Mind-body therapies for the treatment of fibromyalgia: a systematic review

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Authors' objectives
To assess the effectiveness of mind-body therapy (MBT) in people with fibromyalgia syndrome (FM).

Searching
MEDLINE (from 1966 to 1999), EMBASE, PsycLIT, MANTIS, the Science Citation Index, CAMPAIN, the Cochrane Controlled Trials Register, and the trials registers of the Cochrane Complementary Medicine Field and the Cochrane Musculoskeletal Review Group, were searched. The search terms were stated. Sixty-nine conference proceedings and abstracts were searched manually and the bibliographies of identified studies were examined. Non-English publications were eligible.

Study selection
Study designs of evaluations included in the review
Randomised (RCTs) or quasi-randomised controlled trials were eligible. The duration of follow-up ranged from 3 months to 4 years.

Specific interventions included in the review
Studies of MBT, either alone or as part of a multicomponent intervention, were eligible for inclusion. The included studies used the following active interventions, either alone or in combination: biofeedback/relaxation, exercise, education, physical training, true electromyographic feedback, relaxation, Jacobson relaxation, hypnotherapy, information, instruction in self-control, gymnastics, group discussion, behavioural treatment, autogenic training, cognitive education, aerobic exercise, and stress management. The control interventions, used either alone or in combination, were: education/attention, waiting list, sham electromyographic feedback, hydrogalvanic baths, physical therapy, muscle relaxation, discussion by rheumatologist accompanied by a 10-page handout, Analogic Erickson techniques, and usual care. The treatment lasted over 3 to 15 weeks.

Participants included in the review
Studies of people with FM were eligible for inclusion. All but one of the included studies defined patients with FM using the following criteria: Yunus, American College of Rheumatology, Smythe, and Smythe and Moldofsky. The participants were predominately female (92%).

Outcomes assessed in the review
The inclusion criteria were not specified in terms of outcomes. The primary outcomes selected for the review were pain (including visual analogue scales, myalgic scores, tender point counts), physical function, self-efficacy, quality of life, depression, sleep and global improvement rating. Adverse effects were also assessed. Follow-up was classified as short-term (3 months or less after treatment finished), intermediate (between 3 and 12 months after treatment finished), or long-term (at least 12 months after treatment finished).

How were decisions on the relevance of primary studies made?
Two reviewers independently selected studies according to the inclusion criteria.

Assessment of study quality
A modified Jadad scale was used to assess and score validity on the basis of the following items: randomisation; method of randomisation adequate; outcome assessor blinded; and description of drop-outs and withdrawals. Each criterion that was met scored one point, giving a maximum possible score of four points. RCTs scoring 3 or more points were classified as high quality, while those scoring less than 3 points were considered to be low quality. The following items were also assessed (for the sensitivity analysis), but were not included in the validity score: double-blind; method of double-blinding appropriate; patients reported as blinded; outcome assessor blinded; drop-outs and withdrawals.
described; cointerventions either controlled for or avoided; acceptable levels of compliance; and treatment groups comparable at baseline. Two reviewers independently assessed validity and achieved consensus through discussion.

**Data extraction**

Two reviewers independently extracted data on the treatment and control groups, inclusion criteria and follow-up times. The outcomes were classified as positive (MBT significantly more effective than control), neutral (no significant difference between MBT and control) and negative (control significantly more effective than MBT). Significance was taken as a P-value of less than 0.05.

**Methods of synthesis**

How were the studies combined?
The studies were grouped according to the timing of the outcome assessment. Then, studies reporting short-term outcomes were grouped by the interventions compared and a narrative synthesis was undertaken. For short-term outcomes only, the strength of the evidence for each comparison was graded as strong (multiple high-quality RCTs with consistent results), moderate (one high-quality RCT plus at least one low-quality RCT, all with consistent results), limited (one high-quality RCT or multiple low-quality RCTs with generally consistent results), or inconclusive (only one low-quality RCT or no RCTs, or RCTs with inconsistent results).

