Low-dose titrated amitriptyline as second-line treatment for adults with irritable bowel syndrome in primary care: the ATLANTIS RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Plain language summary

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Plain language summary

Background

People with irritable bowel syndrome experience stomach (abdominal) pain and changes to their bowel movements. Irritable bowel syndrome can have a serious impact on people's lives. Previous small trials suggest that a drug called amitriptyline used at a low dose may help irritable bowel syndrome. Amitriptyline is already used to treat other conditions. It is available for irritable bowel syndrome but is not used much by general practitioners.

Methods

We recruited adults aged ≥ 18 years with irritable bowel syndrome from UK general practices who did not have any issues preventing the use of amitriptyline. Patients received either low-dose amitriptyline or placebo (a dummy tablet) for 6 months. Patients could adjust the dose according to symptoms and side effects. Neither the researchers nor the patients knew which treatment they were getting. Participants recorded symptoms using a questionnaire containing an irritable bowel syndrome severity score. We looked at the difference in average irritable bowel syndrome severity score between patients receiving amitriptyline and placebo. We also looked at effects of amitriptyline on mood, ability to work, and non-gut symptoms related to irritable bowel syndrome, as well as safety and acceptability. Some patients and general practitioners were interviewed about their experiences.

Results

Four hundred and sixty-three patients took part. Participants receiving amitriptyline reported a bigger improvement in their irritable bowel syndrome severity scores at 6 months, compared with patients on placebo. Amitriptyline was better across a range of irritable bowel syndrome symptom measures but did not impact anxiety, depression or ability to work. Forty-six people (19.8%) stopped taking amitriptyline and 59 (25.5%) stopped the placebo before 6 months. Patients liked being able to adjust their dose and valued contact with the research team.

Conclusion

This study showed that amitriptyline is more effective than a placebo and is safe. General practitioners should offer low-dose amitriptyline to people with irritable bowel syndrome if symptoms do not improve with other standard treatments. Patients should be supported and helped to adjust their dose as needed. The dose adjustment sheet used in this trial will be made available.

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