Chiropractic Management of Fibromyalgia Syndrome: A Systematic Review of the Literature

Michael Schneider, DC, PhD,[a] Howard Vernon, DC, PhD,[b] Gordon Ko, MD,[c] Gordon Lawson, MSc, DC,[d] and Jerome Perera[e]

Abstract

Objective: Fibromyalgia syndrome (FMS) is one of the most commonly diagnosed nonarticular soft tissue conditions in all fields of musculoskeletal medicine, including chiropractic. The purpose of this study was to perform a comprehensive review of the literature for the most commonly used treatment procedures in chiropractic for FMS and to provide evidence ratings for these procedures. The emphasis of this literature review was on conservative and nonpharmaceutical therapies.

Methods: The Scientific Commission of the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) was charged with developing literature syntheses, organized by anatomical region, to evaluate and report on the evidence base for chiropractic care. This article is the outcome of this charge. As part of the CCGPP process, preliminary drafts of these articles were posted on the CCGPP Web site www.ccgpp.org (2006-8) to allow for an open process and the broadest possible mechanism for stakeholder input. Online comprehensive literature searches were performed of the following databases: Cochrane Database of Systematic Reviews; National Guidelines Clearinghouse; Cochrane Central Register of Controlled Trials; Manual, Alternative, and Natural Therapy Index System; Index to Chiropractic Literature, Cumulative Index to Nursing and Allied Health Literature; Allied and Complementary Medicine; and PubMed up to June 2006.

Results: Our search yielded the following results: 8 systematic reviews, 3 meta-analyses, 5 published guidelines, and 1 consensus document. Our direct search of the databases for additional randomized trials did not find any chiropractic randomized clinical trials that were not already included in one or more of the systematic reviews/guidelines. The review of the Manual, Alternative, and Natural Therapy Index System and Index to Chiropractic Literature databases yielded an additional 38 articles regarding various nonpharmacologic therapies such as chiropractic, acupuncture, nutritional/herbal supplements, massage, etc. Review of these articles resulted in the following recommendations regarding nonpharmaceutical treatments of FMS. Strong evidence supports aerobic exercise and cognitive behavioral therapy. Moderate evidence supports massage, muscle strength training, acupuncture, and spa therapy (balneotherapy). Limited evidence supports spinal manipulation, movement/body awareness, vitamins, herbs, and dietary modification.

Conclusions: Several nonpharmacologic treatments and manual-type therapies have acceptable evidentiary support in the treatment of FMS. (J Manipulative Physiol Ther 2009;32:25-40)

Key Indexing Terms: *Fibromyalgia; Chiropractic; Fatigue Syndrome; Chronic*

[a] Visiting Assistant Professor, School of Health and Rehabilitation Sciences, University of Pittsburgh, Pittsburgh, Pa, USA.

[b] Professor, Graduate Education and Research, Canadian Memorial Chiropractic College, Toronto, Ontario, Canada.

[c] Medical Director, Canadian Centre for Integrative Medicine, Physiatry Intervention Clinic, Sunnybrook Health Sciences Centre, University of Toronto, Toronto, Ontario, Canada.

[d] Assistant Professor, Canadian Memorial Chiropractic College, Toronto, Ontario, Canada.

[e] Student, School of Medicine, University of Toronto, Ontario, Canada.

Submit requests for reprints to: Michael Schneider, DC, Assistant Professor and PhD candidate, School of Health and Rehabilitation Sciences, University of Pittsburgh, Pittsburgh, PA, USA (e-mail: *drmike@city-net.com*).

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Fibromyalgia syndrome (FMS) is an elusive condition of unknown etiology, in which patients report chronic widespread pain as their predominant symptom, along with a variety of other complaints including fatigue, sleep disorders, cognitive deficit, irritable bowel and bladder syndrome, headache, Raynaud syndrome, bruxism, atypical patterns of sensory dysesthesia, and other symptoms.[1] The name of the condition, *fibro-myo-algia*, suggests that the widespread pain is emanating from the fibrous soft tissues or muscles. However, the literature is void of data to support the hypothesis that FMS is a distinct pathologic disorder of the soft tissues. More recent data tend to support the notion that FMS is a disorder of the central nervous system pain processing pathways and not some type of primary autoimmune disorder of the peripheral tissues.[2-4]

The diagnosis of FMS has been burdened by a controversial and problematic history since its inception in

1990, with a disturbing trend toward overdiagnosis in recent years.[5] Chiropractors, who often see chronic pain patients who have exhausted all other conservative treatment options, need to be wary of the diagnosis of FMS. The mere presence of widespread pain and fatigue should not be considered adequate grounds for making a de facto diagnosis of FMS; yet many times, this is the case. The primary symptoms of FMS, that is, widespread pain and fatigue, are also the primary symptoms of a number of other medical conditions including hypothyroidism, anemia, diabetes, Lyme disease, rheumatoid arthritis, undiagnosed cancer, posttraumatic myofascial pain, and many other conditions.

The issue of overdiagnosis and misdiagnosis relates back to the simple fact that a diagnosis of FMS is not based upon any laboratory or diagnostic tests, but rather upon symptoms that have been divided into 2 vague criteria. The first criterion is a history of chronic widespread pain, and the second criterion is the presence of a specific number of tender points (TePs) that exhibit a painful response to less than 4 kg of manual pressure.[6] Although a diagnosis of FMS is predicated upon the presence of multiple TePs, the etiology of these areas of superficial tenderness is not known. The FMS literature contains biopsy studies of TePs that have failed to show any soft tissue abnormality that is specific to FMS patients.[7] It is clear that TePs are not areas of soft tissue inflammation, which explains the findings in the pharmaceutical literature that no steroidal or nonsteroidal anti-inflammatory medication has any significant effect on reducing the painful TePs in FMS patients above placebo.