How were differences between studies investigated?
Associations between the total quality scores or the individual quality items included in the score and the study results were tested using the chi-squared statistic.

**Results of the review**

Thirteen RCTs (802 patients) were included.

Study quality.

Seven of the thirteen RCTs were classified as high quality. There was no significant association between the total quality score and study results, or between any of the individual scored items and results.

Short-term outcomes (3 months or less after treatment finished).

MBT versus waiting list or usual treatment (2 high-quality and one low-quality RCT): there was strong evidence that MBT improved self-efficacy compared with control, but inconclusive evidence for the other outcomes.

MBT versus education/attention control (one high-quality and 2 low-quality RCTs): there was inconclusive evidence for MBT compared with education alone. MBT versus sham biofeedback (one high-quality RCT): there was limited evidence that MBT improved pain and global improvement in comparison with placebo.

MBT versus exercise (3 high-quality RCTs): there was strong evidence that MBT improved pain and physical function in comparison with exercise, but inconclusive evidence for the other outcomes.

MBT versus physiotherapy (one high-quality and one low-quality RCT): the results were inconsistent. There was inconclusive evidence for MBT compared with physiotherapy. MBT (autogenic training) versus psychotherapy (one high-quality RCT): there was limited evidence for MBT compared with psychotherapy. MBT plus exercise versus waiting list or usual treatment (one high-quality and 2 low-quality RCTs): there was moderate evidence that MBT plus exercise improved self-efficacy and quality of life in comparison with control, but inconclusive evidence for the other outcomes.

MBT plus exercise versus attention/education (one high-quality RCT): there was limited evidence that MBT improved pain, function and self-efficacy compared with attention/education.

MBT plus exercise versus exercise alone (one RCT) or MBT alone (3 RCTs): there was limited evidence.
Intermediate outcomes (3 to 12 months after treatment finished; 6 RCTs).

The evidence for a continuing effect of MBT was strongest for MBT plus exercise versus waiting-list control (one high-quality RCT).

Long-term outcomes (at least 1 year post-treatment; 3 RCTs).

One RCT found no significant difference at one and two years between biofeedback plus exercise, exercise alone, combination of exercise plus biofeedback and education control. One RCT found the only difference between MBT, waiting list and exercise at 4.5 years was a significant reduction in the number of tender points with MBT compared with waiting list. The drop-out rates were higher with exercise (75%) than with MBT (30%). One RCT found continued improvement for pain control at one year with both MBT and education/attention.

Adverse effects. None of the RCTs reported adverse effects. Two RCTs found that patients had difficulty becoming proficient in the mind-body intervention.

Authors' conclusions
MBT was more effective than waiting-list control or usual treatment for some of the outcomes. There was insufficient evidence for MBT compared with other active treatments.

CRD commentary
The review question was clear in terms of the intervention and study design. Only participants with fibromyalgia were eligible, but a strict definition of this condition was not one of the eligibility criteria. However, all but one of the RCTs used recognised criteria for the diagnosis of fibromyalgia. The search was adequate with searches of several relevant databases, attempts to locate unpublished studies, and no language limitations. The study selection, validity assessment and data extraction processes were performed in duplicate and this reduced the potential for bias and errors. Validity was assessed and scored using defined criteria and relevant information on the included studies was tabulated. The studies reporting short-term outcomes were appropriately grouped by the interventions compared and a narrative synthesis was undertaken. The level of evidence for each comparison was summarised, taking into account the quality of the studies. Longer term outcomes were less clearly summarised in the review. The evidence presented tends to support the authors' conclusion for short-term outcomes.

Implications of the review for practice and research
Practice: The authors state that MBT should be used early in the course of fibromyalgia and that MBT may augment the effect of other treatments.

Research: The authors state that more large, well-designed studies are required to investigate combinations of MBT with moderate to high intensity exercise and/or antidepressants. They further state that research is required to aid the patients' ability to use MBT and to improve compliance.

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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.