


Cognitive behavioural therapy in addition to antispasmodic therapy for irritable bowel syndrome in primary care: randomised controlled trial

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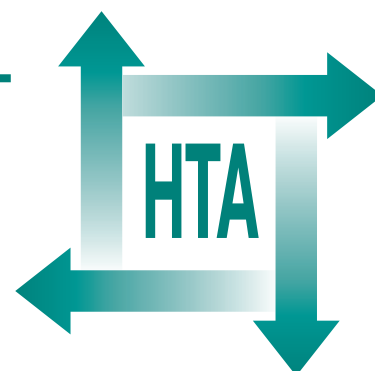
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Executive summary

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Executive summary

Background

Effective treatment of irritable bowel syndrome (IBS) in primary care continues to represent a challenge. Building on evidence of the efficacy of cognitive behavioural therapy (CBT) in functional bowel disorders in other settings, a randomised controlled trial was undertaken of CBT in primary care, delivered by specially trained nurses as an adjunct to standard treatment with the antispasmodic agent mebeverine hydrochloride.

Objective

The aim was to determine whether CBT in addition to antispasmodic treatment offers a cost-effective benefit to primary care patients with IBS and to identify predictors of outcome.

Methods

Practice nurses delivered CBT in a randomised trial of the addition of CBT to mebeverine in patients who had IBS of moderate or greater severity after 2 weeks of GP care and 4 weeks of mebeverine. The Symptom Severity Scale (SSS) was used to identify patients with moderate or severe IBS. Patients who continued to report moderate or severe IBS after 4 weeks of mebeverine at a dose of 270 mg three times a day were randomised to receive six sessions of CBT in addition to mebeverine (72 patients) or mebeverine alone (77 patients). These patients were followed at 3, 6 and 12 months after treatment.

The principal outcome measure was the SSS. Other measures were the fourth question on the SSS (measuring the 'global' impact of IBS), the Hospital Anxiety and Depression Scale, psychopathology, the Work and Social Adjustment Scale (WASA, disability), a modified version of the Illness Perception Questionnaire (illness perceptions), the Beliefs about Medicine Questionnaire (attitudes to medication), the Reported Adherence to Medication Scale (adherence to prescribed medication), the Client

Service Receipt Inventory (economic analysis), the Cognitive Scale for Functional Bowel Disorders (illness cognitions) and the Behaviour Scale for IBS (IBS coping behaviour).

As part of the baseline evaluation, blood tests for antiendomysial and antigliadin antibodies were carried out on 141 patients to determine the prevalence of coeliac disease in this population.

Results

The patients were aged between 17 and 54 (mean 34) years and were predominantly white; 82% were female and half had had IBS for more than 5 years.

The addition of CBT produced a significant benefit compared with the mebeverine-only group at 3 months after treatment on all outcome measures, except for the adherence to medication scales. The difference between the groups was 107.8 points on the SSS, 24.5 points on question 4 of the SSS and 6.3 points on the WASA, representing therapeutic gains of approximately 20%, 28% and 40%, respectively. However, there was also evidence that these improvements began to wane, so that at 6 and 12 months follow-up significant therapeutic benefit of the addition of CBT could only be detected on question 4 of the SSS and on the WASA. The behaviour scale for IBS detected significant, positive changes in coping behaviours at up to 6 months after treatment.

Three factors predicting a poor outcome were identified: male gender, believing that IBS had serious consequences and belief in an external aetiology, all of which were associated with greater than average disability at follow-up.

The addition of CBT to mebeverine did not reduce overall treatment or social costs.

The nested study on testing for coeliac disease provides cautious support for the inclusion of antiendomysial and antigliadin antibody testing in the investigation of patients thought to have IBS.

Conclusions

Specially trained practice nurses can provide effective CBT to primary care patients with a clinical diagnosis of IBS, which although effective does not reduce service or social costs. Using a variety of measures the beneficial therapeutic effects of the addition of CBT to antispasmodic therapy persist for up to 6 months.

Implications for healthcare

Non-specialist practice nurses can be trained to deliver CBT in primary care, and the CBT delivered in this way is likely to be beneficial, at least in the medium term, to patients with IBS whose symptoms have not responded to standard therapy.

Recommendations for research

Future research might include:

- studies of the long-term follow-up of IBS patients treated with CBT, perhaps testing the value of top-up sessions to sustain the therapeutic effect
- cost-benefit analyses comparing CBT with other therapeutic approaches to IBS
- evaluating means of training both non-specialist health professionals and GPs to deliver CBT.

Publication

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NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

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The research reported in this monograph was commissioned by the HTA Programme as project number 96/13/04. The contractual start date was in February 1999. The draft report began editorial review in May 2003 and was accepted for publication in November 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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