The hallmark symptom of FMS is pronounced tenderness to even the mildest palpation. This extreme tenderness to subthreshold stimuli fits the definition of *allodynia*, that is, the perception of pain to a nonpainful stimulus.[8] Allodynia and/or hyperalgesia can be quite pronounced in the classic presentation of FMS; it has been found to be multimodal (pressure, heat, electrical stimulation) and widespread throughout many body regions.[9-11] The presence of allodynia typically implies a disorder of nociceptive pathways within the central nervous system (central sensitization) and not an abnormality of peripheral tissues themselves. There are recent data to support the idea that the widespread allodynia associated with FMS is indeed caused by central nervous system dysfunction (central sensitization) as documented by functional magnetic resonance imaging and positron emission tomography brain scans of patients with FMS receiving innocuous sensory stimulation.[12,13]

Leading FMS researchers now consider the TeP phenomenon to merely be the peripheral manifestation (widespread allodynia) of a central nervous system dysfunction. Several consensus conferences have addressed the issue of FMS diagnosis and treatment since the publication of the original 1990 American College of Rheumatology (ACR) criteria and have reported numerous other symptoms besides the 2 ACR criteria of widespread pain and multiple TePs.[14-16] Fibromyalgia syndrome patients are predominantly female (female-male ratio, 10-20:1); typically report nonrefreshing sleep, general fatigue, and low energy; and experience concomitant anxiety and depression disorders. Fibromyalgia syndrome is reported to be part of a wider syndrome involving headaches, bruxism, irritable bladder, irritable bowel, sleep disorders, depression and/or anxiety disorders, cold sensitivity, Raynaud phenomenon, exercise intolerance, cognitive deficit, and other symptoms suggestive of autonomic nervous system and/or neuroendocrine dysregulation.

The most updated FMS protocols still recommend the same 2 ACR criteria as being mandatory for making an FMS diagnosis, along with a long list of additional clinical symptoms and signs that include the following: neurocognitive manifestations, fatigue, sleep dysfunction, autonomic and/or neuroendocrine manifestations, neurologic manifestations, and other symptoms. Some or all of these symptoms may be found along with the hallmark finding of widespread allodynia. Fibromyalgia syndrome researchers are starting to look at a new conceptual model of FMS as a disorder with multiple subsets and potentially multiple treatment approaches.

The notion that FMS represents a single diagnostic entity is now being challenged by newer hypotheses that various subsets of FMS may exist.[16,17] Fibromyalgia syndrome is more likely to be a syndrome that may have a number of different etiologies, requiring a number of different treatment approaches. Our review of the FMS literature is consistent with this emerging idea of FMS being composed of numerous subsets. As the reader reviews the following evidence rating tables, practice guidelines, and literature syntheses, it will become apparent that a number of different treatment approaches seem to show therapeutic promise and that no one single treatment or "silver bullet" approach is appropriate for the clinical management of FMS.

In the field of FMS, chiropractic is generally regarded as one of the complementary and alternative medical (CAM) therapies. Complementary and alternative medical therapies are commonly used in the treatment of FMS, and there is considerable overlap between chiropractic manipulative and manual approaches and other CAM therapies in this field. For example, many chiropractors use therapeutic exercises, vitamins, herbs, and dietary modifications in the management of FMS. The emerging FMS literature is showing promise for many CAM therapies, as no single therapeutic intervention has been shown to be curative. The trend in the clinical management of FMS syndrome is to treat the various symptoms of the syndrome using a number of different interventions, including CAM therapies. This trend fits well with the traditional chiropractic perspective that health and well-being require a "combination approach" to clinical management.

Methods

Search Strategy

The search strategy for this literature review was focused on conservative nonpharmaceutical treatments for FMS, including chiropractic manipulative therapy. Therefore, our search included any conservative therapy that might be included within the scope of chiropractic practice, in addition to spinal manipulation. Articles that were opinion pieces, hypotheses, extrapolations from basic science research, and other nonobservational types of articles were excluded from our review.

We used a systematic approach to reviewing the FMS literature by following this sequence of online searching strategies:

- A search of the Cochrane Database of Systematic Reviews for systematic reviews and meta-analyses of randomized controlled clinical trials (RCTs) for FMS.
- A search of the National Guidelines Clearinghouse (NGC) for any published guidelines for the management of FMS.
- Direct searches of several online databases for additional RCTs that might not have been included in previous systematic reviews or meta-analyses. These direct searches included the following databases: PubMed, Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine (AMED), Medline, and Cumulative Index to Nursing and Allied Health Literature (CINAHL).
- Additional searching of the Manual, Alternative, and Natural Therapy Index System (MANTIS) and Index to Chiropractic Literature (ICL) for any additional literature on FMS, including experimental and observational studies such as case reports and case series.

The keywords used in our search strategy included the terms *fibromyalgia*, *fibrositis*, and *fibromyalgia syndrome* and covered the literature published in the English language between 1966 and 2006. We did not restrict the searches by using the term *chiropractic*, with the exception of one of the searches within the specific confines of the MANTIS and ICL databases. The titles of all retrieved studies were reviewed for their relevance to chiropractic practice and scope, and the abstracts of any potentially relevant studies were further reviewed before obtaining full text copies of the entire article. Studies that involved injection, medication, surgery, or other invasive therapies were excluded from our review. We did include 2 systematic reviews of the antidepressant medication literature because this class of medication is considered an integral component of the standard medical management of FMS syndrome, albeit outside the scope of chiropractic practice.

A manual review of the reference lists of the previously noted Cochrane systematic reviews and meta-analyses and the NGC practice guidelines found that the most recent of these publications had searched the FMS literature through the year 2002. We therefore performed our own searches for additional controlled trials using the keywords *fibromyalgia* and *fibromyalgia syndrome* between the years January 2000 and June 2006 on the following databases: MEDLINE, CINAHL, AMED, Cochrane Central Register of Controlled Trials, and PubMed. The rationale for going back to the year 2000 was to confirm that we did not miss any relevant studies and to provide some overlap for comparison with the references contained in the search strategies of the previously reported FMS systematic reviews, meta-analyses, and practice guidelines. Our intent was to attempt to find any additional clinical trials that were not included in the reviews performed by the previous meta-analyses and systematic reviews by cross-referencing our list against the list of references from the prior studies.

