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. We looked at the references cited in the identified meta-analyses, systematic reviews, and individual studies to find

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further studies and also searched key texts.[9 11] Six liaison psychiatrists, who were known to have an interest in functional somatic complaints, were asked to cite relevant literature. Box 1 gives the full search strategy

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.

Box 1: Literature search strategy

Step 1: Computer assisted literature searches of the bibliographic databases: PubMed, Cochrane Collaboration database, Embase, and PsychLit for papers published between 1966 and September 2001 using the following search terms:

- 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 (or) therapy
- Pain syndromes (and) treatment

All of the above searches were combined with (or stepwise limits conducted in PubMed): (i)meta-analysis, (ii) review, (iii) randomi*ed control*, (iv) control* trial
Additional searches combined the following key terms:

- Chronic fatigue (or) irritable bowel (or) chronic back pain
- Treatment (or) therapy (or) rehabilitation (or) drug* (or) management (or) intervention
- Randomised controlled (or) RCTKL selected the trials to be included using the broad selection criteria (outlined above) and RR then selected relevant articles using the following criteria:
- Randomised controlled studies on chronic fatigue syndrome, irritable bowel syndrome, or chronic back pain
- Mental health interventions
- Adult study populations (>18 years)
- Studies reported in English language
- Patients with symptoms attributable to physical disease were excluded from study

Step 2: The references contained in articles identified in step 1 were examined to identify further relevant studies.

Step 3: Relevant references in the Department of Health Report *Treatment Choice in Psychological Therapies and Counselling: Evidence Based Clinical Practice Guideline*, and in Mayou et al were identified.[11]

Step 4: Six liaison psychiatrists who have a special interest in this area were asked to cite relevant literature.

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. We extracted data on the source of the patient sample; patient characteristics; the intervention and comparison treatment and who carried them out; outcomes; and study dropouts and reasons for withdrawal. Studies were defined as primary care studies if they included patients who were recruited from the community or through their primary care physician. Ten studies included a mixture of primary and secondary care patients, and these were classified as primary care studies.[12–21]

Both reviewers independently noted methodological details using a checklist including randomisation, blinding of those assessing outcomes, and handling of attrition in the analysis. 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.[22]

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 (tables 1-3). 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 and standardised them using Cohen's d.[23] 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[12-21 24-81] 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 4). This included eight studies of patients who had been recruited solely through their primary care physician.[13 17 18 21 25 40 60 68] A further eight studies included patients who were recruited in two ways within the same trial: either by their primary care physician or self referred after media publicity.[12 14–16 19 20 37 41] The authors did not distinguish the

Table 1 Literature review of mental health interventions for chronic fatigue syndrome

Study	No of participants	Intervention group	Control or comparison group	Outcomes*	
				Short term (0-6 months)	Medium term (>6 months)
Cognitive behaviour therapy†					
Patients from primary care or community:					
Ridsdale (2001)[60]	160	Cognitive behaviour therapy	Non-directive counselling	No significant difference in fatigue, anxiety, depression, social adjustment, use of antidepressants, or consultations. No significant difference in cost effectiveness	
Patients from secondary care:					
Prins (2001)[56]	278	Cognitive behaviour therapy	Support, no intervention		14 month follow up: decrease in fatigue severity and increase in functional support
Deale (1997)[57] (2001)[79]	60	Cognitive behaviour therapy	Relaxation	Increase in functional status and social adjustments, decrease in fatigue, no significant difference in depression and general health	5 year follow up: increase in those reporting "(very) much better," complete recovery, no relapses, and symptom improvement. No significant difference in fatigue or mental health. Only 26% patients judged completely recovered
Sharpe (1996)[58]	60	Cognitive behaviour therapy	Medical care		12 month follow up: improved functional status and coping, decrease in illness cognitions, depression improved non-significantly
Lloyd (1993)[59]	90	Cognitive behaviour therapy (with spouse) with or without immunological therapy	Placebo with or without attending clinic	No significant difference in physical capacity, functional status, or psychological morbidity	
Behaviour therapy					
Patients from secondary care:					
Powell (2001)[67]	148	Behaviour therapy (graded exercise)	Medical care		12 month follow up: increase in physical functioning, decrease in fatigue, and increased belief that chronic fatigue syndrome is related to physical deconditioning
Wearden (1998)[45]	132	Behaviour therapy (graded exercise) + selective serotonin reuptake inhibitor	Exercise + placebo or review appointment + SSRI or review appointment + placebo	Exercise increased functional work capacity but no improvement in depression	
Fulcher (1997)[66]	66	Behaviour therapy (graded exercise)	Relaxation and stretching	Decrease in fatigue, increase in functional capacity and general health	
Antidepressants‡					
Patients from primary care or community:					
Vercoulen (1996)[12]	96	Selective serotonin reuptake inhibitors (therapeutic dose)	Placebo	No significant difference in depression, wellbeing, fatigue, functional status, sleep disturbances, neuropsychological functioning, social interactions, or cognition	
Patients from secondary care:					
Hickie (2000)[44]	90	Monoamine oxidase inhibitors	Placebo	Increase in vigour, no significant difference in disability, fatigue, and depression	
Wearden (1998)[45]	132	Selective serotonin reuptake inhibitors + behaviour therapy (graded exercise)	Exercise + placebo or review appointment + selective serotonin reuptake inhibitor or review appointment + placebo	Serotonin reuptake inhibitors: improve depression but no improvement in fatigue or functional work capacity	
Natelson (1996)[46]	18	Monoamine oxidase inhibitors	Placebo	Improvements on composite measure of symptoms, illness severity, mood, functional status no improvements in above individual measures	

