

Ulcerative colitis (UC) is a long-term condition and about 1 in 5 people with UC report ongoing diarrhoea, even when their disease is stable and not active. This also causes discomfort and distress, reducing peoples' quality of life, and impacting on their psychological health and mood.

This is similar to people living with irritable bowel syndrome (IBS), who often experience diarrhoea. In IBS, a diet low in poorly absorbed sugars (known as fermentable oligo-, di-, and mono-saccharides and polyols (FODMAPs)) improves diarrhoea, because some FODMAPs increase small intestinal water content. Drugs like ondansetron (an anti-sickness drug), amitriptyline (an antidepressant drug), or loperamide (an anti-diarrhoeal drug) can also be effective in IBS with diarrhoea. We wanted to test whether these treatments worked in people with stable inactive UC with ongoing diarrhoea. People aged over 18 years with stable UC who have diarrhoea were eligible to take part.

All participants were provided with standardised dietary advice. People were also given one of: a low FODMAP diet; ondansetron; amitriptyline; loperamide; or nothing in addition to the standardised dietary advice. A computer randomly decided who got which treatment. People were asked to take treatment for 6 months, in addition to their doctor's usual treatment for UC. People were followed up at 8 weeks and 6 months.

Benefits of taking part may have included improvement in symptoms and quality of life, fewer hospital visits, and being able to make better-informed decisions regarding the management of diarrhoea in patients with stable UC.

Risks were the side effects associated with the drugs (although these were thought to be at a reduced rate due to the low doses used).

MODULATE started in December 2021 and closed in January 2023. The team tried to make the trial more convenient for participants to take part by having a remote pathway, where all trial activities could be done at home with the support of a researcher on the telephone. Due to the COVID-19 pandemic, the trial struggled to recruit enough participants and it was decided to close the trial.

Starting in autumn of 2019 until the autumn of 2022, 71 secondary sites were approached to take part in the MODULATE trial. Once invited, sites were e-mailed and/or telephoned regularly to encourage engagement in study set-up. Eight of these sites completed this process, but only four had opened by the time the trial closed.

Between 06/12/2021 and 27/01/2023, a total of 17 potentially eligible people were identified. A screening call took place for eight of these people, two participants were registered onto the trial, and one participant was randomised.

The mean age of total screened patients was 44.1 years (SD 12.7), 12 (70.6%) were female, and 15 (88.2%) were white.

Although the trial closed early and without enough participants to do a full statistical analysis, lessons were learned that can inform future remote trial design and participant pathways.