Systematic review of randomized controlled trials of nonpharmacological interventions for fibromyalgia

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Authors' objectives
To conduct a systematic review of randomised controlled trials (RCTs) of non-pharmacological interventions for fibromyalgia syndrome (FMS).

Searching
MEDLINE, AMED, CINAHL, EMBASE and the Science Citation Index were searched from 1980 to May 2000 using the keywords 'fibromyalgia' and 'fibrositis'. Bibliographies in review papers on the management of FMS were searched manually.

Study selection
Study designs of evaluations included in the review
Study design needed to include randomisation to two or more independent study groups. Studies with a within-subjects design, or where group allocation was not truly random, were excluded. Owing to the nature of the interventions being evaluated, the participants were blinded in only 6 of the 25 studies.

Specific interventions included in the review
At least one of the interventions or modalities evaluated in the study needed to be considered as non-pharmacological in action (i.e. based on physical, educational or psychological principles). Both explanatory (the efficacy of an intervention compared with no treatment or placebo under carefully controlled conditions) and pragmatic studies (the relative effectiveness of two or more interventions under conditions more akin to everyday clinical practice) were included in the review.

Participants included in the review
The studies needed to evaluate the treatment or management of FMS (or 'fibrositis'), as indicated by the use of recognised diagnostic criteria. Studies of the treatment of allied conditions, such as myofascial pain syndrome, were excluded.

Outcomes assessed in the review
No specific outcomes were given as the inclusion criteria. A range of outcome variables were assessed using a range of assessment tools, including validated checklists, visual analogue scales and patient experience measurements. All but one study measured subjective pain as an outcome. Fourteen of the 25 studies measured sleep disturbance and 10 measured fatigue. Only 11 studies specifically measured function.

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

Assessment of study quality
The methodological quality of the included studies was evaluated according to a set of formal criteria, which were adapted from criteria used in published systematic reviews of neck and back pain. Both investigators scored the studies independently and then compared scores. Any discrepancies were resolved through discussion and re-examination of the relevant reports. Methodological evaluation was not used as a criterion for including and excluding studies.

Data extraction
Information on the interventions, outcomes and quality scores was provided in the paper. Details on each study’s power to detect a medium and a large effect size were also given.

**Methods of synthesis**

How were the studies combined?
The studies were combined narratively.

How were differences between studies investigated?
The studies were discussed within sections for intervention type.

**Results of the review**

Twenty-five RCTs with a total of 1,302 participants were included in the review.

The methodological quality of the included studies was moderately low with a mean of 49.5 (standard deviation, SD=12.3; range: 28.5, 72) out of a possible total score of 100. A correlation of 0.451 (p=0.024) was found between the number of significant between-group differences in a study and the methodological score. This suggested that the better quality scores were more likely to demonstrate statistically-significant outcomes. The sample size of the studies tended to be small (median 20; interquartile range: 15, 31.5; range: 6, 58). The average power of the studies to detect a medium effect was 0.36 (SD=0.16; range: 0.12, 0.63), while the average power to detect a large effect was 0.67 (SD=0.21; range: 0.26, 0.96).

Significant between-group differences on at least one outcome measure were reported in 17 of the 25 studies.

Strong evidence did not emerge for any single intervention, although there was preliminary support of moderate strength (based on 3 studies) for aerobic exercise.

**Authors’ conclusions**

There were varying combinations of interventions in the RCTs and a wide range of outcome measures; these factors made it difficult to form conclusions across the studies. Many studies, having a small sample size, were likely to be underpowered to detect an effect on many outcomes. The median follow-up was 16 weeks, which might be considered inadequate for a condition that is characterised by chronicity and a relative lack of symptomatic remission. Methodological quality (such as deficiencies in randomisation) and insufficient or inappropriate statistical analyses contributed to this inconclusive picture. Studies that used a combination approach showed greater improvements than those with a single intervention. FMS may be better managed by a multimodal approach, incorporating aerobic exercise and education to address physical, functional and psychological aspects of FMS.

**CRD commentary**

The review posed a broad question and aimed to build on previous reviews (see Other Publications of Related Interest nos. 1-2). The reviewers searched a range of databases, although only studies published in English and in full were eligible for inclusion in the review. The quality assessments and power calculations provided useful information on the relative reliability of the included studies. The reviewers pointed out, correctly, that firm conclusions could not easily be drawn due to variation in the intervention types and outcome measures. Indeed, several intervention modalities were represented by just one or two (often small) studies. As indicated in this review, there is a need for well-designed, methodologically sound and adequately powered RCTs in this area.

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

Practice: The authors state that the management of FMS patients should be undertaken by a multidisciplinary team, or by those whose breadth of experience allows them to work effectively with the range of features found in FMS. They claim that specialist, clinical units offering an individually tailored approach are most appropriate for the management of FMS patients.
The authors warn that clinicians who do not adopt the more formal diagnostic criteria for fibromyalgia, as used in the reviewed studies, should exercise caution in generalising their findings to the clinical situation.

Research: The authors state that there is a need for larger, more methodologically rigorous RCTs to evaluate the effectiveness of non-pharmacological methods of managing FMS. Standardised outcome measures, such as the Fibromyalgia Impact Questionnaire, should be used both in research and in practice.

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