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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Authors' objectives
To determine the strength of the 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. In addition, to assess whether the results of trials obtained in secondary care can be extrapolated to primary care, and to suggest how future trials should be designed to provide more rigorous evidence.

Searching
PubMed, the Cochrane Library, PsycLIT, and EMBASE were searched for English language papers published between 1966 and September 2001. The search strategy used terms such as: somati* AND (treatment OR therapy OR rehabilitation OR drug* OR management OR intervention); somatoform AND (treatment OR therapy OR rehabilitation OR drug OR management OR intervention); (abnormal illness behaviour) AND (treatment OR therapy); (medically NEAR unexplained symptom*) AND (treatment OR therapy); psychophysiologic AND treatment; psychogenic AND treatment; (functional NEAR (symptom* OR illness)) AND (treatment OR therapy); (unaccounted medical symptoms) AND treatment; ((chronic fatigue) OR (irritable bowel) OR (chronic back pain)) AND (treatment OR therapy OR rehabilitation OR drug* OR management OR intervention)). Additional studies were identified by examining the references cited in identified meta-analyses, systematic reviews and individual studies, by searching key texts, and by contacting experts. Full details of the search strategy were provided in the review.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), systematic reviews and meta-analyses were eligible for inclusion.

Specific interventions included in the review
Mental health interventions employing cognitive behaviour therapy, cognitive therapy, behaviour therapy, brief interpersonal psychodynamic therapy and antidepressant therapy for the treatment of chronic fatigue syndrome, irritable bowel syndrome and chronic back pain were eligible for inclusion in the review.

In the included studies, the antidepressants used for chronic fatigue syndrome were selective serotonin re-uptake inhibitors (SSRIs at therapeutic dose), monoamine oxidase inhibitors and SSRIs with behaviour therapy; tricyclic antidepressants (therapeutic and subtherapeutic doses), mianserin, and combined anxiolytic-tricyclic antidepressants with bran were used for irritable bowel syndrome; and tricyclic antidepressants were used for chronic back pain. The control or comparison groups employed non-directive counselling, support, no intervention, medical care, exercise and placebo or review appointment and SSRI for chronic fatigue syndrome. For irritable bowel syndrome they used self help, symptom monitoring, attention placebo, standard medical treatment, antispasmodic drugs and placebo, or placebo plus bran. For chronic back pain they used usual medical care plus information, pamphlet of advice, group therapy of 30 or 60 hours, group or individual behaviour therapy or waiting list, education, support and exercise. Full details of the interventions and control or comparison interventions were provided in the review.

Participants included in the review
Adults (more than 18 years of age) from a community or primary care setting (e.g. recruited via their primary care physician) with chronic fatigue syndrome, irritable bowel syndrome or chronic back pain were eligible for inclusion. Studies that included a mix of patients from both primary and secondary care were also eligible. Studies that included participants whose symptoms were attributable to physical disease were excluded.

Outcomes assessed in the review
Health status and functional outcomes were eligible for inclusion. In the included studies, the outcomes assessed for chronic fatigue syndrome were: fatigue, anxiety, depression, social adjustment, use of antidepressants, consultations.
general health, physical capacity, functional status, psychological morbidity, functional work capacity, well-being, sleep disturbances, neuropsychological functioning, social interactions, cognition, vigour, disability, illness severity, and mood.

In the included studies, the outcomes assessed for irritable bowel syndrome were: decrease in abdominal pain, frequency and severity of pain, tenderness and diarrhoea; decrease in depression and anxiety, acid and nausea; decrease in composite score; decrease in severe gastrointestinal symptoms; increase in global well-being and satisfaction with bowel movements; non significant improvements in mood, retardation and cognitive function; and decrease in vomiting, sleeplessness, mucus in stools. In the included studies, the outcomes assessed for chronic back pain were: decrease in pain and disability, interference in activities, worries, and fear avoidance beliefs; improvements in pain, disability, depression, control, somatic awareness or distress, and self efficacy; decrease in pain intensity and depression, increase in adaptive cognitions; decrease in pain behaviour and physical and psychosocial dysfunction; decrease in negative affect, motor behaviour, coping, or costs and overall health.

