Efficacy of treatment for somatoform disorders: a review of randomized controlled trials
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CRD summary
The author concluded that there is strong evidence favouring the use of cognitive-behavioural therapy for somatoform disorders and moderate evidence supporting a psychiatric consultation letter. Evidence for antidepressants is promising. Although these conclusions appear to be supported by the data, the questionable quality of the primary studies and the methodological limitations of the review make it difficult to assess their reliability.

Authors' objectives
To determine the effectiveness of treatments for somatoform disorders.

Searching
MEDLINE was searched from 1966 to 2006; the search terms were reported. The reference lists of retrieved articles and relevant reviews were screened. The search was limited to articles published in English.

Study selection
Eligible studies were randomised controlled trials (RCTs) of treatments for somatoform disorder, as defined by the criteria of the the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (4th edition). Studies that focused on specific symptoms (e.g. back pain, headache) were excluded, as were studies of functional somatic syndromes (e.g. fibromyalgia). In most cases the participants in the included studies had somatisation disorder, or lower threshold variants such as abridged somatisation disorder and medically unexplained symptoms. Other disorders addressed in the included studies were hypochondriasis, conversion disorder and body dysmorphic disorder. No studies reported on pain disorder. Some studies included participants with undifferentiated somatoform disorder but did not report the results separately for this group. The median age of the participants in the included studies was 43 years (range: 27 to 51), their median educational status approximated high school level and most were women (75%). The proportion of minority ethnic participants (where reported) was 19% (range: 10 to 37). There were no specific inclusion criteria with respect to the interventions. The most commonly used interventions in the included studies were cognitive-behavioural therapy (CBT), antidepressants (fluoxetine, venlafaxine, opipramol and St John's Wort), a psychiatric consultation letter advising the primary care physician (PCP) about management strategies, and PCP psychosocial training. Other interventions used were non-CBT psychotherapy, a care management intervention, aerobic exercise, writing disclosure, hypnosis, paradoxical intention and explanatory therapy. In studies involving multiple sessions, the duration of the intervention (where stated) varied widely. The median duration was 8 sessions (range: 1 to 30) with median total contact of 12 hours (range: 3 to 25). Some studies compared active interventions with each other, while others had a control group receiving usual or wait-list care, or a placebo drug or condition (e.g. stretching exercises). Studies took place in both in-patient and primary care settings. The intervention was administered by a mental health professional (psychiatrist, psychologist or behavioural medicine specialist) or a primary care provider. Eligible studies reported patient-centred outcomes for one of more of the following three domains: somatic (i.e. symptom count or severity), functional (i.e. functional impairment or quality of life) or psychological. Psychological outcomes could be either domain specific (e.g. hypochondriacal beliefs and behaviours) or generic (e.g. depression, anxiety, psychological distress). The primary study measure in these domains was reported in the review. Health care utilisation and costs were also reported. There were substantial differences in the types and definition of outcomes reported in the included studies. The duration of follow-up varied from 1.5 to 24 months, with a tendency for longer follow-up in the non-pharmacological studies.

The author did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The author did not state that they assessed validity.

Data extraction
The data were reported descriptively in a table. Findings were classified as positive (significantly better outcome in the intervention group), equivocal (non significant trend favouring the intervention group), negative (no difference between groups) or not assessed. A primary study was designated as having positive findings if it reported positive findings for either the designated primary outcome or (where no primary outcome was specified) for at least one of the review outcomes of interest.

The author did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

**Methods of synthesis**

The studies were combined in a narrative and the findings summarised by counting the number of positive, equivocal or negative studies for each intervention and disorder. Findings in the table and text were grouped by the type of intervention and disorder. Heterogeneity was discussed in the text.

**Results of the review**

Thirty-four RCTs (n=3,922) were included.

