

Availability of MTT in the US

Fecal microbiota transplant (FMT) is currently only allowed by the FDA for people with recurrent *C. Difficile* infections, which causes life-threatening severe diarrhea. The FDA does not allow FMT to be used for any other conditions until more research is done.

We are doing research on a type of intensive FMT which we call Microbiota Transplant Therapy, in the hopes that it may eventually be approved for children and adults with autism. The FDA requires Phase 1, 2, and 3 trials prior to considering drugs for approval. Phase 1 is for safety, and our Phase 1 study for children demonstrated both good safety and efficacy (in an open-label trial, which means everyone knew they were receiving the treatment so there is some placebo effect). We are now doing a Phase 2 study (randomized, double-blind, placebo-controlled) for adults with ASD.

We hope to do another study for children with ASD, as soon as we have funds available. If these studies are successful, we hope they will lead to a much larger phase 3 trial (randomized, double-blind, placebo-controlled study) which if successful would lead to FDA approval.

We do not know of any other sites in the US conducting research studies on FMT or MTT for people with ASD.

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