
Complementary and alternative medicine in fibromyalgia and related syndromes

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CRD summary

This review assessed complementary and alternative medicine for fibromyalgia syndrome. The authors concluded that there was strong evidence in support of acupuncture, moderate evidence for magnesium, S-adenosyl-L-methionine and massage, and limited evidence for other treatments. The level of supporting evidence was generally overstated and the authors' conclusions may not be reliable.

Authors' objectives

To assess the effectiveness of complementary and alternative medicine (CAM) for people with fibromyalgia syndrome (FMS).

Searching

MEDLINE (1975 to 2002), BIOSIS Previews (1975 to 2002), EMBASE (1990 to 2002), CINAHL (1982 to 1998), Alternative Medicine Alert and the Cochrane Controlled Trials Register were searched for studies published in the English language; the keywords were stated. The reference lists in identified studies and reports in the authors' own files were also checked.

Study selection

Study designs of evaluations included in the review

Randomised controlled trials (RCTs) and non-randomised controlled clinical trials (CCTs) were eligible for inclusion if they described the methods used to conduct the study in sufficient detail to allow an assessment of the quality of the study design. Non-randomised CCTs were only included if they adequately described the intervention and blinding of the patients. Only studies with a comparable and appropriate control for the interventions being examined were included. Crossover and parallel-group RCTs were included. The review also included reviews.

Specific interventions included in the review

Studies of CAM were eligible for inclusion, whereas studies of exercise and cognitive-behavioural therapy were excluded. The included studies were of: acupuncture; homeopathy; herbal and nutritional supplements including magnesium, botanical oils, balneotherapy, S-adenosyl-L-methionine (SAME) and anthocyanidins; dietary modification; energy therapies (magnet therapy) and manipulative and body-based therapies (chiropractic and massage therapy); and mind-body therapies such as relaxation and biofeedback. The comparator therapies included placebo, other active therapy, or a non-specified control. Cointerventions included amitriptyline.

Participants included in the review

Studies of patients with FMS were eligible for inclusion.

Outcomes assessed in the review

Studies that assessed effectiveness were included in the review. The included RCTs assessed the following: measures of pain including visual analogue scales; stiffness; sleep; patient and physician-rated assessments; functioning; depression, including the Beck Depression Index; tender point count; well-being or general health; trigger point count; fatigue; anxiety; strength; and other (FM) symptoms.

How were decisions on the relevance of primary studies made?

One reviewer screened the abstracts of identified studies with respect to the inclusion criteria.

Assessment of study quality

Validity was assessed and scored using the Consolidated Standards of Reporting Trials (CONSORT) rating system. This

evaluates the inclusion and exclusion criteria, description of the intervention, definition of the outcome, methods used for randomisation, sample size, the reporting of adverse events, and generalisability. The scores ranged from a low of 0 to a maximum of 22 points. RCTs with a score of less than 10 were considered to be methodologically inadequate. The authors did not state who performed the validity assessment.

Data extraction

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The overall findings for each study were classified as positive, negative, or mixed.

Methods of synthesis

How were the studies combined?

The studies were grouped according to the type of CAM and a narrative synthesis was undertaken. The level of evidence for each intervention was graded using a hierarchy of evidence (see Other Publications of Related Interest). Grade A represented strong evidence from generally consistent multiple high-quality RCTs; grade B represented moderate evidence from generally consistent results from one RCT and at least one low-quality RCT, or generally consistent findings from multiple low-quality RCTs; grade C represented limited evidence from one RCT (either low or high quality), or inconsistent or contradictory evidence in multiple RCTs; and grade D represented insufficient evidence with no RCTs found.

How were differences between studies investigated?

Differences among the studies were discussed with respect to quality.

Results of the review

Twenty-two RCTs (1,091 patients) were included. Non-randomised controlled studies were also included in the review, but the number of studies was not stated.

Acupuncture (8 studies including 2 RCTs with 130 patients: the quality scores for the RCTs were 17 and 7 out of 11. There was strong evidence of the effectiveness of acupuncture. All 8 studies showed that acupuncture improved symptoms of FMS. One RCT (70 patients) showed that the pain threshold improved more with electroacupuncture than sham acupuncture after 3 weeks' treatment (70% versus 4%). One RCT (60 patients taking amitriptyline) showed that acupuncture improved pain and depression more than sham acupuncture or usual care after 16 weeks' treatment. There were several methodological limitations: the extent of equivalence between electroacupuncture and acupuncture; neither study measured whether the patients were truly blinded; one study did not assess functional or psychological outcomes, while the other study did not use objective outcome measures; neither study assessed the long-term outcomes.