A full list of the outcomes in the included studies was provided in the review.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The authors state that the methodological quality of much of this literature has been assessed previously in a systematic manner with quality scales. However, as the scales vary in the dimensions covered and in their complexity, the relevant methodological aspects of the included studies were assessed individually with a checklist rather than employing a composite score (see Other Publications of Relevant Interest). The checklist considered randomisation, blinding of those assessing outcomes, and handling of attrition in the analyses. Both reviewers independently noted methodological details using a checklist.

Data extraction
One reviewer extracted the data from the identified papers and a second reviewer checked them. Any discrepancies were resolved by referring to the original studies. Data were extracted on: patient setting, condition, intervention, control or comparison group, and short-term (0 to 6 months) and medium-term (greater than 6 months) outcomes. For all studies, the findings were compared from each setting by tabulating the reported health status and functional outcomes. When studies used similar interventions and the same health status measures, the initial disease severity of the patients was compared with the treatment effect sizes between settings. Where it was possible to 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. The treatment effect sizes, along with 95% confidence intervals (CIs), were calculated from the difference in mean health status after treatment.

Methods of synthesis
How were the studies combined?
Where possible, the studies were combined statistically in a meta-analysis. For the analysis of RCTs, cognitive behaviour and cognitive therapy were pooled since the studies provided insufficient details about the interventions to validate any distinction. The treatment effects (Cohen's d) were combined using a fixed-effect model when two or more studies from the same setting used the same outcome measure. If significant heterogeneity of effect sizes was detected (p<0.05), a random-effects model was used. The studies were also combined narratively according to the setting (primary or secondary care), intervention and condition being treated.

How were differences between studies investigated?
Heterogeneity was investigated but the authors do not state how it was investigated.
Results of the review

Two meta-analyses and 61 RCTs were included in the review. One meta-analysis was on the effectiveness of behaviour therapy for chronic back pain, while the other was on the effectiveness of antidepressants for irritable bowel syndrome. Twenty RCTs were defined as primary care and 41 as secondary care. Of the 16 studies of cognitive behaviour therapy for patients with chronic back pain, 7 studies (n=891) were from primary care and 9 (n=625) were from secondary care.

Chronic back pain.

Patients from both primary and secondary care reported sustained improvements in pain, disability and depression (16 primary care and 17 secondary care studies). A meta-analysis of the effectiveness of behaviour therapy found a moderate positive effect on pain intensity and a small positive effect on behavioural outcomes in patients, regardless of setting. Behaviour therapy also seemed to be effective in both primary and secondary care. Eight of the 9 primary care studies and 5 of the 6 secondary care studies reported improvements in symptoms. There was some evidence from both settings that these improvements were sustained at the one-year follow-up. The initial health status of patients in secondary care was poorer than that of patients in primary care, but they reported greater improvements.

Chronic fatigue syndrome.

There was no evidence that antidepressants produced any sustained improvements for chronic fatigue syndrome (1 primary or community care study and 3 secondary care). Cognitive behaviour therapy was effective in patients with chronic fatigue syndrome in secondary care: for hospital anxiety, the effect sizes were 0.95 (95% CI: -0.5, 2.4) and 0.6 (95% CI: -1.1, 2.2) for primary and secondary care, respectively, and for hospital depression, the effect sizes were -0.13 (95% CI: -1.6, 1.4) and 1.7 (95% CI: -0.1, 3.6) (4 studies). However, brief cognitive behaviour therapy was ineffective (3 studies). In a primary care setting, there was no difference in effectiveness between brief therapy and counselling (1 study). There were insufficient data to draw conclusions about the effectiveness of behaviour therapy in primary care patients with chronic fatigue syndrome.

Irritable bowel syndrome.

A meta-analysis of the effect of antidepressants reported a moderate improvement in symptoms. Antidepressants seemed 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 in 10 of the 11 studies of secondary care patients. A comparison of the effect sizes in 2 of these studies suggested that improvements in pain relief were greater among secondary care than primary care patients: 5.1 versus 25.9 (95% CI: 13.0, 38.8). However, 2 studies had showed that secondary care patients reported only slightly greater severe pain initially than did those from primary care.

