

Primary care

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

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Abstract

Objective To assess the efficacy of cognitive behaviour therapy delivered in primary care for treating irritable bowel syndrome.

Design Randomised controlled trial.

Setting 10 general practices in London.

Participants 149 patients with moderate or severe irritable bowel syndrome resistant to the antispasmodic mebeverine.

Interventions Cognitive behaviour therapy delivered by trained primary care nurses plus 270 mg mebeverine taken thrice daily compared with mebeverine treatment alone.

Main outcome measures Primary measures were patients' scores on the irritable bowel syndrome symptom severity scale. Secondary measures were scores on the work and social adjustment scale and the hospital anxiety and depression scale.

Results Of 334 referred patients, 72 were randomised to mebeverine plus cognitive behaviour therapy and 77 to mebeverine alone. Cognitive behaviour therapy had considerable initial benefit on symptom severity compared with mebeverine alone, with a mean reduction in score of 68 points (95% confidence interval 103 to 33), with the benefit persisting at three months and six months after therapy (mean reductions 71 points (109 to 32) and 11 points (20 to 3)) but not later. Cognitive behaviour therapy also showed significant benefit on the work and social adjustment scale that was still present 12 months after therapy (mean reduction 2.8 points (5.2 to 0.4)), but had an inconsistent effect on the hospital anxiety and depression scale.

Conclusion Cognitive behaviour therapy delivered by primary care nurses offered additional benefit over mebeverine alone up to six months, although the effect had waned by 12 months. Such therapy may be useful for certain patients with irritable bowel syndrome in primary care.

Introduction

Irritable bowel syndrome is a common, chronic, non-inflammatory condition affecting up to 20% of the general population.¹ It is diagnosed on the basis of symptoms,²⁻⁴ and treatment is directed at symptom

control. Apart from hypnotherapy,⁵ no psychological treatment has been shown to confer exceptional advantage. Cognitive behaviour therapy has been found to be effective in hospital patients with irritable bowel syndrome, but more recent trials have reported equivocal results.^{6,7} Such therapy has not been evaluated in primary care.

We investigated whether cognitive behaviour therapy is of benefit to primary care patients with troublesome irritable bowel syndrome.

Participants and methods

Patients

Patients attending 10 general practices in central and south London who were aged 16-50 years and had a clinical diagnosis of irritable bowel syndrome were invited to participate in our study. The patients completed questionnaires covering baseline assessment, exclusion criteria (see bmj.com for details), and the Rome I diagnostic criteria.³

Eligible patients who did not respond to two weeks of conventional treatment, and then to two weeks' treatment with mebeverine 275 mg three times a day, were randomised to receive mebeverine alone or mebeverine plus cognitive behaviour therapy. However, allocation concealment was not adequately maintained on every occasion, and in some cases the nurse who would provide cognitive behaviour therapy was aware of the planned allocation.

Patients were assessed again at six weeks after randomisation or on discharge from nurse therapy, and at three, six, and 12 months after treatment had finished.

Treatments

Four general practice nurses were recruited and trained to deliver cognitive behaviour therapy; their training occupied one day a week for 12 weeks.⁸ Therapy consisted of six 50 minute sessions at weekly intervals of face to face contact and was based on Lang's three systems model (see bmj.com for details).⁹ Therapy included education about the nature of irritable bowel syndrome, behavioural techniques aimed at