In addition to searching these standard online databases for randomized controlled trials, we specifically wanted to capture any type of chiropractic literature, including observational studies, that might have been published in nonindexed journals. Therefore, we specifically performed another comprehensive search of the MANTIS and ICL databases, which are more inclusive of the chiropractic and CAM therapy literature. We used 2 search strategies on these databases. First, we performed a wide search using the terms *fibromyalgia* and *fibromyalgia syndrome* without any restrictions to journal type, but restricted the year of publication from 1990 to 2006, The rationale for this search strategy was simple: 1990 is generally considered the inaugural year for fibromyalgia becoming officially recognized as a diagnosis by virtue of publication of the ACR criteria for diagnosis of FMS. Our second search strategy was to use the keywords *fibromyalgia AND chiropractic* for the years of publication from 1950 to

Fig 1. *Rating scales for studies obtained from MANTIS and ICL searches.*

A. The Oxford Rating Scale (http://www.library.utoronto.ca/medicine/ebm/)
1a: Systematic review with homogeneity of RCTs
1b: Individual RCT with narrow confidence interval
2a: Systematic review with homogeneity of cohort studies
2b: Individual cohort study or low-quality RCT
3a: Systematic review with homogeneity of case-control studies
3b: Individual case-control study
4: Case series, low-quality cohort or case-control studies
5:. Expert opinion

B. The SIGN Checklist (http://www.sign.ac.uk/methodology/index.html)
1. ++ = All or most methodological criteria have been fulfilled/bias has been maximally reduced.
2. + = Some of the criteria have been fulfilled/bias has been somewhat reduced.
– = Few or no criteria fulfilled/bias is clearly present.

Fig 2. *Council on Chiropractic Guidelines and Practice Parameters protocol for grading of recommendations (http://www.ccgpp.org).*

Grade A: good evidence from relevant studies:
- Studies based on appropriate research designs of sufficient strength to answer the questions addressed.
- Results are both clinically important and consistent with minor exceptions at most.
- Results are free of any significant doubts about generalizability, bias, and flaws in research design.
- Studies with negative results have sufficiently large sample sizes to have adequate statistical power.

Grade B: fair evidence from relevant studies:
- Studies based on appropriate research designs of sufficient strength, but with some uncertainty due to inconsistencies in results, or minor doubts about generalizability, bias, design flaws, or sample size.
- Results from weaker designs, but confirmed in separate studies.

Grade C: limited evidence:
- Studies of appropriate design, but substantial uncertainty due to inconsistencies in results or due to serious doubts about generalizability, bias, research design flaws, or adequacy of sample size.
- Results from a limited number of studies or because of weak design for answering the question addressed.

Grade D: expert opinion, and usual and customary practice:
- Evidence from expert opinion only; research cannot be or has not been done.

2006. We also used reference tracking to ensure that the search was comprehensive.

Evaluation and Rating Systems

As relevant studies were identified, we obtained full text versions of the articles and reviewed them using several recognized protocols. The systematic reviews, meta-analyses, and randomized trials were reviewed using the Oxford Rating Scale developed by the Centre for Evidence-Based Medicine (http://www.library.utoronto.ca/medicine/ebm) and the appropriate evidence rating checklists developed by the Scottish Intercollegiate Guidelines Network (SIGN) (http://www.sign.ac.uk/methodology/index.html), shown in Figure 1. There are separate SIGN checklists for each type of experimental and higher-quality observational studies. The guidelines retrieved from the NGC were evaluated using the appraisal instrument/checklist developed by the Appraisal of Guidelines for Research and Evaluation (AGREE) Collaboration (www.agreecollaboration.org).

Finally, after summarizing the literature into evidence tables, we developed some evidence rating tables based upon our interpretation and evaluation of the quality of this literature. The evidence rating tables followed a standard format suggested by the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) (http://www.ccgpp.org) as outlined in Figure 2.

Table 1. *Systematic reviews, meta-analyses, and practice guidelines*

Type of treatment addressed	Systematic literature review	Meta-analysis	Practice guideline	Totals
Total	8	3	5	16
Multidisciplinary rehabilitation[18]	1			1
CAM therapies[19]	1			1
Exercise[20]	1			1
Pharmacologic vs nonpharmacologic therapies[21]		1		1
Nonpharmacologic therapies[22]	1			1
CBT[23]	1			1
Mind-body therapies[24]	1			1
Massage[25]	1			1
Acupuncture[26]	1			1
Antidepressant medications[27,28]		2		2
FMS treatment and management[29-33]			5	5

These references were found upon searching the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and American College of Physicians Journal Club (for the years 1996-2006) and the NGC.

Results

Systematic Reviews and Meta-Analyses of the FMS Literature

Our search of the Cochrane Database of Systematic Reviews (1996-2005) using keywords *fibromyalgia*, *fibrositis*, and *fibromyalgia syndrome* identified a total of 26 references in this database. After reviewing the abstracts, we found that only 11 of these studies reviewed conservative therapies that were directly related to the subject of FMS or widespread pain. Of relevance to chiropractic practice were 8 systematic reviews[18-25] and 3 meta-analyses[26-28] of the FMS literature. These 11 references are listed in Table 1, along with the guidelines we obtained from the NGC. All were found to be of extremely high scholarly quality.

Of the above-noted 8 relevant systematic reviews of the FMS literature, the one that is most pertinent to chiropractic practice was published by Holdcraft et al.[19] This systematic review was further updated and expanded into a clinical practice guideline document published by the American Pain Society (APS) a few years later and will be discussed shortly. The Holdcraft et al systematic review of the literature specifically assessed the effectiveness of CAM therapies for people with FMS. They searched the following online databases: MEDLINE (1975-2002), BIOSIS Previews (1975-2002), EMBASE (1990-2002), CINAHL (1982-1998), Alternative Medicine Alert, and the Cochrane Controlled Trials Register. They reviewed a large number of studies, encompassing a wide variety of various nonpharmacologic therapies including the following: acupuncture (8 studies including 2 RCTs with 130 patients),

