JAMA | Preliminary Communication

Effect of Fecal Microbiota Transplantation on 8-Week Remission in Patients With Ulcerative Colitis
A Randomized Clinical Trial

Samuel P. Costello, MBBS; Patrick A. Hughes, PhD; Oliver Waters, MBBS; Robert V. Bryant, MScR; Andrew D. Vincent, PhD; Paul Blatchford, PhD; Rosa Katsikeros, BSc; Jesica Makanyanga, MBChB; Melissa A. Campaniello, BSc; Chris Mavrangelos, BSc; Carly P. Rosewarne, PhD; Chelsea Bickley, BSc; Cian Peters, MS; Mark N. Schoeman, PhD; Michael A. Conlon, PhD; Ian C. Roberts-Thomson, PhD; Jane M. Andrews, PhD

JAMA. 2019;321(2):156-164. doi:10.1001/jama.2018.20046

RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Costello SP, 2015	RCT	73	+	?	+	+

Characteristics of studies

Costello SP, 2015

Population	1. RESULTS Among 73 patients who were randomized (mean age, 39 years; women, 33 [45%]), 69 (95%) completed the trial. 2. Other exclusion criteria were previous colonic surgery, gastrointestinal infection, pregnancy, anticoagulant therapy, or current use of antibiotics or probiotics. 3. Patients were excluded if they had severe disease defined by either a total Mayo score of 11 to 12 or Truelove and Witts criteria 16 (passing >6 bloody stools/day plus ,â•1 of the following: temperature >37.8¬∞C, pulse >90 bpm, hemoglobin <10.5 g/dL, or erythrocyte sedimentation rate >30 mm/h).
Intervention	1. Patients could enroll taking an oral dose of prednisolone ,â§25 mg, with a mandatory taper of 5 mg per week. 2. Interventions Participants received 3 L of polyethylene glycol bowel preparation the evening before and loperamide, 2 mg orally, immediately prior to colonoscopy. 3. The container for colonoscopic delivery contained 50 g of stool in 200 mL and the 2 containers for enema delivery contained 25 g of stool in 100 mL. Autologous stool containers had identical ratios and volumes of stool, saline, and glycerol but they were processed under aerobic conditions.
Outcomes	1. The primary outcome was steroid-free remission of UC as defined as a total Mayo score of ,â§2 (range, 0-12) with an endoscopic Mayo score of ,â§1 (range, 0-3) at week 8. 2. The primary outcome was steroid-free remission of UC, defined as a total Mayo score of 2 with an endoscopic Mayo score of 1 or less at week 8. 3. Clinical response (measured by a ,â•3-point reduction in total Mayo score at week 8 and 12 months), clinical remission (measured by a Simple Clinical Colitis Activity Index score ,â§2 at week 8 and 12 months), and endoscopic remission (measured by a Mayo score of <1 at week 8 and 12 months) were compared for participants receiving dFMT with those receiving aFMT. Patients' perception and acceptability of

FMT were assessed using a written questionnaire completed by patients prior to enrollment and at 12 months (eAppendix 5 in Supplement 2).

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomization Accrued participants were randomized 1:1 using a computergenerated simple randomization algorithm (http://www. 2. Nonnested random intercepts were included to account for batch effects (individuals receiving the same donor mix) and site effects (treating institution). 3. INTERVENTIONS Patients were randomized to receive either anaerobically prepared pooled donor FMT (n = 38) or autologous FMT (n = 35) via colonoscopy followed by 2 enemas over 7 days.
Allocation concealment	high/unclear	1. Randomization Accrued participants were randomized 1:1 using a computergenerated simple randomization algorithm (http://www. 2. INTERVENTIONS Patients were randomized to receive either anaerobically prepared pooled donor FMT (n = 38) or autologous FMT (n = 35) via colonoscopy followed by 2 enemas over 7 days. 3. The container for colonoscopic delivery contained 50 g of stool in 200 mL and the 2 containers for enema delivery contained 25 g of stool in 100 mL. Autologous stool containers had identical ratios and volumes of stool, saline, and glycerol but they were processed under aerobic conditions.
Blinding of participants and personnel	low	1. The randomization record was kept in a separate document to the patient record and other study data such that participants and clinicians performing the procedures and assessing the primary and secondary end points were blinded to the therapy received. 2. The container for colonoscopic delivery contained 50 g of stool in 200 mL and the 2 containers for enema delivery contained 25 g of stool in 100 mL. Autologous stool containers had identical ratios and volumes of stool, saline, and glycerol but they were processed under aerobic conditions. 3. A total of 73 adults with mild to moderately active UC were enrolled in a multicenter, randomized, double-blind clinical trial in 3 Australian tertiary referral centers between June 2013 and June 2016, with 12-month follow-up until June 2017.
Blinding of outcome assessment	low	1. The randomization record was kept in a separate document to the patient record and other study data such that participants and clinicians performing the procedures and assessing the primary and secondary end points were blinded to the therapy received. 2. Random intercepts were included for each group of individuals receiving the same donor mix (batch effects) and post hoc nonnested random intercepts were included for each treating institution (site effects). 3. A total of 73 adults with mild to moderately active UC were enrolled in a multicenter, randomized, double-blind clinical trial in 3 Australian tertiary referral centers between June 2013 and June 2016, with 12-month follow-up until June 2017.