

## Global disparities in faecal microbiota transplantation research

Faecal microbiota transplantation (FMT) is recommended therapy for recurrent *Clostridioides difficile* infection in adult and paediatric patients<sup>1</sup> and is being explored as treatment for a growing range of microbiome-mediated diseases.<sup>2</sup> Although microbiome-based therapies could play a key role in global health,<sup>3,4</sup> global FMT research remains inequitably distributed.

To explore the distribution of access to FMT research by geography and patient age, we searched the WHO's International Clinical Trials Registry Platform,<sup>5</sup> which aggregates 17 registries, including one African and one South American registry, using search terms "FMT", "f(a)ecal bacteriotherapy", "flora transplant\*", "f(a)ecal transplant\*", "f(a)ecal microbiota transplant\*", and "intestinal microbiota transplant\*" in December, 2019.

We identified 384 clinical studies involving FMT. Between 2010 and 2019, the number of studies increased, and the disease indications being explored diversified (figure). In 2013, 21 studies—most (17 of 21) studying *C difficile* infection or inflammatory bowel disease (IBD)—were registered. In 2017, 76 trials were registered, but less than a third (24 of 76) studied *C difficile* infection or IBD. Most studies were small (median enrolment target 35 patients, IQR 20–60), and early phase (170 [81%] of 209 were phase 1 or 2).

Most studies were registered in North America, Western Europe, and East Asia (figure). 98 (27%) of 367 had a site in the USA and 84 (24%) of 367 had a site in China. Only one study had a site in Africa. None had a site in South America. Most studies (271 [71%] of 384) were registered

on ClinicalTrials.gov, with another 38 (10%) in the Chinese Clinical Trial Registry, 30 (8%) in the Japan Primary Registries Network, and 45 (12%) in all other registries combined.

Most studies focused on adults. Only 24 (6%) of 384 trials included very young participants (age zero to 5 years), and only another 44 (11%) included young adults (age 6 and 17 years). Most studies with very young participants targeted *C difficile* infection, IBD, or the gut–brain axis (21 [88%] of 24) and were concentrated in North America (13 [54%] of 24). However, young adult studies, half of which (22 of 44) targeted IBD, were concentrated in Asia (28 [64%] of 44).

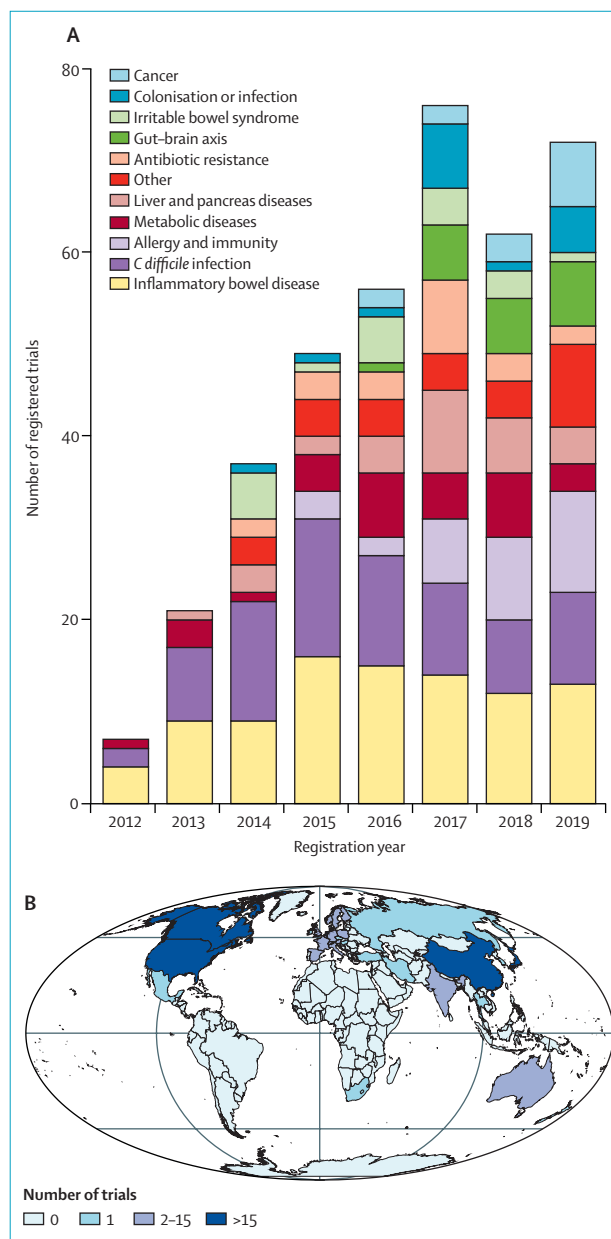
Although the landscape of FMT research has diversified in terms of indications, FMT research remains focused on adult populations in high-income countries, with IBD research in China a notable exception. Researchers should urgently address barriers to more inclusive FMT trials and broaden access to experimental microbiome therapies for children and populations in low-income and middle-income countries.<sup>3,4</sup>

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**Figure:** Faecal microbiota transplantation studies registered between 2010 and 2019

(A) Distribution of studies by registration year and indication. (B) Distribution of studies by country.

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For more on the **International Clinical Trials Registry Platform** see <http://apps.who.int/trialsearch/>