*Reported changes in outcome are significant (P<0.05) unless stated otherwise.
†Studies reporting the use of cognitive therapy are reported under cognitive behaviour therapy because behaviour techniques were also used in the intervention.
‡All antidepressants were administered at established therapeutic levels (*British National Formulary*, 2001) unless otherwise stated.

source of referral when presenting their results. A further four studies recruited volunteers, but the inclusion criteria of two of these studies specified that participants must have had sick leave for their somatic symptom, and in the third study, the general practitioner was contacted to exclude organic disease.[39 41 77] The conclusions are summarised in box 2.

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 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.[17 19 20 24–36] A meta analysis of the effectiveness of behaviour therapy found a moderate positive effect on intensity of pain and a small positive effect on behavioural outcomes in patients, regardless of setting.[3] Behaviour therapy also seems to be effective in both primary and secondary care. Eight out of nine primary care studies on 659 patients and five out of six secondary care studies with a total of 398 patients reported improvements in symptoms.[17 19 20 26 28 29 37–43] There was some evidence from both settings that these

Table 2 Literature review of mental health interventions for irritable bowel syndrome

Study	No of participants	Intervention group	Control or comparison group	Outcomes*	
				Short term (0-6 months)	Medium term (>6months)
Cognitive behaviour therapy/cognitive therapy					
Patients from primary care or the community:					
Payne (1995)[13]	34	Cognitive behaviour therapy	Self help, symptom monitoring	Decrease in pain, tenderness, & diarrhoea. Delayed decrease in depression & anxiety at 3 months	
Greene (1994)[14]	20	Cognitive behaviour therapy	Symptom monitoring	Improvement in composite score	
Blanchard (1992)[16]	115	Cognitive behaviour therapy	Attention placebo, symptom monitoring	Attention placebo: No significant difference in composite symptom score, trait anxiety, & depression Symptom monitoring: no improvement	
Patients from secondary care:					
Van Dulmen (1996)[61]	47	Cognitive behaviour therapy	Waiting list control group	Fall in duration & severity of pain, avoidance behaviours, increase in coping, no significant difference in psychological well being	2 year follow up: Decrease in duration of pain & severity and avoidance behaviours
Rumsey (1991)[62]	45	Cognitive behaviour therapy	Standard medical treatment	Decreased anxiety & depression	
Lynch (1989)[63]	27	Cognitive behaviour therapy	Waiting list control group	Decrease in composite symptom score & depression, decrease in individual symptom: discomfort & constipation	
Neff (1987)[64]	19	Cognitive behaviour therapy	Symptom monitoring	Fall in composite symptom score and in flatulence	
Bennett (1985)[65]	33	Cognitive behaviour therapy	Tricyclic antidepressants, antianxiety drugs, laxative	Decrease in anxiety, pain, discomfort, motions, & abnormal motions	
Behaviour therapy					
Patients from primary care or the community:					
Keefer (2001)68	16	Behaviour therapy	Symptom monitoring	Decrease in composite symptom score	
Blanchard (1993)[15]	23	Behaviour therapy	Symptom monitoring	Decrease in composite symptom score and abdominal pain	
Patients from secondary care:					
Shaw (1991)69	35	Behaviour therapy	Antispasmodic drugs	Decrease in frequency & severity of pain	
Corney (1990)[70]	42	Behaviour therapy	Standard medical treatment		No significant difference in gastrointestinal symptoms & psychological outcomes
Antidepressants					
Patients from primary care or the community:					
Myren (1984)[47]	428	Tricyclic antidepressants	Placebo	Decrease in abdominal pain, acid, nausea & depression	
Patients from secondary care:					
Rajagopalan (1998)[49]	40	Tricyclic antidepressants	Placebo	Decrease in pain, increase in global well-being and satisfaction with bowel movements	
Mertz (1998)[50]	7	Tricyclic antidepressants (subtherapeutic dose)	Placebo	Decrease in severe gastrointestinal symptoms, no improvements to sensory feelings of fullness, discomfort or pain (under laboratory conditions)	
Tanum (1996)[51]	49	Mianserin	Placebo	Decrease in pain, abdominal distress, & functional disability	
Vij (1991)[48]	50	Tricyclic antidepressants	Placebo	Decrease in pain, constipation, incomplete bowel evacuation, & diarrhoea	
Alevizos (1989)[52]	40	Tricyclic antidepressants	Placebo	Non-significant improvements in mood, retardation, & cognitive function	
Greenbaum (1987)[53]	41	Tricyclic antidepressants	Placebo or atropine	Decrease in stool frequency, diarrhoea, pain, slow rectal contractions, & depression in diarrhoea-prone patients	
Tripathi (1983)[55]	50	Tricyclic antidepressants (subtherapeutic dose)	Placebo	Increase in gastrointestinal improvement	
Myren (1982)[47]	61	Tricyclic antidepressants	Placebo	Decrease in vomiting, sleeplessness, mucus in stools, & depression. No improvement for tiredness, anxiety, nausea, belching, headache, & composite improvement measure	
Lancaster-Smith (1982)[78]	48	Combined anxiolytic/tricyclic antidepressants + bran	Placebo + bran	Decrease in abdominal pain & diarrhoea. No improvement: constipation or sensation of distension	
Steinhart (1981)[80]	14	Tricyclic antidepressants (subtherapeutic dose)	Placebo	No difference in composite symptom score	
Heffner (1978)[54]	44	Tricyclic antidepressants	Placebo	Decrease in bowel movement irregularities & interference with daily life. No significant difference in depression, pain/discomfort	
Brief psychodynamic interpersonal therapy					
Patients from secondary care:					
Guthrie (1993) & (1991)[71 72]	102	Brief psychodynamic interpersonal therapy	Supportive listening + laxative + antispasmodic drug	Decrease in abdominal pain & diarrhoea	1 year follow up: Decrease in depression, psychiatric status & symptoms in women only (non-significant falls for men)
Svedlund (1985) & (1983)[73 74]	101	Brief psychodynamic interpersonal therapy + antispasmodics	Antispasmodic drug		1 year follow up: Decrease in pain and dysfunction 15 month follow up: Decrease in gastrointestinal symptoms composite score

*All changes are significant (P<0.05) unless stated otherwise.

improvements were sustained at one year follow up.[18 39 41] The initial health status of secondary care patients was poorer than that of patients in primary care (table 5) but they reported greater improvements (figs 1 and 2, table 6).

