

Observation of Faecal Microbiota Transplantation Use for Restoration of Gut Microbiota in Gastrointestinal Disorders in the Real-World Setting (The REAL-BIOME Study). A Real-World, Prospective, Observational Study.

ACTRN12623000492651

Status	RECRUITING
Sponsor	BiomeBank
Enrollment	150 participants

Plain Language Summary

Faecal microbiota transplantation (FMT) involves transferring stool from a healthy donor into a patient's gut to restore a healthy balance of gut bacteria. It has been proven effective for treating a dangerous bacterial infection called *C. difficile*, and there is growing evidence it may also help with conditions like ulcerative colitis, Crohn's disease, irritable bowel syndrome, and chronic constipation.

The REAL-BIOME Study is tracking patients across Australia who are receiving FMT through the official TGA-approved access scheme for these bowel conditions. By observing what happens in a real clinical setting — rather than in a tightly controlled trial — researchers can learn how safe and effective FMT is when used for a broader range of patients in everyday practice.

You may be eligible if you are 18 or older, have a confirmed diagnosis of one of the gastrointestinal conditions listed, and your specialist has received TGA approval to prescribe FMT for you. Women who are pregnant and people with severe food allergies (anaphylactic level) are not eligible. Participation involves completing questionnaires and allowing your clinical data to be recorded.

Key Eligibility Criteria

Inclusion (4)

- Aged 18 years or older.
- Confirmed diagnosis of ulcerative colitis, Crohn's disease, irritable bowel syndrome, immune checkpoint inhibitor-induced enterocolitis, or functional constipation.
- Prescribed BiomeBank FMT by treating specialist physician for their gastrointestinal disorder. The prescribing physician must have received approval from the TGA to treat the patient with FMT off-label via the Special Access Scheme. This must occur before patient is eligible for the study, but is not a part of the study process.
- Has not received FMT in 8 weeks prior to study entry.

Exclusion (2)

- Anaphylactic food allergy.
- Pregnancy.

Locations (1 total)

ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12623000492651>

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