Cognitive-behavioural therapies and exercise programmes for patients with fibromyalgia: state of the art and future directions


CRD summary
This review examined the effectiveness of non-pharmacological treatments in patients with fibromyalgia. It concluded that, in general, the beneficial effects of non-pharmacological interventions are limited. There were a number of methodological and quality issues with the included studies, but the authors appear to have considered such limitations and their conclusions are likely to be reliable.

Authors' objectives
To assess the effectiveness of non-pharmacological treatments in patients with fibromyalgia.

Searching
MEDLINE (1966 to January 2006), PsycINFO (1806 to January 2006), EMBASE (1980 to January 2006) and the Cochrane Library (1993 to January 2006) were searched; the search terms were reported. In addition, references of original manuscripts and review articles were searched manually.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared non-pharmacological interventions such as cognitive-behavioural therapy (CBT) and/or exercise with a control (e.g. standard treatment, placebo or no treatment) were eligible for inclusion. The included studies evaluated CBT interventions (e.g. CBT, relaxation (biofeedback), education), exercise interventions (e.g. aerobics, strength training, flexibility exercises, hydrotherapy) and interventions combining CBT and exercise. The interventions were delivered on an individual or group basis, at home, or as an out-patient. Treatment intensity varied and duration ranged from 19 days to 2 years. The control treatment included waiting list, standard treatment, treatment as usual, education, relaxation, false biofeedback relaxation, flexibility exercises, relaxation plus flexibility exercises, thermotherapy and a discussion group.

Participants included in the review
Studies involving patients diagnosed with fibromyalgia using recognised diagnostic criteria were eligible for inclusion. The included studies were in patients with mean ages ranging from 33.7 to 59.5 years. The majority of studies reported a higher proportion of females.

Outcomes assessed in the review
Studies were eligible for inclusion if they measured pain, disability and mood. The included studies assessed the long- and short-term effects on outcomes, as measured by various tools: visual analogue scales, myalgic scores, tender points, physical fitness and various questionnaires. The duration of follow-up ranged from post-intervention to 4 years.

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

Assessment of study quality
The authors did not state that they assessed validity. However, they did mention aspects of validity such as drop-outs, sample size and the use of intention-to-treat analysis in tables or the text.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.
extraction. Data were extracted on each outcome to determine the treatment effect post-intervention and at follow-up. For each study, treatment effects were classified as positive, negative, or no effect.

**Methods of synthesis**

**How were the studies combined?**
The studies were grouped by type of intervention and combined in a narrative.

**How were differences between studies investigated?**
Differences in certain study characteristics were presented in the tables.

**Results of the review**

Thirty RCTs (n=2,446: 1,469 receiving intervention and 977 receiving control) were included in the review.

The sample sizes from 12 to 170 participants, with only 1 study reporting completion by all participants. Nine studies reported drop-out rates of more than 20%.

**CBT.**

The 3 studies assessing educational programmes reported no treatment effect on pain, disability or mood. Two of the 3 studies assessing relaxation showed positive treatment effects for pain in the short term; none of the 3 studies reported a positive effect on disability or mood. Three of the 5 studies examining multi-method CBT reported positive treatment effects for at least one outcome, which was maintained at follow-up for two of the studies.

**Exercise.**

Seven of the 10 studies investigating aerobic exercise alone indicated improvements in at least one outcome, but only one of the 3 studies with long-term follow-up reported long-term improvements; one also reported a negative effect on disability. Two of the 3 studies investigating strength training reported positive effects on disability; studies reported no effect on mood or pain. All 5 studies assessing combined aerobic exercise with strength training reported positive treatment effects for pain and/or disability, two of which reported long-term improvements.

**CBT and exercise.**

Two of the 6 studies examining education and exercise combined showed short-term improvements for at least one outcome, with two also reporting long-term improvements. The study assessing relaxation with exercise reported positive effects at follow-up for pain and disability in comparison with the control group. Both studies examining multi-method CBT with exercise indicated improvements for all three outcomes post-intervention, with improvements maintained for pain at follow-up.

**Authors' conclusions**
The beneficial effects of non-pharmacological interventions appear limited.

**CRD commentary**
The review question was clear and appropriate inclusion criteria were stated for the interventions, comparators, outcomes, study design and participants. Relevant literature searches were conducted using electronic databases and other appropriate sources. It was unclear whether any language restrictions were applied, thus the potential for language bias cannot be ruled out. This, together with an apparent lack of searching for unpublished material, means it is possible that relevant papers were missed. Attempts to minimise errors and reviewer bias in the review process were not reported. Although some aspects of validity were mentioned, a systematic assessment was not performed; this means that the reliability of the included studies and their subsequent synthesis is unclear. In addition, potentially important clinical characteristics (such as criteria used to diagnose fibromyalgia) were not presented, and some studies used CBT or exercise programmes as the control group.
It was not clear whether studies classified as showing a positive effect showed a statistically significant improvement in outcome measures or just an improvement. Sample sizes were small and drop-out rates high in many of the studies. The analysis was further limited by methodological differences, including content and duration of the interventions, outcome measures and data analysis, and only 45% of the studies reported follow-up. However, the authors acknowledged such limitations and their conclusions are likely to be reliable.

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

**Practice:** The authors stated that individual differences between patients with fibromyalgia should be considered since these may influence the effectiveness of the interventions.

**Research:** The authors stated that further research is required to examine the mechanisms that are associated with the development and maintenance of pain and disability, such as avoidance behaviour and pain-related fear. Future studies should tailor interventions by identifying the most effective interventions in different subgroups of patients.

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