Table 3 Literature review of mental health interventions for chronic back pain

Study	No of participants	Intervention group	Control or comparison group	Outcomes*	
				Short term (0-6 month)	Medium term (>6 month)
Cognitive behaviour therapy/cognitive therapy					
Patients from primary care or the community:					
Moore (2000)[25]	226	Group cognitive behaviour therapy	Usual medical care & information	Decrease in pain & disability, interference in activities, worries, and fear avoidance beliefs	1 year follow up: decrease in worries & fear avoidance beliefs maintained
Linton (2000)[81]	243	Group cognitive behaviour therapy	Pamphlet of advice or information package		1 year follow up: no significant difference in pain, decreased healthcare use & sick leave
Rose (1997)[18]	84	15 hours' individual therapy	Group therapy, 30 or 60 hours	No significant difference in improvements in pain, disability, depression, control, somatic awareness/distress, & self efficacy for both duration & group/individual	
Newton-John (1995)[17]	44	Group cognitive behaviour therapy	Group behaviour therapy or waiting list control	Decrease in pain intensity & depression. Increase in adaptive cognitions	
Bru (1994)[39]	111	Group cognitive behaviour therapy	Behaviour therapy, cognitive behaviour therapy, or waiting list control	Decrease in pain intensity in neck and low back. Improvements in low back pain show relapse at 4 month follow up	
Turner (1993)[19]	102	Group cognitive behaviour therapy	Group behaviour therapy or waiting list control		1 year follow up: decreased pain intensity, depression, & disability
Turner (1988)[20]	81	Group cognitive behaviour therapy	Group behaviour therapy or waiting list control	Decrease in pain behaviour + physical & psychosocial dysfunction	1 year follow up: sickness impact & pain behaviour continue to improve
Patients from secondary care:					
Kole-Snijders (1999)[26] & Goossens (1998)[27]	148	Group cognitive behaviour therapy	Individual behaviour therapy (with spouse), individual behaviour therapy (without spouse), or waiting list control	Decrease in negative affect and increase in coping & overall health measure. 6 month follow up: further improvement in motor behaviour	1 year follow up: no significant difference in negative affect, motor behaviour, coping, or costs & overall health between intervention groups
Strong (1998)[24]	30	Individual cognitive behaviour therapy + usual treatment (pain control, psychiatry, occupational therapy & physiotherapy)	Usual treatment (pain control, psychiatry, occupational therapy & physiotherapy)	Increased control over pain, use of coping. Decreased helplessness, depression, disability, pain intensity (not sustained at 3 months)	
Bendix (1997 98, 98)[32-35]	123	Cognitive behaviour therapy (group multidisciplinary)	Cognitive behaviour therapy (coping & behaviour therapy) or cognitive behaviour therapy (physical training + back school)		1 year follow up: multidisciplinary group showed decrease in healthcare use, back pain, disability, and analgesia use. Increase in work-ready rate. No difference between other two groups. 5 year follow up: multidisciplinary group showed improvements in working and daily activities.
Basler (1997)[36]	94	Cognitive behaviour therapy + standard medical treatment	Standard medical treatment	Decrease in pain, avoidance behaviour, & catastrophising. Increase in pleasurable activities + feelings, control over pain, social disability, mental performance, functional capacity.	
Vlaeyen (1995)[28]	71	Cognitive behaviour therapy (part group, part individual)	Behaviour therapy (part group, part individual) or waiting list control	Decrease in pain behaviours, mood, cognitions (catastrophising). Improved functional status. No significant difference in depression & pain intensity	
Altmaier (1992)[31]	45	Cognitive behaviour therapy + education, support, exercise (part group, part individual)	Education, support + exercise (part group, part individual)	No effect on disability, pain intensity, levels of interference of pain (including mood) & return to work	
Nicholas (1992)[30]	20	Group cognitive behaviour therapy + physiotherapy	Group physiotherapy + discussion	Increase in coping & functioning, decrease in sickness impact & medication use	