Table 2. *Additional clinical trials*

Type of treatment addressed	Type of article: Controlled clinical trial	Type of article: Total	Duplicates: Articles previously reviewed within other systematic reviews or practice guidelines (total = 19)
Total	44	44	
Chiropractic	–	–	
Osteopathic manipulation[34]	1	1	
Exercise[35-48]	14	14	Schacter,[46] van Santen et al[48]
Vitamins and diet therapy[49-53]	5	5	Hakkinen et al,[36] Jones et al,[37] King et al,[39] Mannerkorpi et al[40,41]
Medications[54-59]	6	6	Citera et al,[50] Merchant et al,[53] Kaartinen et al,[52] Azad et al,[49] Edwards et al,[51] Anderberg et al[54]
Body awareness and qi gong[60]	1	1	Kendall et al[60]
Laser therapy[61]	1	1	
Education[62,63]	2	2	
Massage[70,71]	2	2	
Spa/water therapy (balneotherapy)[66,67,77]	3	3	Buskila et al,[66] Evcik et al[67]
Magnet therapy[68]	1	1	Alfano et al[68]
Meditation and qi gong[69]	1	1	Astin et al[69]
Ultrasound and interferential current[70]	1	1	
Tai chi[71]	1	1	Taggart et al[71]
Exercise and CBT (combination therapy)[72,73]	2	2	
CBT[74]	1	1	Soares and Grossi[74]
Multidisciplinary approaches[75,76]	2	2	

chiropractic (1 RCT with 19 patients), magnesium (2 crossover RCTs with 39 patients), *S*-adenosyl-L-methionine (1 review of 7 studies including 4 RCTs), chlorella (1 crossover RCT with 37 patients), relaxation (1 unblinded RCT with 55 patients), biofeedback (3 RCTs with 274 patients), magnet therapies (2 RCTs with 144 patients), homeopathy (1 crossover RCT with 30 patients), botanical oils (1 RCT with 30 patients), balneotherapy (1 RCT with 48 patients), anthocyanidins (1 crossover RCT with 12 patients), and dietary modifications (1 RCT with 78 patients).

They concluded that most of these CAM 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. They commented that there was strong evidence of the effectiveness of acupuncture, with all 8 studies showing that acupuncture improved the symptoms of FMS. There was moderate evidence for the effectiveness of the nutritional supplement *S*-adenosyl-L-methionine, with limited but potentially promising evidence for the remaining CAM therapies listed above.

Published Guidelines Found on the NGC

Our search of the NGC database produced a total of 5 published guidelines on the management of FMS.[29-33] Three of the guidelines[29-31] were rated with the AGREE Instrument as "recommended," and the other 2 guidelines[32,33] were rated as "strongly recommended." We found that, of the 2 strongly recommended guidelines, the most current (2005) FMS guideline published by the APS[33] was very comprehensive, of excellent quality, and inclusive of most nonpharmacologic and CAM therapies, including chiropractic. These guidelines will each be reviewed briefly below, with these references listed in Table 1 along with the previously noted systematic reviews and meta-analyses.

One guideline exists regarding FMS and work-related injury, from the Washington State Department of Labor and Industries.[29] This guideline states that FMS is not considered to be an occupational disease based upon their review of the scientific literature that failed to establish a causal relationship between a traumatic injury or occupational exposure and the development of FMS. Under special circumstances, the Department may authorize temporary treatment of FMS;

Note to Table 2

These 44 references were found upon additional searches of the Medline, PubMed, CINAHL, AMED, EMBASE, Database of Abstracts of Reviews of Effects, and TRIP databases for the years 2000 to 2006. These represent the FMS literature for individual clinical trials that could potentially have been omitted from the previously retrieved systematic reviews and practice guidelines. Note that a total of 20 of these 44 references were included in the most recent FMS practice guideline[33] and systematic review[19] of the FMS literature. No additional chiropractic trials were found on any of these medical databases.

Table 3. *Additional studies from MANTIS and ICL searches*

Type of treatment addressed	Type of article					
	Randomized controlled trial	Survey	Case-control	Case series	Case report	Total
Total	17	2	2	14	3	38
Chiropractic (manipulation and soft tissue therapy)[80,81,114,115]	2			1	1	4
Osteopathic manipulation[82,83]				2		2
Exercise[84-87]	4					4
Acupuncture[88,89]	2					2
Multidisciplinary rehab[90,91]	2					2
Body awareness and qi gong[92]	1					1
Bright light therapy[93]	1					1
Therapeutic touch[94]				1		1
Craniosacral therapy and muscle energy technique[95]				1		1
Microcurrent stimulation[96]				1		1
Dietary interventions[97-99]				3		3
Prolotherapy[100]				1		1
Homeopathy[101-104]	3			1		4
Eye movement desensitization[105]				1		1
Educational programs[106]				1		1
CBT[107]			1			1
Hair analysis[108]			1			1
Surface EMG[109]				1		1
Thyroid hormone[110]	1					1
Water therapy[111]	1					1
Chiropractic manipulation and cranial electrical stimulation[112]					1	1
Acupuncture and diet[113]					1	1
Survey of CAM therapies used by FMS patients referred to Mayo clinic[116]		1				1
Psychologic profile of FMS attending private chiropractic clinics [117]		1				1

These 38 references were obtained from literature searches of the MANTIS and ICL databases from 1950 to 2006. These 2 databases are not restricted to peer-reviewed, indexed journals. Only 3 of these studies were included in the most recent systematic review of the FMS literature[19] and FMS practice guideline[33] (Blunt et al,[80] Deluze et al,[88] and Abraham and Flechas[97]). *EMG*, Electromyography.

but such treatment is limited to physical therapy, low-dose antidepressant and muscle relaxant medication, and spinal manipulations. Trigger point injections, methotrexate, opioids, and nonsteroidal anti-inflammatory drugs (NSAIDs) are not approved for the treatment of FMS by the Department.

One FMS clinical guideline was found on the NGC Web site that was published in 2004 by Intracorp,[30] a public for-profit organization that had its internal medical technology and quality assurance committees review the FMS literature. They generated the following recommendations regarding the clinical management of FMS: recommended—exercise, education, low-dose antidepressants and analgesic medications, heat, and gentle massage; not recommended—steroids and NSAIDs.

The University of Texas School of Nursing published a guideline[31] for the treatment of FMS in 2005 that suggests a stepwise approach as summarized below:

- Educate about prognosis, pathophysiology, and treatment principles.
- Emphasize adequate sleep; treat fatigue and depression.
- Treat muscle spasm and generalized pain with appropriate medications.
- Encourage regular exercise, heat, and massage.
- Address comorbid psychosocial issues.

