



Synopsis

Management of diarrhoea in patients with stable ulcerative colitis with low FODMAP diet, amitriptyline, ondansetron or loperamide: the MODULATE RCT

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Plain language summary

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Plain language summary

Ulcerative colitis is a long-term condition, and about one in five people with ulcerative colitis report ongoing diarrhoea. This also causes discomfort and distress, reducing people's quality of life, and impacting on their psychological health and mood.

This is similar to people living with irritable bowel syndrome, who often experience diarrhoea. In irritable bowel syndrome, 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 antisickness drug), amitriptyline (an antidepressant drug) or loperamide (an antidiarrhoeal drug) can also be effective in irritable bowel syndrome with diarrhoea. People aged over 18 years with stable ulcerative colitis who have diarrhoea were eligible to take part.

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

Benefits of taking part may have included improvement in symptoms and quality of life, including mood, fewer hospital visits and better-informed decisions regarding the management of diarrhoea in patients with stable ulcerative colitis.

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 opened to recruitment 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 phone. A second redesign of the trial was planned in an effort to make the trial less burdensome for trial sites and participants. However, this second stage was not implemented. While the trial was open, 17 people were screened, and one person was randomised.

Due to the COVID-19 pandemic, the trial struggled to recruit enough participants, and it was decided to close the trial.