Nicholas (1991)[29]	58	Group cognitive behaviour therapy +/– relaxation	Group behaviour therapy +/– relaxation or physiotherapy + discussion or physiotherapy only		1 year follow up: no significant difference in pain intensity, functional status, cognitions, use of active coping.
Turner (1982)[43]	36	Group cognitive behaviour therapy	Group behaviour therapy or waiting list control	Fall in pain, disability, depression	2 year follow up: decrease in healthcare use, increase in time spent working
Behaviour therapy					
Patients from primary care or the community:					
Newton-John (1995)[17]	44	Group behaviour therapy	Group cognitive behaviour therapy or waiting list control	Fall in pain intensity & depression, increase in adaptive cognitions	
Bru (1994)[39]	111	Group behaviour therapy	Group cognitive behaviour therapy or waiting list control	Fall in pain intensity in low back pain	
Donaldson (1994)[38]	36	Behaviour therapy (biofeedback) 36 participants	Relaxation or education	Decreased pain in behaviour therapy (biofeedback) only	
Turner (1993)[19]	102	Group behaviour therapy	Group cognitive behaviour therapy or waiting list control		1 year follow up: decrease in pain intensity, depression, disability. No difference between intervention groups
Lindstrom (1992)[40]	103	Behaviour therapy	Analgesics, some "preset" physiotherapy, rest	Return to work earlier	1 year follow up: less time off work, fewer symptoms
Turner (1990)[37]	96	Group behaviour therapy (with spouse) + group exercise	Group exercise or group behaviour therapy (with spouse), or waiting list control	Decrease in pain behaviour and physical and psychosocial disability	1 year follow up: no difference in improvement between intervention groups
Linton (1989)[41]	66 women only	Group behaviour therapy	Waiting list control	Decrease in pain, fatigue, anxiety, negative mood. Increase in sleep and activity level	
Turner (1988)[20]	81	Group behaviour therapy	Group cognitive behaviour therapy	Decreased pain behaviour + physical & psychosocial dysfunction but no significant difference in pain severity	1 year follow up: improvements in sickness impact & pain behaviour level off
Nouwen (1983)[77]	20	Behaviour therapy (biofeedback)	Waiting list control	No significant effect on pain	
Patients from secondary care:					
Kole-Snijders (1999) & Goossens (1998)[26 27]	148	Individual behaviour therapy (with spouse)	Group cognitive behaviour therapy, individual behaviour therapy (without spouse), or waiting list control	Compared with behaviour therapy (with or without spouse): decreased negative affect and increase in coping & overall health measure	1 year follow up: no significant difference in negative affect, motor behaviour, or coping between intervention groups
Vlaeyen (1995)[28]	71	Behaviour therapy (part group, part individual)	Cognitive behaviour therapy (part group, part individual) or waiting list control	Decrease in pain behaviours, negative mood, and cognitions (catastrophising). Increase in functional status, no significant difference in depression & pain intensity	
Altmaier (1992)[31]	45	Education, support + exercise (considered here to be behaviour therapy) (part group, part individual)	Cognitive behaviour therapy + education, support, exercise (part group, part individual)	No significant difference in improvements in disability, pain intensity, levels of interference of pain (including mood) & return to work	
Nicholas (1991)[29]	58	Group behaviour therapy +/– relaxation	Group cognitive behaviour therapy +/– relaxation or physiotherapy + discussion or physiotherapy only	Improvement in functional status, pain beliefs, and coping	1 year follow up: no significant difference in functional status, pain beliefs, & intensity and coping
Philips (1987)[42]	40	Behaviour therapy (pain management)	Waiting list control		1 year follow up: decrease in pain avoidance behaviours, affective reaction to pain & depression. Increased control over pain.
Turner (1982)[43]	36	Group behaviour therapy	Group cognitive behaviour therapy or waiting list control	Decrease in pain, disability, and depression.	2 year follow up: decreased healthcare use, increase in time spent working
Antidepressants					
Patients from secondary care:					
Loldrup (1989)[75]	15	Tricyclic antidepressants	Mianserin or placebo	Decrease in pain compared with placebo only (only 10 patients)	
Pheasant (1983)[76]	16	Tricyclic antidepressants	Placebo	Decreased use of analgesia, no significant difference in activity level	

