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Systematic review of mental health interventions for patients with common somatic symptoms: can research evidence from secondary care be extrapolated to primary care?

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Abstract

Objectives To determine the strength of evidence for the effectiveness of mental health interventions for patients with three common somatic conditions (chronic fatigue syndrome, irritable bowel syndrome, and chronic back pain). To assess whether results obtained in secondary care can be extrapolated to primary care and suggest how future trials should be designed to provide more rigorous evidence.

Design Systematic review.

Data sources Five electronic databases, key texts, references in the articles identified, and citations from expert clinicians.

Study selection Randomised controlled trials including participants with one of the three conditions for which no physical cause could be found. Two reviewers screened sources and independently extracted data and assessed quality.

Results Sixty one studies were identified; 20 were classified as primary care and 41 as secondary care. For some interventions, such as brief psychodynamic interpersonal therapy, little research was identified. However, results of meta-analyses and of randomised controlled trials suggest that cognitive behaviour therapy and behaviour therapy are effective for chronic back pain and chronic fatigue syndrome and that antidepressants are effective for irritable bowel syndrome. Cognitive behaviour therapy and behaviour therapy were effective in both primary and secondary care in patients with back pain, although the evidence is more consistent and the effect size larger for secondary care. Antidepressants seem effective in irritable bowel syndrome in both settings but ineffective in chronic fatigue syndrome.

Conclusions Treatment seems to be more effective in patients in secondary care than in primary care. This may be because secondary care patients have more severe disease, they receive a different treatment regimen, or the intervention is more closely supervised. However, conclusions of effectiveness should be considered in the light of the methodological weaknesses of the studies. Large pragmatic trials are needed of interventions delivered in primary care by appropriately trained primary care staff.

Introduction

As many as one in five new consultations in primary care are for somatic symptoms for which no specific cause can be found.¹ Patients with such symptoms often become frequent attenders, and their management poses considerable challenges for both general practitioners and specialists.² Although systematic reviews have shown that certain mental health interventions are effective in these patients, the treatments are not always provided.³⁻⁶ This may be partly because general practitioners question the quality of the evidence and its relevance for their patients or because the evidence of effectiveness is not widely known.⁷⁻⁹ Much of the research has been carried out in specialist settings, as is often the case when management is shared between primary and secondary care, and findings from specialist settings may not be applicable to primary care.

We did this study to investigate whether there is good evidence that mental health interventions are effective for patients with common somatic symptoms and whether the results of trials in secondary care can be extrapolated to primary care. We selected three common somatic conditions for which general practitioners had indicated they would welcome guidance: chronic fatigue syndrome, irritable bowel syndrome, and chronic back pain.¹⁰ In assessing the quality of published research, we also sought to identify how future trials should be designed to provide more rigorous evidence.

Method

We undertook a systematic review of randomised controlled trials, systematic reviews, and meta-analyses of mental health interventions for chronic fatigue syndrome, irritable bowel syndrome, and chronic back pain.

Search strategy

We searched PubMed, the Cochrane Library, PsycLIT, and Embase for English language papers published between 1966 and September 2001, carried out reference checks, searched key texts and asked experts to cite relevant literature (see bmj.com).

Inclusion criteria

We identified published studies of cognitive behaviour, cognitive, behaviour, brief interpersonal psychodynamic, and antidepressant therapy. For analysis of the randomised controlled trials, we pooled cognitive behaviour and cognitive therapy because there is no practical distinction between them and the studies gave insufficient details about the interventions to validate any distinction. Studies that included subjects whose symptoms were attributable to physical disease were excluded.

Data extraction and assessment of study quality

One of us (RR) extracted data from the identified papers and a second reviewer checked them (KL). Discrepancies were resolved by referring to the original studies. Studies were defined as primary care studies if they included patients who were recruited from the community or through their primary care physician or included a mixture of primary and secondary care patients.

Both reviewers independently noted methodological details using a checklist. The methodological quality of much of this literature has been previously systematically assessed using quality scales.³⁻⁵ However, the scales vary in the dimensions covered and their complexity. We therefore assessed the relevant methodological aspects individually rather than use a composite score.¹¹

Outcome measures and analysis

For all studies, we compared the findings of research from each setting by tabulating the reported health status and functional outcomes (see bmj.com). We compared initial disease severity of patients and treatment effect sizes between settings when studies used similar interventions and the same health status measures. In the limited number of cases in which we could compare primary and secondary care patients using the same outcome measure, the severity in each study was calculated by combining patients from all treatment arms. We calculated treatment effect sizes with 95% confidence intervals from the difference in mean health status after treatment.¹² We combined treatment effects using fixed effects meta-analysis when two or more studies from the same setting used the same health status measure. A random effects meta-analysis was used if there was significant heterogeneity ($P < 0.05$) of study effect sizes.

Results

We identified 61 randomised controlled studies (see bmj.com) and two meta-analyses: one on the effectiveness of behaviour therapy for chronic back pain, and one on the effectiveness of antidepressants for irritable bowel syndrome.^{3,4} One third (20) of the randomised controlled studies were defined as primary care studies (table). The conclusions are summarised in the box.