Another guideline for the management of FMS was authored by Goldenberg et al[32] and published in the *JAMA* in 2004. This guideline was developed by an independent panel of experts who convened under the sponsorship of the APS and performed a comprehensive review of the FMS literature. They produced a consensus document/guideline based upon the best available evidence. Their conclusions were that the FMS diagnosis first must be confirmed and the condition explained to the patient and family. Any comorbid illness, such as mood disturbances or primary sleep disturbances, should be identified and treated. Medications for initial consideration are low doses of tricyclic antidepressants or cyclobenzaprine. Some selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), or anticonvulsants may become first-line FMS medications as more RCTs are reported. All patients with FMS should begin a cardiovascular exercise program. Most patients will benefit from cognitive behavioral therapy (CBT) or stress reduction with relaxation training. A multidisciplinary approach combining each of these modalities may be the most beneficial. Other

Table 4. *Summaries of additional studies*

Clinical trials	Title	Summary	SIGN/ Oxford rating
Bell et al[101]	Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo	N = 62; RCT comparing oral homeopathic remedy with indistinguishable placebo; only 53 completed the trial; equivocal finding that homeopathic treatment was better than placebo	1+/2b
Blunt et al[80]	Effectiveness of chiropractic management of fibromyalgia patients: a pilot study	N = 19; preliminary RCT with spinal manip, stretching, soft tissue therapy; positive outcome for interventions but no control group and small sample size make findings equivocal	1+/2b
DaCosta et al[85]	A randomized clinical trial of an individualized home-based exercise programme for women with fibromyalgia	N = 79; RCT compared moderate-intensity home exercises to usual care control group; home-based exercises better outcome than control	2+/1b
Faull et al[111]	A pilot study of the comparative effectiveness of two water-based treatments for fibromyalgia syndrome: Watsu and Aix massage	Nonrandomized clinical trial; n = 13 Watsu did better than Aix, but no control group and small sample size make findings equivocal	2+/2b
Harris et al[89]	Treatment of fibromyalgia syndrome with formula acupuncture	Single-blind RCT; n = 114 comparing 4 types of acupuncture traditional/nontraditional needle placement with/without electrical stimulation; no control group; all 4 types were effective	2+/1b
Lemstra and Olsvnski[90]	Effectiveness of multidisciplinary rehabilitation in the treatment of fibromyalgia: a randomized controlled trial	N = 79 compared standard medical care with a combo of group exercise, stress management, massage therapy, and education. Positive outcome for intervention vs standard care.	2+/1b
Mannerkorpi and Arndorw[92]	Efficacy and feasibility of a combination of body awareness therapy and qigong in patients with fibromyalgia: a pilot study	N = 36; RCT compared qigong plus body awareness to a control group; no difference between groups on changes in pain/function	1+/2b
Pearl et al[93]	The effects of bright light treatment on the symptoms of fibromyalgia	N = 14; RCT crossover trial compared bright light therapy to a "filtered" light therapy. No significant difference between groups. Very small sample size and no control group make findings equivocal	1+/2b
Sencan et al[86]	A study to compare the therapeutic efficacy of aerobic exercise and paroxetine in fibromyalgia syndrome	N = 60; RCT comparing 3 groups; AE on a bike, paroxetine, placebo TENS; AE group had less analgesic use, AE and paroxetine groups had better outcomes than the placebo TENS group.	2+/1b
Wigers et al[87]	Effects of aerobic exercise versus stress management treatment in fibromyalgia: a 4.5 year prospective study	N = 60; RCT comparing 14 wk of treatment with AE, SM, or treatment as usual; AE and SM had positive short-term effects, AE was overall most effective treatment, no long-term benefits from any group	2+/1b
Wise et al[81]	Effectiveness of chiropractic treatment on fibromyalgia syndrome: a randomized controlled trial	Published in WFC 7th biennial congress conference proceedings, scant description of study and results. Wait-list control group.	1−/2b
Zijlstra et al[91]	Spa treatment for primary fibromyalgia syndrome: a combination of thalassotherapy, exercise and patient education improves symptoms and quality of life	N = 136; RCT compared 2 1/2 weeks of treatment at a spa resort with treatment as usual; spa therapy reduced pain at 3 mo, but not at 6 or 12 mo	2+/1b

(*continued on next page*)

Table 4. (*continued*)

Clinical trials	Title	Summary	SIGN/ Oxford rating
Case reports and/ or case series	Title	Summary	
Abraham and Flechas[97]	Management of fibromyalgia: rationale for the use of magnesium and malic acid	N = 15 case series of patients	1+/3b
Denison[94]	Touch the pain away: new research on therapeutic touch and persons with fibromyalgia syndrome	Case series; no specific no. of subjects reported	1−/3b
Friedberg[105]	Eye movement desensitization in fibromyalgia	N = 6 patients who had 2 treatment sessions	1+/3b
Gemmell et al[104]	Homeopathic Rhus Toxicondendron in the treatment of fibromyalgia	N = 3 case series of patients; no significant effects found	1+/3b
Hains and Hains[114]	Combined ischemic compression and spinal manipulation in the treatment of fibromyalgia: a preliminary estimate of dose and efficacy	N = 15 case series of patients given 30 chiropractic treatments, most patients had a favorable response to intervention	1+/3b
Harte[113]	Clinical forum: fibromyalgia syndrome	Single-case report	1−/4
Henriksson et al[106]	Evaluation of four outpatient educational programmes for patients with longstanding fibromyalgia	N = 191; survey data comparing 4 educational programs varying in total length of time and no. of staff/patient contact hours. No differences between groups.	2+/2b
Leach and Hosek[109]	Clinical and myoelectric observations on fibromyalgia: a prospective descriptive clinical series	Published in Proceedings of the International Conference on Spinal Manipulation; no specific description of research design	1−/3b
Lo et al[82]	Osteopathic manipulative treatment in fibromyalgia syndrome	N = 19 patients treated with OMT; most had a favorable outcome with intervention	1+/3b
Lukaczer et al[98]	A pilot trial evaluating Meta050, a proprietary combination of reduced iso-alpha acids, rosemary extract and oleañolic acid in patients with arthritis and fibromyalgia	N = 54 patients with "rheumatic disease"; osteoarthritis, RA, and/or FMS	1+/3b
McMakin et al[96]	Cytokine changes with microcurrent treatment of fibromyalgia associated with cervical spine trauma	N = 54 consecutive patients	1+/3b
Michalsen et al[99]	Mediterranean diet or extended fasting's influence on changing the intestinal microflora, immunoglobulin A secretion and clinical outcome in patients with rheumatoid arthritis and fibromyalgia: an observational study	N = 51 consecutive patients; 16 RA patients and 35 FMS patients	1+/3b
Silva et al[95]	A retrospective review of outcomes of fibromyalgia patients following physical therapy treatments	N = 23 charts analyzed from a physical therapy clinic that used Upledger craniosacral therapy and muscle energy techniques	1+/3b
Stotz and Kappler[83]	The effects of osteopathic manipulative treatment on the tender points associated with fibromyalgia	N = 18; case series of patients	1+/3b
Tyers and Smith[112]	A comparison of cranial electrotherapy stimulation alone or with chiropractic therapies in the treatment of fibromyalgia	Case series with no specific number of patients cited	1-/3b
Wise and Walsh[115]	Chiropractic treatment of fibromyalgia: two case studies	N = 2 case reports	1+/4