*All changes are significant (P<0.05) unless stated otherwise.

Table **4** 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.

Chronic fatigue syndrome

Antidepressants in patients with chronic fatigue syndrome produced no sustained improvement.[12 44–46]

Box 2: 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

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.[21–55] 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 (table 7).[21 51] 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, and patients in all these studies were similar in terms of symptom chronicity and age (table 5).[21 51]

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.[56–59] In primary care patients, there was no difference in effectiveness between brief therapy and counselling (table 7).[60]

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.[13 14 16 61–65] All the secondary care studies reported significant improvements with cognitive behaviour therapy in symptoms and in coping.[61–65] 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.[15 45 66–74]

Discussion

We found little or no research on the effectiveness of some interventions, such as brief psychodynamic interpersonal therapy. However, 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.

Table 5 Health state before treatment in patients in primary care and secondary care studies (higher scores indicate greater severity for all measures except coping skills questionnaire)

	Primary care		Secondary care	
Health status measure	**Study**	**Mean score (95% CI)**	**Study**	**Mean score (95% CI)**
Back pain:				
Coping skills questionnaire	Newton-John[17]	50.0 (42.9 to 57.2)	Nicholas[30]	36.0 (18.5 to 53.5)
			Nicholas[29]	35.4 (28.3 to 42.5)
Visual analogue scale (pain)	Donaldson[38]	27.4 (20.0 to 34.8)	Turner[43]	56.0 (47.6 to 64.3)
	Linton[41]	37.5*	Vlaeyen[28]	67.4 (63.5 to 71.4)
	Turner[19]	54.5 (50.4 to 58.6)		
Beck depression inventory	Linton[41]	8.6*	Vlaeyen[28]	13.3*
	Turner[19]	10.7 (9.4 to 12.0)	Turner[43]	14.6 (12.4 to 16.9)
	Newton-John[17]	12.3 (10.1 to 14.5)	Nicholas[30]	18.9 (14.7 to 23.1)
			Nicholas[29]	20.2 (18.2 to 22.3)
Pain beliefs†	Newton-John[17]	41.5 (36.5 to 46.4)	Nicholas[30]	53.6 (43.4 to 63.9)
			Nicholas[29]	66.2 (61.8 to 70.7)
Sickness impact profile	Turner[20]	8.5 (6.8 to 10.2)	Turner[43]	17.4 (14.5 to 20.3)
	Turner[19]	12.2 (10.5 to 13.9)	Nicholas[29]	30.3 (27.9 to 32.7)
	Turner [37]	17.2 (14.4 to 19.9)	Nicholas[30]	31.5 (25.6 to 37.4)
State trait anxiety inventory (state)	Newton-John[17]	39.5 (36.2 to 42.8)	Nicholas[29]	50.8 (47.6 to 54.0)
Chronic fatigue syndrome:				
Hospital anxiety and depression (anxiety)	Ridsdale[61]	9.7 (9.0 to 10.4)	Sharpe[59]	7.4 (6.3 to 8.4)
