

LITERATURE REVIEW

COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE TREATMENT OF PAIN IN FIBROMYALGIA: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

Lauren Terhorst, PhD,^a Michael J. Schneider, DC, PhD,^b Kevin H. Kim, PhD,^c Lee M. Gozdzich, DC,^d and Carol S. Stillely, PhD, RN^e

ABSTRACT

Objective: The purpose of this study was to systematically review the literature for randomized trials of complementary and alternative medicine (CAM) interventions for fibromyalgia (FM).

Methods: A comprehensive literature search was conducted. Databases included the Cochrane library, PubMed, PsycINFO, Cumulative Index to Nursing and Allied Health, Natural Medicines Comprehensive Database Manual, Alternative and Natural Therapy Index System (MANTIS), Index for Chiropractic Literature, and Allied and Complementary Medicine (AMED). Inclusion criteria were (a) subjects were diagnosed with fibromyalgia and (b) the study design was a randomized controlled trial that compared a CAM therapy vs a control group. Studies were subgrouped by CAM treatment into 11 categories. Evidence tables and forest plots were organized to display quality ratings and effect sizes of each study.

Results: The literature search yielded 1722 results; 102 abstracts were selected as potential articles for inclusion. Sixty studies met criteria and were rated by 2 reviewers; 18 were rated as good quality; 20, moderate; 18, low; and 4, very low. Synthesis of information for CAM categories represented by more than 5 studies revealed that balneotherapy and mind-body therapies were effective in treating FM pain. This study analyzed recent studies and focused exclusively on randomized controlled trials. Despite common use of manual therapies such as massage and manipulation to treat patients with FM, there is a paucity of quality clinical trials investigating these particular CAM categories.

Conclusion: Most of these studies identified were preliminary or pilot studies, thus had small sample sizes and were likely underpowered. Two CAM categories showed the most promising findings, balneotherapy and mind-body therapies. Most of the other CAM categories showed a trend favoring the treatment group. It appears that several CAM therapies show some preliminary treatment effect for FM pain, but larger trials that are more adequately powered are needed. (*J Manipulative Physiol Ther* 2011;34:483-496)

Key Indexing Terms: *Fibromyalgia; Complementary and Alternative Medicine; Randomized Controlled Trials; Systematic Review*

^a Assistant Professor, University of Pittsburgh School of Nursing, Pittsburgh, PA.

^b Assistant Professor, University of Pittsburgh School of Rehabilitation Sciences, Pittsburgh, PA.

^c Associate Professor, University of Pittsburgh School of Education, Pittsburgh, PA.

^d Chiropractor, Private Practice, National Pike Chiropractic, Brownsville, PA.

^e Associate Professor, University of Pittsburgh School of Nursing, Pittsburgh, PA.

Submit requests for reprints to: Lauren Terhorst, PhD, 3500 Victoria St, Rm 360, Pittsburgh, PA 15261 (e-mail: lat15@pitt.edu).

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Fibromyalgia (FM) is a clinical syndrome characterized primarily by chronic widespread pain and fatigue as well as a cluster of other symptoms including sleep disorders, cognitive dysfunction, irritable bowel and bladder, headache, and a variety of somatic complaints.^{1,2} This condition of unknown etiology affects approximately 2% to 7% of the population, with women 10 times more likely to develop FM than men; and the occurrence of the condition increases with age.³⁻⁶

The etiology of FM is still unknown; and therefore, the standard of medical care has been focused chiefly on pain management and modulation of fatigue. The public health, economic, and disability burdens of FM are substantial. United States patients with clinically diagnosed FM incur direct medical costs approximately twice that of matched controls.⁷ Workers with FM have been shown to have 2 to 3 times higher

absenteeism rates and visits to hospital emergency departments compared with matched workers without FM.⁸

The lack of any known cure for FM—along with a poor prognosis and ongoing chronic symptoms—has led many patients to turn to complementary and alternative medicine (CAM) therapies in search of possible pain relief. Eisenberg et al⁸ performed a national survey of CAM use in the United States and found that a little over a third of Americans reported the use of a least 1 CAM therapy in the previous year.⁹ Many studies¹⁰⁻¹² have documented even higher rates of CAM usage by patients with FM, including a study showing that 50% of patients attending the Mayo Clinic's FM treatment program reported using some type of CAM therapy.¹³