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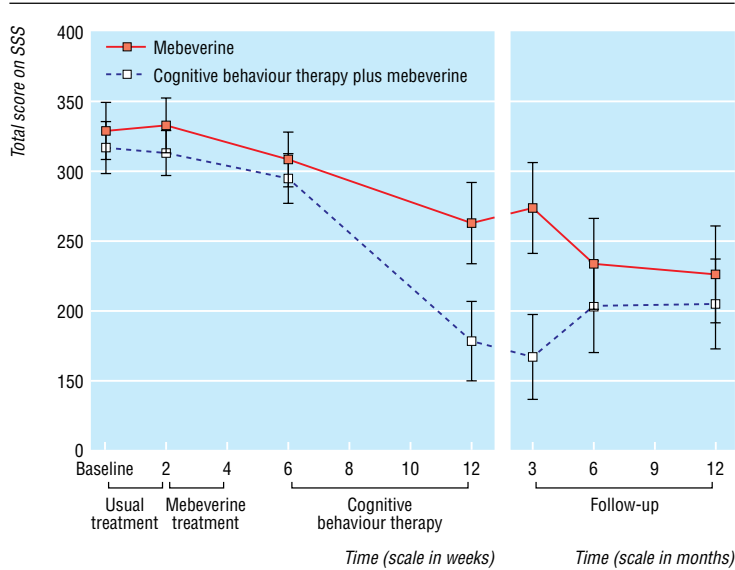
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Mean (95% confidence interval) scores on irritable bowel symptom severity scale (SSS) for 149 patients, by treatment

improving bowel habits, cognitive techniques to address unhelpful thoughts related to the syndrome, and techniques to reduce symptom focusing, manage stress, and prevent relapse.

Outcome measures

The main outcome measure was patients' scores on a symptom severity scale specific for irritable bowel syndrome.¹⁰ This includes an assessment of the impact of symptoms on general wellbeing (global impact). With a maximum score of 500, patients' symptoms may be scored as mild (score 75-174), moderate (175-299), or severe (300-500). Scores of < 75 indicate normal bowel function.

Subsidiary outcome measures were scores on the hospital anxiety and depression scale¹¹ and the work and social adjustment scale¹² (see bmj.com for details).

Power calculation

An a priori power calculation assumed that the mean score on the irritable bowel symptom severity scale at six months' follow-up would be 133 (mild) (SD 80) in the cognitive behaviour therapy plus mebeverine group and 180 (moderate) (SD 80) in the control group. We estimated that we required 240 patients.

Statistical analysis

We dealt with missing data items, not by carrying forward the previous value, but by imputing a score based on changes in other items, when at least 75%

of those items were present (such as irritable bowel symptom severity scale).

We conducted a regression analysis based on intention to treat, using generalised estimating equations on follow-up assessments (see bmj.com for details).

Results

Of the 334 patients referred over 27 months, 235 were eligible and agreed to participate. Two hundred and nineteen patients attended the second assessment, when a two week supply of mebeverine 275 mg three times a day was prescribed for 193. At the third assessment 149 patients (mean age 33.8 years (SD 8.6)) with irritable bowel syndrome of sufficient severity remained in the trial and were randomised to cognitive behaviour therapy plus mebeverine (n = 72) or mebeverine alone (n = 77). (See bmj.com for details of patients' baseline characteristics.)

Number of cognitive behaviour therapy sessions

Six patients received seven sessions of cognitive behaviour therapy, and fewer than half of patients were considered by the therapist to have completed therapy, with 41% either declining therapy or dropping out for other reasons. The commonest reasons given for non-attendance were that the patient had been unable to get time from work or from home commitments such as child care.

Main outcomes (irritable bowel symptom severity scale)

The figure shows that the addition of cognitive behaviour therapy to mebeverine treatment had a beneficial summary effect over one year on the symptom severity scale, reducing the total score by 37 points (95% confidence interval 8 to 67, P = 0.01). Therapy had a similar beneficial summary effect on the syndrome's global impact (question 4 on the symptom severity scale), reducing the score over the year by 14.4 points (8 to 21, P = 0.001). The table shows the treatment effect estimates: the benefits from cognitive behaviour therapy declined over time, with neither measure showing a significant effect by 12 months after therapy.

The symptom severity scale allows banding of bowel symptoms from "normal" through "mild" and "moderate" to "severe," which clinicians may find more helpful than actual scores. The summary odds ratio for the effect of cognitive behaviour therapy over one year for having "severe" symptoms was 0.43 (95% confidence interval 0.30 to 0.62, P < 0.001), and the table shows the odds ratios for each follow-up assessment.