Hospital anxiety and depression (depression)	Ridsdale[61]	7.6 (7.0 to 8.1)	Sharpe[59]	6.8 (5.8 to 7.7)
Irritable bowel syndrome:				
Beck depression inventory	Blanchard [15]‡	10.9 (9.3 to 12.5)	Lynch[69]	10.3*
	Greene[14]	11.2 (8.5 to 13.9)		
	Payne[13]	12.5 (10.5 to 14.6)		
	Blanchard[16] §	13.7 (10.9 to 16.6)		
State trait anxiety inventory (trait)	Blanchard ‡	46.9 (44.8 to 49.1)	Lynch[69]	46.2*
	Greene[14]	47.0 (42.7 to 51.3)		
	Payne[13]	48.5 (46.3 to 50.6)		
	Blanchard[16] §	48.2 (45.7 to 50.8)		
Visual analogue scale (pain)	Myren [21]	45.2*	Tanum[52]	49.8 (44.8 to 54.8)

*Confidence interval not available.
†High score indicates stronger adherence to maladaptive beliefs.
‡ Large study.
§Small study.

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 (box 3). 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.[16 17 20 25 26 36 37 42] Quality checks were hardly ever mentioned; at best there was rating by an independent assessor to check that the intervention and control condition were distinct and intervention credibility checks.[13 56 60 63 68] 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.[12 16 19 28 29 44 46 48 52–54 56 67 71 75]

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.[82] Cost effectiveness is

Table 6 Standardised treatment effect sizes immediately after treatment for studies comparing intervention against control for back pain. Negative effect sizes indicate a benefit of treatment over control. Effect sizes with two or more references (shown in superscript) are aggregated

	Effect size (95% CI)	
Health measure	**Cognitive behaviour therapy**	**Behaviour therapy**
Coping skills questionnaire:		
Primary care	−0.29 (−1.04 to 0.47)[17]	−0.26 (−1.01 to 0.49)[17]
Secondary care	−0.73 (−1.31 to −0.15)[29 30]	−0.08 (−0.76 to 0.60)[29 30]
Pain (visual analogue scale):		
Primary care	−0.29 (−0.86 to 0.28)[19]	−0.52 (−0.96 to −0.09)[19 38]
Secondary care	−1.82 (−2.84 to −0.80)[43]	−1.67 (−2.65 to −0.69)[43]
Beck depression inventory:		
Primary care	0.11 (−0.35 to 0.56)[17 19]	−0.56 (−1.08 to −0.05)[17 19]
Secondary care	−0.30 (−0.78 to 0.18)[29 30 43]	−0.64 (−2.14 to 0.85)[29 43]
Pain beliefs:		
Primary care	−0.78 (−1.56 to 0.00)[17]	−0.96 (−1.76 to −0.17)[17]
Secondary care	−0.34 (−0.91 to 0.22)[29 30]	−0.60 (−1.30 to 0.10)[30]
Sickness impact profile:		
Primary care	−0.08 (−0.49 to 0.33)[19 20]	−0.42 (−0.76 to −0.08)[19 20 37]
Secondary care	−0.67 (−1.14 to −0.19)[19 20 43]	−0.80 (−1.33 to −0.27)[29 43]
State trait anxiety scale:		
Primary care	−0.26 (−1.01 to 0.50)[17]	−0.43 (−1.19 to 0.33)[17]
Secondary care	−0.27 (−0.93 to 0.40)[29]	−0.23 (−0.87 to 0.41)[29]

Effect sizes are estimated as the difference in scores after treatment.