Table 4. (*continued*)

Clinical trials	Title	Summary	SIGN/ Oxford rating
Survey research	Title	Summary	
Jamison[117]	A psychologic profile of fibromyalgia patients: a chiropractic case study	Survey forms given to FMS patients, maintenance chiropractic patients, and the DCs treating them at 5 separate chiropractic clinics in Australia; >50% of FMS were distressed and only 14% of maintenance patients.	2+/2b
Wahner-Roedler et al[116]	Use of complementary and alternative medical therapies by patients referred to a fibromyalgia treatment program at a tertiary care center	N = 289 patients at the Mayo clinic FMS treatment program were given survey forms to complete, 98% had used some form of CAM therapy, as follows: 48% used exercise, 45% used prayer or spiritual healing, 44% used massage therapy, 37% had used chiropractic, about 25% used various vitamin therapies and dietary changes.	2+/2b
Case-control study	Title	Summary	
Ng[108]	Hair calcium and magnesium levels in patients with fibromyalgia: a case center study	N = 24; 12 patients who had hair analysis performed and met the ACR criteria for FMS were age-/sex-matched with 12 healthy control patients who had hair analysis performed for general screening purposes; significantly higher amounts of calcium and magnesium in FMS group	1+/3b
Goldenberg et al[107]	A controlled study of a stress-reduction, cognitive-behavioral treatment program in fibromyalgia.	N = 121; 79 FMS patients completed a 10-wk stress reduction, cognitive behavioral meditation program. Control group was 42 FMS patients on wait list. CBT group showed superior outcomes to controls.	2+/2b

Expanded summaries of results of literature search on MANTIS and ICL databases using the keywords *fibromyalgia* (1990-2006) and *fibromyalgia AND chiropractic* (1950-2006). The explanation of SIGN/Oxford rating protocol is in Figure 1. *AE*, Aerobic exercise; *TENS*, transcutaneous electrical nerve stimulation; *SM*, stress management; *WFC*, World Federation of Chiropractic; *OMT*, osteopathic manipulative treatment; *RA*, rheumatoid arthritis.

medications, such as tramadol or combinations of medications, should be considered. Patients with FMS not responding well to these steps should be referred to a rheumatologist, physiatrist, psychiatrist, or pain management specialist.

The most current of all the FMS guidelines identified by our search (as of June 2006) was authored by Buckhardt et al[33] and published by the APS in 2005. We found this guideline to be very comprehensive, well written, and applicable to a wide variety of different clinicians, including the chiropractic profession. It basically offers recommendations for the management of FMS according to the 3 most strongly evidence-based therapies described in most of the Cochrane systematic reviews, that is, low-dose antidepressant medications, aerobic exercise, and CBT.

The 2005 APS guideline further suggests that physicians should consider the option of having their patients try other complementary treatments such as acupuncture, biofeedback, chiropractic manipulation, hypnosis, and massage. They cautioned against the use of the following procedures for which there is no evidence of therapeutic efficacy in the treatment of FMS: opioids, corticosteroids, nonsteroidal anti-inflammatories, benzodiazepines, and tender or trigger point injections.

The most important conclusions and recommendations from the 2005 APS guideline for FMS are summarized below.

1. Recommend tricyclics, SSRIs, anxiolytics, and pain medications for improving sleep, reducing anxiety/depression, and decreasing pain. Nonsteroidal anti-inflammatory drugs and corticosteroids are not recommended as primary medications for the treatment of FMS.
2. Use CBT to reduce pain and psychologic disability by enhancing self-efficacy, self-management, and skills for coping with pain.
3. Use aerobic exercise to minimize pain, improve sleep quality, enhance self-efficacy, and increase positive mood.
4. Offer clinician-assisted treatments such as clinical hypnosis and biofeedback, acupuncture, chiropractic manipulation, therapeutic massage, and balneotherapy, which may be helpful for pain relief.
5. Use multidisciplinary approaches that incorporate 2 or more strategies to decrease pain and improve function in FMS, especially in people who have not responded to simpler approaches.
6. Emphasize sleep hygiene as part of the treatment plan, using both pharmacologic and nonpharmacologic techniques.

Table 5. *Summary of recommendations for clinical management of FMS (protocol used to arrive at these recommendations is in Fig 2)*

Topic	Conclusion and strength of evidence rating
FMS	
Evaluation	Rating A: pressure algometry There is strong evidence that pressure algometry has high reliability and validity in the assessment of the TePs found in FMS. Rating A: FIQ The FIQ has achieved wide recognition as a reliable and valid instrument as part of FMS management and research, and has been translated into several languages.
Manual therapies	Rating B: massage. There is moderate evidence from several RCTs and 1 systematic review that massage is helpful in improving sleep and reducing anxiety in chronic pain. Rating C: manipulation. There is limited evidence consisting of 1 small chiropractic pilot RCT that manipulation may relieve pain in FMS. The literature also contains 2 chiropractic and 2 osteopathic manipulation case reports/series.
Exercise	Rating A: aerobic exercise. There is strong evidence from multiple RCTs/systematic reviews that mild aerobic exercise is helpful in relieving the pain and fatigue associated with FMS. Rating B: muscle strength training. There is moderate evidence that mild strength training programs are helpful in FMS; however, the evidence does not support moderate or heavy intensity strength training for FMS patients. Rating C: movement and body awareness. There is preliminary evidence from 3 small RCTs that gentle body awareness exercise methods such as tai chi and qi gong are helpful with FMS.
Vitamins, herbs, diet modification	Rating C: vitamins, herbs, diet modification. There are several small RCTs with preliminary evidence showing a potential beneficial effect of these therapies for FMS.
CBT	Rating A: CBT. There are several large RCTs and systematic reviews showing a strong treatment effect of CBT alone, and in combination with exercise and various medications, for the clinical management of FMS symptoms.
Medications[a]	Rating A: The medications with the strongest evidence of effectiveness (multiple systematic reviews and RCTs) for FMS are amitriptyline and cyclobenzaprine used alone or in combination with SSRIs or SNRIs. Emerging evidence is for pregabalin, gabapentin, and tramadol. No evidence for NSAIDs or corticosteroids used alone.
Balneotherapy (spa therapy)	Rating B: balneotherapy. There is moderate evidence from several consistent RCTs showing reduction of FMS symptoms with hot water/spa treatments.
Acupuncture[a]	Rating B: acupuncture. There is 1 systematic review and 1 additional RCT that show moderate reduction of pain in FMS patients with acupuncture treatment.