Treatment effect estimates of adding cognitive behaviour therapy to drug treatment with mebeverine for patients with irritable bowel syndrome. (Values are differences in means (95% confidence interval) unless stated otherwise; larger negative values indicate greater treatment effects of therapy)

Follow-up assessment (months)	Total No of patients	Symptom severity scale			Work and social adjustment scale
		Total score	Question 4*	Odds ratio (95% CI) for banding†	
1.5	129	-68 (-103 to -33)	-18 (-26 to -10)	0.3 (0.2 to 0.6)	-4.1 (-6.5 to -1.8)
3	101	-71 (-109 to -32)	-22 (-30 to -13)	0.2 (0.1 to 0.4)	-5.0 (-7.5 to -2.6)
6	111	-14 (-51 to 23)	-11 (-20 to -3)	0.7 (0.4 to 1.5)	-1.7 (-4.1 to 0.7)
12	110	3 (-34 to 40)	-7 (-15 to 1)	0.9 (0.4 to 1.8)	-2.8 (-5.2 to -0.4)

*Global impact.

†Banding of symptoms as normal, mild, moderate, and severe. Odds ratios were for having "severe" symptoms.

We observed no significant harms in this study. The number needed to treat to change one patient's "severe" symptoms to "normal" at three months in the cognitive behaviour therapy group was 5.9 (3.3 to 27.8).

Secondary outcomes

The summary effect of cognitive behaviour therapy over one year was to reduce the score on the work and social adjustment scale by 3.4 (1.5 to 5.3, $P < 0.001$). Although the effect declined over time, disability was still reduced 12 months after treatment (see table).

For the hospital anxiety and depression scale, the summary effect of cognitive behaviour therapy over one year was to reduce the score by 2.0 (0.5 to 3.5, $P = 0.009$). The effects at each follow up were variable, with scores reduced by 1.5 (0.5 to 3.5, $P = 0.1$) at six weeks, by 3.3 (1.1 to 5.4, $P = 0.003$) at three months, by 0.6 (-1.5 to 2.7, $P = 0.6$) at six months, and by 2.7 (0.6 to 4.8, $P = 0.01$) at 12 months after therapy.

Discussion

This study is the first to report on the use of cognitive behaviour therapy for irritable bowel syndrome in primary care, and to show that the therapy improved patient outcomes when added to drug therapy.

Potential limitations of study

Limitations of this study include the absence of a control for cognitive behaviour therapy and the failure to ensure allocation concealment from the nurses giving the therapy. The nurses who delivered cognitive behaviour therapy were part of the research team and not integral to the healthcare teams where they operated, so that our degree of control over the quality of the therapy delivered was probably greater than that which could be expected in routine practice.

Implications of findings

The beneficial effect of providing up to six sessions of cognitive behaviour therapy in addition to drug treatment was detectable up to six months after therapy, both in terms of symptom relief and of improvement in social and work disability. Research is clearly required to determine whether patients might benefit from "booster" therapy sessions to maintain their initial improvement. Cognitive behaviour therapy has been shown to reduce relapse in depression, and may do likewise in irritable bowel syndrome. In this study, the therapy did not have a consistent effect on mood as measured by the hospital anxiety and depression scale but had a reasonable influence over 12 months on disability (work and social adjustment scale). Patient entry into our study was unrestricted, so our patients represented all subgroups of irritable bowel syndrome; we did not identify any adverse events, and both treatment arms were well received by patients.

Further controlled evaluations of drug and non-drug therapies, alone and in combination, and studies to identify the characteristics of patients likely to benefit from different treatments are needed to define the optimum treatment strategies for irritable bowel syndrome, particularly in relation to the benefits and harms of new treatments.

What is already known on this topic

Irritable bowel syndrome is a common problem that is managed predominantly in primary care

Drug treatment is unpredictable and often unsatisfactory; non-drug treatments, such as cognitive behaviour therapy, may be helpful but have not been studied in primary care

What this study adds

General primary care nurses were trained to deliver cognitive behaviour therapy to patients with irritable bowel syndrome

The therapy, given in addition to mebeverine, produced substantial short to medium term improvement in symptoms and in function in patients with treatment-resistant irritable bowel syndrome

For selected patients, cognitive behaviour therapy seems a useful addition to drugs treatment for irritable bowel syndrome in primary care

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