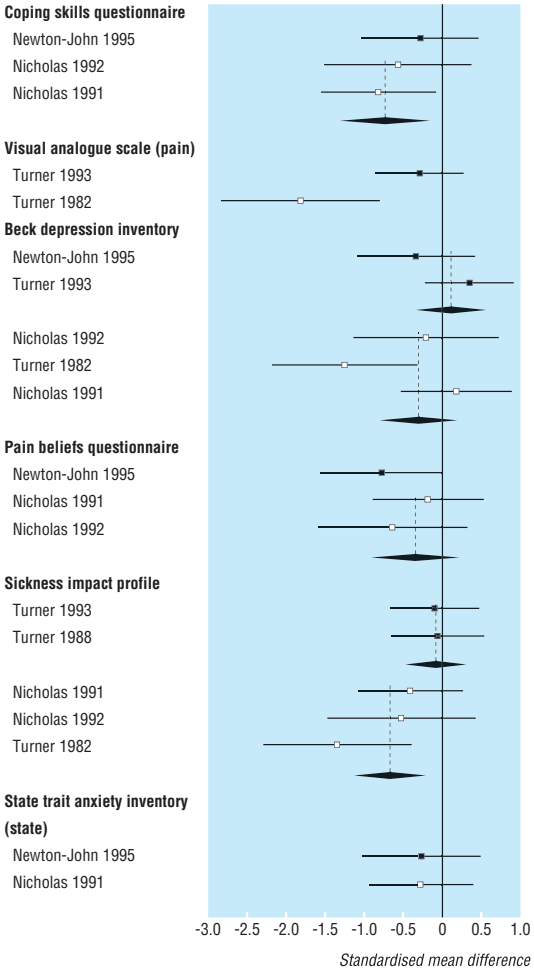

Fig 1 Standardised treatment effects and 95% confidence intervals for cognitive behaviour therapy versus control interventions in patients with back pain (negative effect sizes indicate a benefit for cognitive behaviour therapy)

likely to be an important motivator for changing practice, but only one study examined this.[83]

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.[84]

Another methodological shortcoming was that studies were commonly not powerful enough to detect clinically important differences. Sample sizes were often less than 20 patients.[14 30 46 50 64 68 75 76 77 80] 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.[18 28–35 39 40 43 50 52 53 55 59 61–63 70 71 75 73 74 78]

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.[46 50] 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.[58 60] 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

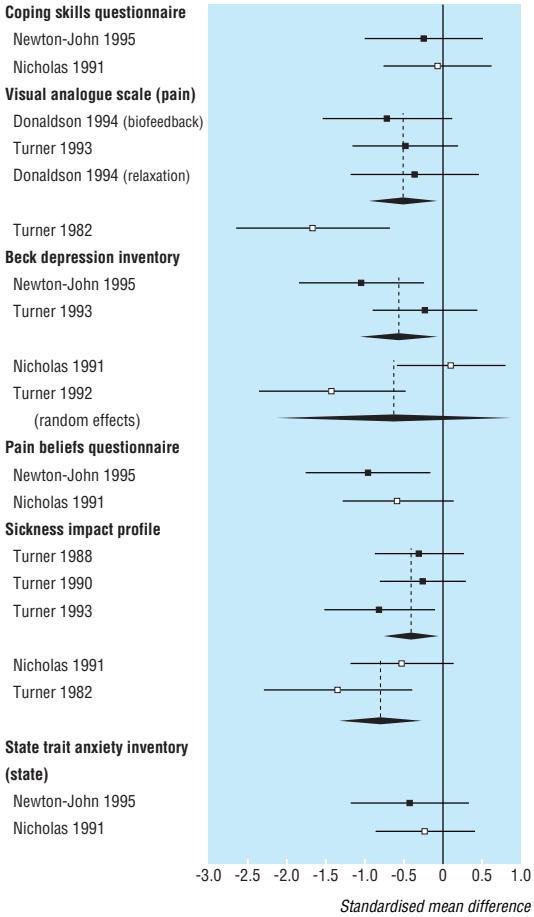

Fig 2 Standardised treatment effects and 95% confidence intervals for behaviour therapy versus control interventions in patients with back pain (negative effect sizes indicate a benefit for behaviour therapy)