FIQ, Fibromyalgia Impact Questionnaire.

[a] Although prescription medications and acupuncture are outside the scope of chiropractic practice in many jurisdictions, we have included them in the evidence tables because of their popular and widespread use among FMS patients.

7. Treat anxiety and depression aggressively with both pharmacologic and nonpharmacologic approaches.

We rated the 2005 APS guideline as the highest-quality guideline we reviewed using the AGREE Instrument and considered it to be the most complete and comprehensive guideline for the clinical management of FMS that was currently available at the conclusion of our literature search in June 2006. We highly recommend that the serious reader of the FMS literature obtain a copy of this guideline. Most of our summary ratings agree with the ratings found within this guideline.

Additional Searches for FMS Controlled Clinical Trials

Our search for additional randomized controlled trials on the MEDLINE, CINAHL, AMED, Cochrane Central Register of Controlled Trials, and PubMed databases yielded a total of 44 studies,[34-77] of which 25 were found to be relevant and not previously included in prior systematic reviews or meta-analyses. The other 19 studies were previously considered within the context of at least one or more of the systematic reviews listed in Table 1. These 44 references are summarized in Table 2. Of these 44 studies, the largest number of RCTs (n = 14) was of various exercise interventions for FMS symptoms, 7 of which were included in prior systematic reviews. Because exercise is already an established treatment of FMS, these additional 7 exercise studies do not change any recommendations from the previously noted systematic reviews. There were no additional clinical trials pertaining to chiropractic treatment or management of FMS. We retrieved 5 trials on vitamins and on nutritional and dietary interventions; however, all of these studies were included in previous systematic reviews and practice guidelines. A total of 19 studies of the 44 references (Table 2) found during our search were previously

included in the reference sections of prior systematic reviews or practice guidelines and therefore were considered redundant.

The 25 studies that we found that were not previously considered in any of the prior systematic reviews or practice guidelines are listed in Table 2. We used the Oxford Rating Scale[78,79] as well as the SIGN Checklist, as summarized in Figure 1, to rate the quality of these clinical trials. The additional studies that have the most potential relevance to chiropractic practice, which are of reasonably good scientific quality, are the following (SIGN/Oxford ratings are presented in parentheses): osteopathic manipulation (1 small pilot RCT [1+/2b]), massage therapy (2 small RCTs [2+/2b]), laser therapy (1 small RCT [1+/2b]), spa water therapy/balneotherapy (1 moderate-sized RCT [(1+/1b]), and ultrasound and interferential current (1 small RCT [1+/2b]).

The results of our search for clinical trials from 2000 to 2006 basically confirm the previously summarized findings and conclusions of the Cochrane systematic reviews and meta-analyses of FMS literature, as well as the most recently published practice guidelines on the clinical management of FMS. We concluded that the 25 additional studies we found and rated would not substantially alter any of the recommendations made in any of the current published FMS practice guidelines, systematic reviews, or meta-analyses.

Search of the MANTIS and ICL Databases

Our combination of 2 search strategies of the MANTIS and ICL databases from 1990 to 2006 produced a total of 701 citations, most of which were found to be opinion papers, hypotheses, anecdotal reports, and other types of narrative publication. Thirty-eight studies did meet our liberal inclusion criteria of being at minimum a single-case report, case series, or other type of acceptable observational study. We accepted any published observational study, regardless of whether it was published in a peer- or non–peer-reviewed journal.

A total of 38 articles[80-117] were selected from the MANTIS and ICL databases using the keywords *fibromyalgia* and *fibromyalgia AND chiropractic*. These 38 articles are summarized in Table 3 and consist of the following types of studies: 17 clinical trials, 17 case reports and/or case studies, 2 case-control studies, and 2 survey-type studies.

Reference tracking was used to look for potential overlap of references from the MANTIS and ICL searches. Three of the studies found from our MANTIS and ICL searches were included in the most recent systematic review[19] of the FMS literature and FMS practice guideline[33] (Blunt et al,[80] Deluze et al,[88] and Abraham and Flechas[97]). Therefore, 35 articles were found that represented unique and separate contributions to the FMS literature. Expanded summaries of all these studies are listed in Table 4, along with their respective Oxford/SIGN ratings. Regarding chiropractic treatment of FMS, we found 1 additional RCT,[81] 1 case-series report,[115] and 1 single-case report.[114] The RCT describing chiropractic treatment of FMS was published in the World Federation of Chiropractic seventh biennial congress conference proceedings,[81] which consisted of a very scant description of the study and results. A hand search for a detailed full text peer-reviewed version of this study was attempted, but we could not find any full text peer-reviewed publication of this study.

Discussion

A consistent theme emerges from all of the systematic reviews, meta-analyses, and practice guidelines that we reviewed: there is no known cause or etiologic agent(s) responsible for the development of the symptom complex known as FMS. All treatment options are merely directed toward amelioration of the major symptoms of widespread pain and fatigue, and are not expected to cure the condition. Most systematic reviews have concluded that 3 basic therapies have the strongest and most established evidence base with respect to treatment of FMS:

1. Cognitive behavioral therapy and other relaxation methods.
2. Mild aerobic and general flexibility exercises.
3. Various low-dose antidepressant medications (tricyclics and SNRIs), with emerging evidence for anticonvulsants (gabapentin, pregabalin) and tramadol.

It is interesting to note that 2 of the 3 published meta-analyses were on the subject of antidepressant medications, which are not directly applicable to chiropractic practice. At first glance, this seems to contradict our search strategy to focus on nonpharmacologic FMS therapies. However, we decided to include these 2 medication meta-analyses in our review because the use of low-dose antidepressant medications is considered by all major guidelines to be 1 of the 3 most evidence-based treatments for FMS (see bullets above). Therefore, we thought it important to include these studies for completeness and to provide a brief synthesis of this literature for the reader's convenience.