Treatments evaluated in primary and secondary care

Back pain

The effectiveness of cognitive behaviour therapy and behaviour therapy has been measured in both primary and secondary care patients. Of 16 studies of cognitive behaviour therapy for patients with back pain, seven

Number of comparisons conducted in each treatment setting

	Studies from primary care or the community	Studies from secondary care
Chronic fatigue syndrome:		
Cognitive behaviour therapy*†	1	4
Behaviour therapy†	0	3
Brief dynamic psychotherapy	0	0
Antidepressants	1	3
Irritable bowel syndrome:		
Cognitive behaviour therapy*†	3	5
Behaviour therapy†	2	2
Brief dynamic psychotherapy	0	2
Antidepressants	1	11
Chronic back pain		
Cognitive behaviour therapy*†	7	9
Behaviour therapy*†	9	6
Brief dynamic psychotherapy	0	0
Antidepressants	0	2

*Cognitive therapy is included in the category cognitive behaviour therapy as we were unable to distinguish the two in the published studies.

†Some studies compared cognitive behaviour therapy with behaviour therapy as well as cognitive behaviour therapy with a control and behaviour therapy with a control intervention. These studies have been included more than once.

were in primary care (891 patients) and nine in secondary care (625 patients). Patients from both settings reported sustained improvements in pain, disability, and depression. A meta analysis of the effectiveness of behaviour therapy found a moderate positive

Summary of research findings for effectiveness of mental health interventions for patients with somatic symptoms in primary and secondary care

Chronic fatigue syndrome

Cognitive behaviour therapy—Seems to be effective in secondary care patients. One study suggests a lack of supremacy of cognitive behaviour therapy over counselling in primary care patients

Behavioural therapy—Some evidence of effectiveness of graded exercise in secondary care patients

Brief psychodynamic interpersonal therapy—No trials identified

Antidepressants—No evidence for sustained symptomatic improvement in primary or secondary care patients

Irritable bowel syndrome

Cognitive behaviour therapy—Mixed results. In studies that showed effectiveness (in both settings), this may reflect the training and experience of the therapist, rather than the efficacy of the intervention.

Behavioural therapy—Limited evidence for the effectiveness of relaxation training in primary care patients

Brief psychodynamic interpersonal therapy—Some evidence of effectiveness in secondary care refractory patients

Antidepressants—Seems to be effective in primary and secondary care patients

Chronic back pain

Cognitive behaviour therapy—Seems to be effective in primary and secondary care patients

Behavioural therapy—Seems to be effective in primary and secondary care patients

Brief psychodynamic interpersonal therapy—No trials identified

Antidepressants—Insufficient evidence to allow conclusions to be drawn

effect on intensity of pain and a small positive effect on behavioural outcomes in patients, regardless of setting.³ There was some evidence from both settings that these improvements were sustained at one year follow up. The initial health status of secondary care patients was poorer than that of patients in primary care but they reported greater improvements (see bmj.com).

Chronic fatigue syndrome

Antidepressants in patients with chronic fatigue syndrome produced no sustained improvement.

Irritable bowel syndrome

A meta-analysis of the effect of antidepressants, regardless of setting, reported a moderate improvement in symptoms.⁴ Antidepressants seem to be effective in both primary and secondary care: improvements in physical symptoms and depression were reported in the study that included primary care patients and 10 out of 11 studies of 444 secondary care patients. We could compare treatment effect sizes in two of these studies, and these suggest that improvement in pain relief was far greater among secondary than primary care patients (see bmj.com). The two studies in which we could directly compare initial pain severity suggested that secondary care patients reported only slightly more severe pain than their counterparts in primary care.

Treatments with uncertain effectiveness in primary care patients

The effectiveness of cognitive behaviour therapy in patients with chronic fatigue syndrome and irritable bowel syndrome has been measured in patients in both primary and secondary care but differences in treatment regimens limit the conclusions that can be drawn. Cognitive behaviour therapy has been effective in patients with chronic fatigue syndrome in secondary care, although brief cognitive behaviour therapy was ineffective. In primary care patients, there was no difference in effectiveness between brief therapy and counselling.

Three studies of 169 primary care or community patients and five studies of 171 secondary care patients examined the effectiveness of cognitive behaviour therapy for irritable bowel syndrome. All the secondary care studies reported significant improvements with cognitive behaviour therapy in symptoms and in coping. The two smaller primary care studies reported greater symptomatic improvement with cognitive behaviour therapy than in controls, but in the largest study cognitive behaviour therapy was no better than placebo. There were insufficient data to draw conclusions about treatment effectiveness in primary care for behaviour therapy in patients with chronic fatigue syndrome (promising results were reported in secondary care) and for behaviour therapy and brief psychodynamic therapy in patients with irritable bowel syndrome.