Magnesium (2 crossover RCTs with 39 patients, one of the studies appeared to consist of 2 trials); one scored 14 for quality and the other score was not reported. There was very limited evidence of the effectiveness of magnesium. One RCT (24 patients) showed no effect of magnesium on tender points or pain, but a second uncontrolled trial in this study reported positive outcomes after 6 months. One RCT (15 patients) that was only presented in the text showed that magnesium reduced tender point index scores compared with placebo. The methodological limitations included small sample sizes, no long-term follow-up, and the second trial for the first study was uncontrolled.

SAMe (one review of 7 studies including 4 RCTs): the quality scores ranged from 11 to 14. There was moderate evidence of the effectiveness of SAMe. The review (7 studies including 4 RCTs) showed that five of the 7 studies found that SAMe reduced the number of tender points. One of the larger RCTs showed no difference between SAMe and control for pain, number of tender points, depression, or physician-rated assessment.

There was very limited evidence for the following interventions: Chlorella (1 crossover RCT with 37 patients, quality score 10; 1 uncontrolled study with 18 patients); relaxation (1 unblinded RCT with 55 patients, quality score 16); biofeedback (3 RCTs with 274 patients, quality score: 12 to 14); magnet therapies (2 RCTs with 144 patients, quality scores 17 and 18); homeopathy (1 crossover RCT with 30 patients, quality score 10); botanical oils (1 RCT with 30 patients, German article, not rated for quality); balneotherapy (1 RCT with 48 patients, quality score 14); anthocyanidins (1 crossover RCT with 12 patients, quality score 13); dietary modifications (1 RCT with 78 patients,

quality score 11); and chiropractic (1 RCT with 19 patients, quality score 15). These studies had several methodological limitations: no washout period in crossover RCTs; small sample sizes; lack of blinding; analysis not conducted on an intention-to-treat basis; no appropriate control condition; and lack of an assessment of the long-term outcomes.

Authors' conclusions

There was strong evidence for acupuncture, moderate evidence for magnesium, SAME and massage, and limited evidence for other interventions (Chlorella, relaxation, biofeedback, magnet therapies, homeopathy, botanical oils, balneotherapy, anthocyanidins and dietary modifications).

CRD commentary

The review question was clear in terms of the study design, intervention and participants, but the criteria used to diagnose FMS were not part of the eligibility criteria. The inclusion criteria were broadly defined in terms of outcomes. Several relevant sources were searched and the search terms were stated, but by limiting the included studies to those in English some relevant studies might have been omitted. No attempt was made to locate unpublished studies, thus raising the possibility of publication bias. Only one reviewer selected the studies for inclusion and this lack of duplication might have led to errors and bias. The methods used to assess validity and extract the data were not described; hence, any efforts made to reduce errors and bias cannot be judged. The validity of the included RCTs was assessed using the CONSORT system. It was unclear whether the validity of the included non-randomised controlled trials was formally assessed.

Some relevant information on the included RCTs was tabulated but, since values were not given for the results, the size of the treatment effects could not be assessed. A narrative synthesis was appropriate given the small number of studies for each intervention. The synthesis included a summary of the level of the evidence and a discussion of the methodological limitations of the identified studies. The results from a review of RCTs and non-randomised studies was also included without any critical evaluation of the quality of the review. The results from RCTs and non-controlled trials were presented with equal emphasis in some parts of the text. The RCTs generally included a number of outcome measures; without any clear definition of the primary outcome in the review, there was the possibility of preferentially reporting those outcomes with positive results. The authors' classification of the evidence for some interventions, such as magnesium, as moderate did not appear to be justified given the limited evidence (based on a positive result from 1 RCT with 15 patients and 1 uncontrolled study and 1 RCT showing no effect). In view of these concerns, the authors' conclusion may not be reliable and the level of supporting evidence might have been overstated.

Implications of the review for practice and research

Practice: The authors stated that the treatment for FMS with the strongest evidence of effectiveness was acupuncture.

Research: The authors stated that large well-designed RCTs are required to evaluate therapies with insufficient to moderate evidence. They also stated that research to determine the optimal dose, duration and other details of CAM therapies is required, and that more appropriate placebo treatments are required for acupuncture, biofeedback and other CAM therapies.

Bibliographic details

Holdcraft L C, Assefi N, Buchwald D. Complementary and alternative medicine in fibromyalgia and related syndromes. *Best Practice and Research Clinical Rheumatology* 2003; 17(4): 667-683

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12849718

Other publications of related interest

Karjalainen KA, Hurri H, Jauhiainen M, Koes BW, Malmivaara A, Roine R, et al. Multidisciplinary rehabilitation for fibromyalgia and musculoskeletal pain in working age adults (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2002. Oxford: Update Software.

Indexing Status

Subject indexing assigned by NLM

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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.