Five studies of secondary care patients reported significant improvements with cognitive behaviour therapy when compared with controls: the Beck depression inventory scores were 3.6 (95% CI: -1.0, 8.2) and -3.0 (no CIs) for primary and secondary care, respectively; the State trait anxiety inventory (trait) scores were 3.5 (95% CI: -1.6, 8.6) and -7.6 (no CIs) for primary and secondary care, respectively. Two of the 3 studies of primary or community care patients reported greater symptomatic improvements with cognitive behaviour therapy than in controls, although in the largest study, cognitive behaviour therapy was no better than placebo. There were insufficient data to draw conclusions about the effectiveness of behaviour therapy and brief psychodynamic therapy in primary care patients with irritable bowel syndrome.

Further results were reported in the review.

Authors' conclusions

Research from both primary and secondary care suggests that cognitive behaviour therapy and behaviour therapy may help patients with back pain and that patients with irritable bowel syndrome may improve with antidepressants, but effect sizes tend to be larger in secondary care. 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. It should not 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. However, the quality and amount of evidence on mental health fatigue interventions for back pain, chronic fatigue syndrome and irritable bowel syndrome is sometimes poor; conclusions relating to effectiveness should be considered in the light of the methodological weaknesses of the studies. Large pragmatic trials are needed of interventions that are delivered in primary care by appropriately trained primary care staff.

**CRD commentary**

The review question and the study selection criteria were stated clearly. The literature search seemed reasonably comprehensive, although there was insufficient information as to exactly which databases were searched via PubMed (MEDLINE only or MEDLINE and PreMEDLINE). In addition, the restriction to articles in English may mean that some relevant material was missed. The authors did not state how the literature was selected, although information was given on the validation and data extraction processes. There was no mention of the nature of the test for heterogeneity, nor whether publication bias was assessed. The decision not to undertake a general statistical pooling in a meta-analysis seems appropriate given the heterogeneity of the studies and outcome measures used, although some pooling was undertaken where the settings and outcomes were the same.

There was adequate presentation and discussion of the findings of the review. The authors’ conclusions seem appropriate in the light of the evidence they present and discuss.

**Implications of the review for practice and research**

**Practice:** The authors state that the meta-analyses suggest that behaviour therapy is effective for chronic back pain and that antidepressants are effective for irritable bowel syndrome. The analysis of individual studies indicates that cognitive behaviour therapy and behaviour therapy for patients with back pain is more effective in secondary care patients than in primary care patients; antidepressant treatment for irritable bowel syndrome may also be more effective in secondary care. It should not be assumed that interventions which are effective in secondary care will produce the same magnitude of effect in primary care; these findings need to be replicated independently in primary care patients. 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. Conclusions relating to effectiveness should be considered in the light of the methodological weaknesses of the studies.

**Research:** The authors state that large pragmatic trials are needed of interventions that are delivered in primary care by appropriately trained primary care staff. Also required are pragmatic studies of the effectiveness of psychological interventions in primary care and on unselected patients, to provide a basis for decisions about health care provision. Studies should identify which elements of an intervention require specialist training and which require specialist intervention. They should also measure the effectiveness of interventions performed by primary care staff following a realistic amount of training and with the aid of standard manuals for patients and practitioners.

There is a need to improve and harmonise the standards of reporting of trials, to ensure that sufficient information is provided. The revised Consolidated Standards of Reporting Trials (CONSORT) criteria provide general guidance on trial reporting, but more detailed directions are required when describing complex mental health interventions. Trials of mental health interventions should measure both cost-effectiveness and long-term outcomes, and outcomes should be measured with an outcome instrument where possible. Trials of effectiveness should be accompanied by qualitative research on the health beliefs and attitudes of participants and non-participants, to enable interventions to be tailored to improve recruitment and drop-out rates. Study designs should include an appropriate randomisation method, blind assessment of the outcomes, and consistent handling of drop-outs from each group.

**Bibliographic details**

PubMedID
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http://www.bmj.com/content/325/7372/1082

Other publications of related interest

This additional published commentary may also be of interest. Kenardy J. Review: cognitive behaviour therapy and behaviour therapy may be effective for back pain and chronic fatigue syndrome, and antidepressants may be effective for irritable bowel syndrome. Evid Based Med 2003;8:88.

Indexing Status
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