Table 7 Treatment effect sizes for chronic fatigue syndrome and irritable bowel syndrome in studies comparing intervention against control immediately after treatment and follow up. Positive effect sizes indicate a benefit of treatment over control

Health status measure	Effect size (95% CI)	Length of follow up (months)
Cognitive behaviour therapy for chronic fatigue syndrome		
Hospital anxiety and depression (anxiety):		
Primary care	0.95 (–0.5 to 2.4)[60]	6
Secondary care	0.6 (–1.1 to 2.2)[58]*	5
Hospital anxiety and depression (depression):		
Primary care	–0.13 (–1.6 to 1.4)[60]	6
Secondary care	1.7 (–0.1 to 3.6)[58]*	5
Cognitive behaviour therapy for irritable bowel syndrome		
Beck depression inventory:		
Primary care	3.6 (–1.0 to 8.2)[13]	3
Secondary care	–3.0†[63]	3-4
State trait anxiety inventory (trait):		
Primary care	3.5 (–1.6 to 8.6)[13]	3
Secondary care	–7.6†[63]	3-4
Antidepressants for irritable bowel syndrome		
Visual analogue score (pain):		
Primary care	5.1[21]†	After treatment
Secondary care	25.9 (13.0 to 38.8)[51]	After treatment

*Difference in change score (before treatment to follow up).
†Confidence intervals could not be calculated because no measures of variation were reported.

in the primary care study they were provided with an educational package that could be regarded as an active treatment.[38 43]

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.[85] 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.[86]

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 (box 4).[87] As well as precise details of the intervention, baseline clinical data and data about participants deemed ineligible should be provided to inform decisions about the extrapolation of the findings to other people with the condition.

Trials of mental health interventions should measure cost effectiveness and long term outcomes. Although outcomes and illness presentations are multifaceted and often difficult to encapsulate in one or two rating scales, this does not negate the need to rationalise the use of outcome instruments. Where possible, well tested instruments should be used and a primary outcome measure salient to both patients and clinicians should be selected. The use of both generic instruments, such as the SF-36, and of disease and symptom specific instruments should be considered.[88] 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 dropouts from each group. Whenever possible, the only difference in care between study groups should be the intervention being studied.

Box 3: Randomised trials of mental health interventions for somatic conditions: methodological shortcomings and how they should be overcome.

1. Dearth of studies in primary care settings, with intervention provided by members of the primary care team (doctor, nurse, counsellor) or lay person
→ Identify elements of interventions which can be conducted in primary care and conduct pragmatic trials in primary care, by primary care professionals, on unselected patients
2. Inadequate information about the content and quality of the intervention and the comparison group
→ Use treatment manual and quality checks
3. Lack of data on characteristics of the patient sample
→ Conduct exploratory phase to assess illness attributions. Use results to increase recruitment and to reduce drop outs, and to tailor intervention to the beliefs and attitudes of the patients
→ Collect data on participants, non-eligible patients and drop outs
4. Limited assessment of outcome: short term only, no cost effectiveness data
→ Measure long term health outcomes in each group
→ Conduct economic analyses as part of trial
5. Studies commonly not powerful enough to detect clinically important differences with high precision.
→ Undertake power calculations to enable clinically important differences to be detected and measured with high precision
6. Great diversity of measurement instruments used
→ Limit the use of health outcome measures to validated instruments. Use generic and symptom or disease specific measures
7. Problems of internal validity
→ Address causes of selection, performance, detection and attrition bias

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

Conclusion

Research from both primary and secondary care suggests that 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. Thus, it cannot be assumed that results from secondary care can be extrapolated to primary care. The quality and amount of evidence on mental health interventions for back pain, chronic fatigue syndrome, and irritable bowel syndrome is sometimes poor.

Box 4: Checklist of items to include when reporting randomised trials of mental health interventions for somatic conditions

Give precise details of the interventions intended for each group, including:

- How, when, and by whom they are administered (including the nature and level of training of therapist, and details of the terms used to describe the intervention to the patient)
- Provision of treatment manual (including frequency, timing, content of interventions)
- Description of quality checks (such as adherence to protocol, independent assessors of quality of intervention)
- Additional resources required (including equipment, space, support staff)
- Also give clear information on
- Characteristics of eligible *v* ineligible patients, recruited *v* not recruited patients, and those who completed study *v* dropouts
- Baseline demographic and clinical characteristics (including age, sex, comorbidity, baseline severity, duration, illness attributions by patient (these may be difficult to specify but are useful, particularly in developing the intervention)
- Reasons for dropout

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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