Discussion

Meta-analyses suggest that behaviour therapy is effective for chronic back pain and that antidepressants are effective for irritable bowel syndrome. Analysis of individual studies indicates that cognitive behaviour

therapy and behaviour therapy for patients with back pain is more effective in patients in secondary care than those in primary care; antidepressant treatment for irritable bowel syndrome may also be more effective in secondary care. It should not, therefore, be assumed that interventions which are effective in secondary care will produce the same magnitude of effect in primary care. Instead, these findings need to be replicated independently in primary care patients.

Limitations of the evidence

For most treatments, we could draw only qualified conclusions because of methodological weaknesses in the research conducted. A major limitation of all the studies is that they evaluated the effect of interventions delivered by specialist therapists rather than primary care staff. Yet the main burden of disease occurs in primary care, and patients are unlikely to be referred to specialists because many would find it unacceptable and there is often a shortage of specialist resources.

There was sometimes insufficient detail for us to be sure how the intervention was implemented and whether it was provided in a standardised way. Only eight studies stated that a treatment manual was used, and only two studies (by the same author) monitored adherence to the protocol. Quality checks were hardly ever mentioned. There was also a lack of data on characteristics of the patients. Age and symptom duration were usually the only data provided. Dropout rates and their causes were rarely given.

There were few studies of long term outcome. Most studies (79%) measured only immediate outcome. Longer term outcome studies would provide evidence of sustained effectiveness and reduce the possibility of non-specific effects such as those due to therapist attention or patient expectations.¹³ Cost effectiveness is likely to be an important motivator for changing practice, but only one study examined this.¹⁴

Patients with the conditions we studied characteristically have symptoms for many years, and such patients are likely to be frequent attenders in primary care. If, as shown for patients with other conditions, the effect of cognitive behaviour therapy continues to improve with time, it could be a highly cost effective intervention.¹⁵

Another methodological shortcoming was that studies were commonly not powerful enough to detect clinically important differences. Sample sizes were often less than 20 patients. In addition, many different outcome measures were used, which limited the number of comparisons that could be made between settings. Finally, the studies commonly had problems of internal validity—for example, the absence of strict randomisation and of blind assessment of observer rated outcomes.

Explanations for findings

We identified four factors that may contribute to the greater improvements seen in secondary care than primary care. The first factor relates to differences between patients in the two settings. Patients in secondary care were more severely ill than their primary care counterparts (for cognitive behaviour therapy and behaviour therapy in back pain). Other unaccounted patient differences may explain the greater improvement in secondary care than primary care for patients with irritable bowel syndrome taking

antidepressants. The second factor concerns differences in the treatment regimen. In the two studies of antidepressants in irritable bowel syndrome for which we could compare treatment effect sizes, the minimum therapeutic dose was used in the primary care study, whereas a dose exceeding the recommended maximum dose was used in the secondary care study. Similarly, primary care patients with chronic fatigue syndrome received just four hours of cognitive behaviour therapy whereas secondary care patients received 16 hours of treatment. The third factor concerns differences in treatment provision: for cognitive behaviour therapy in irritable bowel syndrome, studies that reported an improvement used fewer therapists, most of whom were supervised by doctors, than studies that found no effect. The final factor is concerned with differences in study design. In the studies of behaviour therapy for back pain, the control group in the secondary care setting was assigned to the waiting list, whereas in the primary care study they were provided with an educational package that could be regarded as an active treatment.

Implications

Pragmatic studies of the effectiveness of psychological interventions in primary care and on unselected patients are needed to provide a basis for decisions about healthcare provision.¹⁶ Studies should identify which elements of an intervention require specialist training and which require specialist intervention. They should also measure the effectiveness of interventions carried out by primary care staff after a realistic amount of training and with the aid of standard manuals for patients and practitioners.¹⁷

The standards of reporting of trials need to be improved and harmonised to ensure that sufficient information is provided. The revised CONSORT criteria provide general guidance on trial reporting but more detailed directions are required when describing complex mental health interventions.¹⁸

Trials of mental health interventions should measure cost effectiveness and long term outcomes and outcomes should be measured with an outcome instrument when possible. Trials of effectiveness should be accompanied by qualitative research on the health beliefs and attitudes of participants and non-participants. This will enable interventions to be tailored to improve recruitment and dropout rates. Study designs should include an appropriate randomisation method, blind assessment of outcomes, and consistent handling of drop outs from each group.

This study is part of a research programme examining the methods of group decision making for developing clinical guidelines. This research programme is overseen by a steering committee comprising three of the authors (A Haines, NB, and TS) and T Marteau and S Carter.

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What is already known on this topic

Patients with functional somatic symptoms are common in primary care and may not receive effective mental health interventions

What this study adds

Research in secondary and primary care shows that cognitive behaviour therapy and behaviour therapy help patients with back pain and that antidepressants benefit patients with irritable bowel syndrome

Effect sizes are larger in secondary care than in primary care

Patients in secondary care with chronic fatigue syndrome may benefit from cognitive behaviour therapy

Future research should focus on large pragmatic trials with longer term follow up and economic evaluation

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Endpiece

Forever young

In a dream you are never eighty.

Anne Sexton (1928-74), American poet in *Old*, 1962

Submitted by Fred Charatan, retired geriatric physician, Florida