

Blinded, randomized controlled trial.

Moderately active UC patients were randomised to:

Group 1: free diet and single donor standard FMT by colonoscopy on Day 1 and rectal enemas on Days 2 and 14 without dietary conditioning of the donor.

Group 2: received FMT but with dietary pre-conditioning of the donor for 14 days and a UC Exclusion Diet [UCED] for the patients.

Group 3: received the UCED alone.

(This trial was stopped due to futility after 53% of intended patients were enrolled)

Primary endpoint:

The primary endpoint was Week 8 clinical steroid-free remission, defined as SCCAI <3

Results:

- Remission w8: group 1, 11.8%; group 2, 21.1%; group 3, 40%, p=ns.
- Endoscopic remission: group 1, 12%; group 2, 16%; group 3, 27%

Conclusions:

UCED alone appeared to achieve higher clinical remission and mucosal healing than single donor FT with or without diet. The study was stopped for futility by a safety monitoring board.

Use of Faecal Transplantation with a Novel Diet for Mild to Moderate Active UC: The CRAFT UC Randomised Controlled Trial

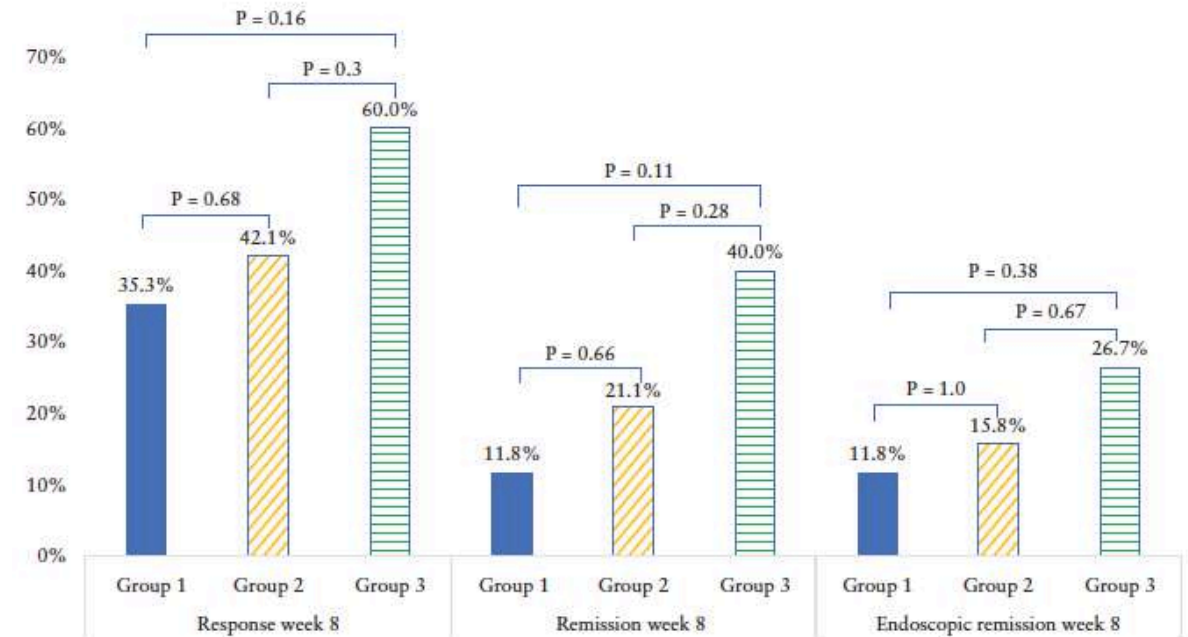


Figure 3. Clinical response, clinical remission, and endoscopic remission at Week 8 by intention to treat.

