMT they provide). You will also be offered follow up in the General Infectious Diseases clinic arranged around 12 weeks after your FMT treatment for further assessment of your symptoms and the outcome of the FMT. Your doctor will ask you questions about your health after FMT, any side effects of the treatment and how satisfied you were with the treatment. This data will be anonymised and used to evaluate the success or failure of FMT treatment here at Leeds Teaching Hospitals NHS Trust (LTHT). Anonymised data may be used for teaching and audit purposes to enable ongoing improvement of our service.

Questions?

If you have any further questions, please speak to a doctor or nurse caring for you. At Leeds Teaching Hospitals, the delivery of FMT is overseen by the Infectious Diseases team who will also be happy to address any further questions you, or the team looking after you, have.

You can contact them on **0113 206 6614** or **0113 206 5468**

References

Faecal microbiota transplant for recurrent Clostridioides difficile infection. NICE Medical technologies guidance [MTG71] Published: 31 August 2022. Available at: Faecal microbiota transplant for recurrent Clostridioides difficile infection NICE https://www.nice.org.uk/guidance/mtg71

Fecal Microbiota Transplantation (FMT) with Colonoscopy is Superior to Enema and Nasogastric Tube While Comparable to Capsule for the Treatment of Recurrent Clostridioides difficile Infection: A Systematic Review and Meta-Analysis. Ramai *et al*. *Digestive Diseases and Sciences* **volume 66**, pages369–380 (2021)

Microbiome Treatment Centre - University of Birmingham https://www.birmingham.ac.uk/university/colleges/mds/facilities/advanced-therapies-facility/microbiome-treatment-centre.aspx

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