Over half of the studies reported enrolment rates: the median was 76% (range: 30 to 100) of eligible participants. Many studies failed to specify the primary outcome or report a power calculation and simply reported a range of outcomes. Many had small sample sizes. Blinding of the participants was not possible in most studies and it was generally unclear whether the outcome assessment was blinded. The antidepressant studies tended to have larger samples, placebo control and pre-specified primary outcomes but a shorter duration of follow-up.

There was marked heterogeneity between studies with respect to disorders, disease definitions, interventions, outcomes, duration of follow-up and the reporting of statistical data; this made it difficult to compare the findings of the studies.

Somatisation disorder or lower threshold variants (23 RCTs, n=3,298): the following interventions had positive findings (in one or more domains) measured by one or more RCTs:

- CBT - improvement, most frequently reported in symptomatic domain, in 5 out of 7 RCTs (374 out of 564 participants);
- antidepressants - symptomatic and psychological improvement in 3 out of 4 RCTs (522 out of 634 participants);
- psychiatric consultation letter - functional improvement in 3 out of 4 RCTs (240 out of 278 participants);
- PCP training - symptomatic improvement in one out of 3 RCTs (127 out of 1,089 participants);
- a multicomponent nurse-administered intervention including CBT and antidepressants as indicated - psychological improvement in one RCT (n=200);
- non-CBT psychotherapy - functional and psychological improvement in one out of 2 RCTs (98 out of 168 participants).

Two RCTs were negative, one of aerobic exercise (n=228) and one of disclosure through writing (n=137).

Hypochondriasis (5 RCTs, n=365): all 4 studies of CBT (n=345) had positive findings, as did a pilot study of explanatory therapy (n=20). The reported benefits were mainly in the psychological domain.

Body dysmorphic disorder (3 RCTs, n=140): CBT had positive findings in functional and/or psychological domains in 2 RCTs (n=73), as did fluoxetine in one RCT (n=67).

Conversion disorder (3 RCTs, n=119): the results of 2 RCTs using hypnosis and one using paradoxical intention were inconclusive.
Cost information
Eleven RCTs (n=1,044) reported health care utilisation or cost as an outcome. Ten reported a benefit in the intervention group. Interventions associated with benefit were a consultation letter to the PCP, psychotherapy, CBT, general practitioner training and explanatory therapy. No benefit in health care utilisation rates was found for writing disclosure (one RCT, n=137).

Authors’ conclusions
There is strong evidence supporting the use of CBT for somatoform disorders and moderate evidence supporting a psychiatric consultation letter. Evidence for antidepressants is promising.

CRD commentary
The research objective and inclusion criteria were clear but only one database was searched, thus some studies might have been missed. Moreover, as the search was restricted to articles published in English, the review may be subject to publication and language biases. It is unclear whether steps were taken to minimise error and bias in the study selection and data extraction processes by having more than one reviewer make decisions independently. There is no evidence that study validity was systematically assessed, which makes it difficult to evaluate the evidence presented. The heterogeneity of the studies makes the narrative synthesis appropriate, but the ‘vote counting approach’ used is crude, as the author noted. It was also noted that the reporting of multiple outcomes in most studies, with no pre-specified primary outcome, may bias the review in favour of positive findings. Although the author's conclusions appear to be supported by the data, the heterogeneity and questionable quality of the primary studies, the restricted literature search, lack of information about study quality and poor reporting of review methods, make it difficult to assess their reliability.

Implications of the review for practice and research
Practice: The author stated that CBT is the best established treatment for several somatoform disorders. A consultation letter to the PCP also appears to be beneficial and there is some evidence to support the use of antidepressants.

Research: The author stated that it needs to be determined whether the effect of antidepressants on somatoform disorders is due to a general reduction in depression and anxiety, or whether antidepressants have a specific effect on somatic symptoms. Research is also needed to determine the optimal balance between PCP care, collaborative care and referral for CBT. A wider range of therapies warrants further research (e.g. psychological therapies other than CBT, optimising pain relief, pain self-management programmes). Combination treatments should also be investigated.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.