Efficacy of cognitive-behavioral therapies in fibromyalgia syndrome: a systematic review and metaanalysis of randomized controlled trials

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CRD summary
The review found that cognitive behavioural therapy (CBT) appeared to improve coping with pain and reduced depressed mood and healthcare-seeking behaviour in individuals with fibromyalgia. In view of limitations of the review (in particular clinical, methodological and statistical heterogeneity between the studies) these conclusions should be regarded with caution.

Authors' objectives
To evaluate the efficacy of cognitive behavioural therapy (CBT) to treat fibromyalgia syndrome.

Searching
Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, MEDLINE and PsycINFO were searched to June 2009 without language restriction. Search terms were reported. The reference lists of retrieved studies, systematic reviews and evidence-based guidelines were checked for further studies. The search was limited to fully published studies.

Study selection
Eligible randomised controlled trials (RCTs) compared CBT with no treatment, treatment as usual, attention control or active therapy for individuals of any age with fibromyalgia syndrome (diagnosed with recognised criteria). CBT was defined as face-to-face cognitive, operant behavioural or cognitive behavioural therapy with defined psychotherapeutic content as a central part of treatment. Studies were required to assess pain, sleep, fatigue and/or health-related quality of life. Secondary outcomes were depressed mood, pain self-efficacy (coping with pain) and healthcare seeking behaviour. Studies of CBT combined with other treatment were excluded.

The median age of participants was 47 years (range 16 to 54 years). Most were women (88% to 100%) and 86% to 94% were Caucasian. Nearly all studies excluded participants with somatic disease and half excluded those with mental disorders. Participants were recruited from diverse settings (hospital registers, referral by health providers, local self-help groups and newspaper advertisements). Studies were conducted in single centres in North America and Europe. Interventions were CBT, cognitive mindfulness-based stress reduction and operant behavioural therapy. Interventions were delivered as group therapy, mostly in out-patient settings, over five to 15 weeks, for a median of 27 hours in total (range six to 75 hours). Median attendance rate was 75% (where reported). Controls received treatment as usual/no therapy, another active therapy (such as aerobic exercise) or attention control (such as education). Primary outcomes varied widely (such as pain, coping with pain and depression, disability, affective distress, physician visits, sleep quality, depressed mood, health-related quality of life, side effects). Most studies included follow up (median six months, range two to 48 months).

Two reviewers independently selected the studies.

Assessment of study quality
The following aspects of study validity were considered: adequacy of randomisation, allocation concealment, blinding of assessment, use of intention-to-treat analysis, and representativeness of the study sample. The quality of the intervention was assessed with a nine point published scale (Yates 2005).

Two pairs of reviewers independently assessed study validity.

Data extraction
For each study, the reviewers selected one measure for each outcome and one control group (prioritised as follows: attention placebo, treatment as usual, active control). Mean differences between the study groups (in end scores or change scores) were calculated. Standard deviations were extracted, calculated or imputed. The direction of
measurement scales was standardised across studies. Odds ratios were calculated for dichotomous outcomes and mean differences for continuous outcomes, with 95% confidence intervals (CIs).

Two reviewers independently extracted the data, with disagreements resolved by consensus or by a third author. Primary study authors were contacted for more information if required.

**Methods of synthesis**

Studies were combined using a random-effects inverse variance model to calculate standardised mean differences (SMDs) between the groups. Heterogeneity was evaluated with $I^2$ (>50% indicating strong heterogeneity). $T^2$ was used to assess differences between subgroups. Publication bias was assessed with funnel plots. Subgroup or sensitivity analyses were conducted to examine the effects of type and duration of CBT, type of control, inclusion (or not) of individuals with affective or anxiety disorders, study quality and publication year.

**Results of the review**

Fourteen RCTs were included (approximately 910 participants in included arms, range 14 to 131). Five were adequately randomised, two had adequate allocation concealment, three used blinded assessment and ten used intention-to-treat. Reported quality of treatment was low in most studies (score range 2-8 out of 9 points). Median follow up (where reported) was six months (range two to 48 months).

At post treatment, CBT significantly reduced depressed mood, with a small effect (SMD -0.24, 95% CI -0.40 to -0.08; 10 RCTs, $I^2$=0%) and improved pain self-efficacy with a large effect (SMD 0.85, 95% CI 0.25 to 1.46; eight RCTs, $I^2$=89%) compared with controls. CBT had no significant effect on pain (12 RCTs), fatigue (four RCTs), sleep (four RCTs) or health-related quality of life (eight RCTs).

At the latest follow-up, CBT significantly improved self-efficacy pain (SMD 0.90, 95% CI 0.14 to 0.66; seven study arms, $I^2$=90%), and operant behavioural therapy significantly decreased physician visits (SMD -1.57, 95% CI -2.00 to -1.14; two arms, $I^2$=0%) compared with controls, both with a large effect. CBT had no significant effect on pain (10 arms), fatigue (four arms), sleep (four arms), depressed mood (eight arms), or health-related quality of life (seven arms).

Four RCTs reported side-effects but no comparative statistical data were reported.

There was high statistical heterogeneity for most outcomes (pain, sleep, fatigue, health-related quality of life and self-efficacy pain at both follow-up times). In sensitivity analyses by study quality, the benefit of CBT on depressed mood was not clearly distinguishable from the effects of potential study bias. There was no indication of publication bias.

**Authors’ conclusions**

CBT appears to improve coping with pain and to reduce depressed mood and healthcare-seeking behaviour in individuals with fibromyalgia.

**CRD commentary**

The objectives and inclusion criteria of the review were clear and relevant sources were searched for studies in any language. The restriction to published studies meant that some studies may have been missed but assessment of publication bias did not suggest this. Steps were taken to minimise the risk of reviewer bias and error by having more than one reviewer independently select studies, undertake validity assessment and extract the data.

Statistical methods used to combine the data and assess differences between the studies were appropriate in most respects, but it appeared that one group of participants were double-counted in some analyses, which would bias the effect estimates. Although most studies were assessed as having used intention-to-treat analysis, analyses in the review only included participants who completed the study. Most studies were small and overall their quality appeared poor. As the authors noted, there were marked clinical and methodological differences between the studies (such as interventions, controls, outcomes, sample size, participant age and clinical status) and few data in most subgroup analyses. The results of planned subgroup analyses were not fully reported and there was high statistical heterogeneity for some outcomes which was not clearly explained.

In view of limitations in the review (in particular clinical, methodological and statistical heterogeneity between the
studies) the authors' conclusions should be regarded with caution.

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

**Practice:** The authors stated that CBT could not be recommended for the key symptoms of fibromyalgia. They suggested that it could be considered to treat depressive symptoms, due to its relatively low toxicity compared with antidepressants (these data were not reported in the review) and that operant behaviour therapy could be considered to reduce healthcare-seeking behaviour.

**Research:** The authors stated that future studies of CBT for fibromyalgia should use robust designs and deliver high quality treatment. Outcome measures should be standardised and should include side-effects and predictors of positive response. Studies should clarify the role of CBT in adolescents, males and subgroups of individuals with fibromyalgia (such as those with and without affective disorder).

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