The National Center for Complementary and Alternative Medicine broadly categorizes the various types of CAM therapies into the following groups¹⁴:

- Natural products, such as vitamins, minerals, probiotics, and other dietary supplements;
- Mind-body medicine, including meditation, guided imagery, and hypnosis;
- Manipulative practices such as chiropractic manipulation and massage; and
- Other CAM practices, including movement therapies, energy fields, and whole medical systems such as homeopathy.

There have been many previous review articles, clinical practice guidelines, and systematic reviews of the FM literature that have summarized the research on CAM and standard medical therapies.¹⁵⁻²⁹ Many of these reviews were focused on a single CAM intervention such as acupuncture, massage, and other.^{16,18,22-24} Other review articles and guidelines were published more than 5 years ago and did not include the most current research evidence.²⁰ The aims of this study were to perform an updated systematic review of randomized controlled trials (RCTs) that used a CAM therapy as treatment of pain in adults with FM, rate the methodological quality of the trials, and examine the magnitude of the difference in posttreatment pain between the treatment and control groups.

METHODS

Search Strategy and Inclusion Criteria

A comprehensive literature search of several databases was conducted using a combination of the keywords *fibromyalgia*, *randomized controlled trials*, *complementary medicine*, and *alternative/complementary medicine*. In addition to the aforementioned keywords, specific CAM therapies were also included in the search, including but not limited to balneotherapy, acupuncture, homeopathy, chiropractic, massage, electromagnetic fields, meditation, and

hypnosis. The databases explored included the Cochrane library (Cochrane Central Register of Controlled Trials), PubMed, PsycINFO (from 1967 to 2010), Cumulative Index to Nursing and Allied Health, and Medline (from 1950 to 2010). Relevant alternative and complementary medicine databases such as the Natural Medicines Comprehensive Database, Manual, Alternative and Natural Therapy Index System (MANTIS), Index for Chiropractic Literature, and the Allied and Complementary Medicine Database (from 1985 to 2010) were also queried. Dissertation Abstracts Online was also searched in an attempt to include nonpublished studies in the review. In addition to individual RCTs, we also retrieved several systematic reviews and meta-analyses to find any potentially relevant studies that had not come up in the database search. We conducted the last search of the databases at the end of December 2010.

To complement the database search, we combed through the reference sections of retrieved articles for relevant publications or articles that had not been previously identified. Peer-reviewed journals (eg, *Journal of Manipulative and Physiological Therapeutics*, *Journal of Alternative and Complementary Medicine*, *Arthritis and Rheumatism*, *Rheumatology*) were also reviewed for pertinent citations that included a combination of *randomized controlled trials*, *fibromyalgia*, and any of the keywords.

Once potential studies had been identified, abstracts were inspected to determine article eligibility. Study inclusion criteria included (a) RCTs comparing a CAM therapy to a control group and (b) adult subjects diagnosed with FM using American College of Rheumatology, Yunus, or Smythe criteria.³⁰⁻³² Inclusion status was determined after 2 authors independently reviewed the full-length manuscripts. There was no disagreement between the reviewers regarding the eligibility of studies for inclusion.

Rating Methodological Quality

The system used to provide evidence of individual study quality was created after 2 authors participated in webinars pertaining to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) rating method from the Cochrane Website (<http://ims.cochrane.org/revman/other-resources/gradepro/resources>). The GRADE system is typically used to rate the quality of a body of evidence for a particular outcome.³³ We adapted ideas from the GRADE system and the *Cochrane Handbook for Systematic Reviews of Interventions, Version 5.0.1*³⁴ to assign a ranking of "good," "moderate," "low," or "very low" to each study. A point system was implemented using the following criteria:

- Randomization: To be awarded a point, the specific method of random assignment was mentioned, for example, a computer-generated randomization schedule with allocation concealment. If randomization was mentioned without specific details, then the study

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