We found that the 2005 APS guideline[33] provided the most comprehensive review of the literature and best evidence synthesis to date, which was inclusive of all the pertinent chiropractic and CAM literature. We strongly recommend that clinicians consult this guideline for the most current evidence synthesis and best practices document regarding the clinical management of FMS. After careful review of the additional studies we retrieved from searches of several standard databases, as well as MANTIS and ICL, we could not find any compelling new evidence that would substantially alter the recommendations presented in the

most current systematic reviews, meta-analyses, and practice guidelines.

Although we formally concluded our search of the FMS literature in June 2006, we did review the recently published guidelines by the European League Against Rheumatism (EULAR) in 2007 that gave evidence tables for the management of FMS.[118] The 2007 EULAR guidelines essentially recommend the same medications as those in the 2005 APS guidelines, with the addition of strong evidence for SNRIs, tramadol, gabapentin, and pregabalin. All of these medications were given the highest evidence rating by the EULAR panel. It is interesting to note the ratings of the nonpharmaceutical treatments recommended: medium evidence for heated pool treatments (balneotherapy), weak evidence for aerobic and strength exercises, weak evidence for relaxation and psychologic support, and poor evidence for CBT. These nonpharmaceutical ratings are somewhat contradictory to the APS ratings and evidence tables. The EULAR guidelines did not specifically provide any rating for spinal manipulation or chiropractic care.

It was very surprising to find such a paucity of chiropractic literature about the clinical management of FMS, considering that chiropractors frequently report that they treat FMS patients. We were only able to find 4 relevant chiropractic clinical studies regarding FMS treatment in the MANTIS and ICL databases, for a total of 2 small clinical trials,[80,81] 1 case series,[114] and 1 single-case report.[115] Only one of these chiropractic trials was of sufficient quality to be included in the APS guideline.[80] The other chiropractic trial[81] was published only in the form of an expanded abstract as preliminary findings in conference proceedings, and we could not find any full text version of these findings in the peer-reviewed or non–peer-reviewed literature.

The National Board of Chiropractic Examiners has gathered data about chiropractic practice in the United States through surveys performed in 1991, 1998, and 2003. The results have been collectively published in a series of 3 texts known as the *Job Analysis of Chiropractic*, with the most recent version published in 2005.[119] The 2005 Job Analysis of Chiropractic data revealed that 4 soft tissue conditions are reported by clinicians as "often" or "sometimes" seen in chiropractic practice: muscular strain/tear, tendinitis/tenosynovitis, myofascitis, and FMS.

Chiropractors report that they treat the first 3 conditions listed above "often" and without the need for medical co-management in about 75% to 80% of cases. In this regard, they act as the sole health care provider managing these cases. However, in the case of FMS, chiropractors report that they only see this condition "sometimes" and choose to co-manage this condition with another health care provider in about 55% to 64% of cases. These findings suggest that chiropractors feel very confident in their ability to manage muscle and tendon conditions, but much less confident in managing FMS by themselves as noted by the high rate of medical co-management.

The results of our literature synthesis were compiled into a summary of recommendations for the most evidence-based procedures for the clinical management of FMS as presented in Table 5. It is important to note that many of the therapies listed in our evidence ratings table are within the scope of chiropractic practice and show at least good to fair levels of evidence. However, the standard medical management of FMS still relies heavily on prescription medications, which are clearly outside the chiropractic scope of practice.

Yet the other 2 most evidence-based treatments for FMS, exercise and CBT, could be incorporated in most chiropractic practices. This requires an understanding of the importance of central sensitization as the key mechanism underlying the widespread allodynia found in FMS, and that patients need an active care approach to treatment that will incorporate both a mild exercise program with an empathetic bedside manner in which the chiropractor provides education, positive emotional support, and possible referral for group or individual psychologic counseling.

There is certainly a trend within the FMS literature to expand treatment and research efforts outside of the traditional allopathic model to include a number of CAM therapies that are within the scope of chiropractic practice. It would be desirable to see more chiropractic interest in developing high-quality experimental and observational research into this area. There is a great potential for future collaboration between chiropractic researchers and other professions to develop multidisciplinary approaches to the clinical management of FMS that involve CAM therapies under the umbrella of chiropractic care.

Conclusions

Most systematic reviews and guidelines all recommend 3 interventions as having the strongest evidence support: (1) low-dose antidepressant medications, (2) light aerobic exercise, and (3) CBT. Moderate evidence supports the use of massage, muscle strength training, acupuncture, and spa therapy (balneotherapy). Limited evidence supports spinal manipulation; movement/body awareness; and vitamins, herbs, and dietary modifications. Presently, there is no single therapy or intervention that can be considered a cure for FMS. Combinations of therapies appear to be most helpful, and future research seems to be looking toward strategies by which to find subgroups of FMS patients who might respond better to certain therapies. Our project stopped searching the literature as of June 2006, and newer evidence has surfaced since that time. The most recent studies would include the EULAR evidence-based recommendations for the management of FMS[118] and a recently published narrative review of the mechanisms and pathophysiology of fibromyalgia.[120] These publications continue to provide evidence that FMS is not a peripheral disorder of the soft

tissues, but rather a disorder of aberrant pain processing and central sensitization.

In conclusion, we found that there is an emerging literature regarding a number of CAM therapies for the conservative treatment of FMS syndrome, including spinal manipulation. There is a dearth of experimental chiropractic literature on the management of soft tissue conditions and FMS. It is recommended that the chiropractic research community take notice of this information gap and take steps to design high-quality experimental research studies to help close this information gap. Such research by the chiropractic profession could be an excellent opportunity to build bridges and collaborate with other health care professions and the scientific community.

Practical Applications

- Strong evidence supports aerobic exercise and cognitive behavioral therapy.
- Moderate evidence supports massage, muscle strength training, acupuncture, and spa therapy (balneotherapy).
- Limited evidence supports spinal manipulation; movement/body awareness; and vitamins, herbs, and dietary modification.

Acknowledgment

The primary author and all coauthors are members of the soft tissue committee of the CCGPP commissioned to do this comprehensive review. None of the authors has received any financial support from the CCGPP for this study, and no competing financial interests are declared. The authors thank Tom Hyde who assisted us with review of full text manuscripts.

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