LITERATURE SYNTHESIS:
CHIROPRACTIC MANAGEMENT OF SOFT TISSUE CONDITIONS

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Overview of topics included in this Soft Tissue Chapter

The soft tissue committee of the CCGPP was asked to find those soft tissue conditions most commonly treated by chiropractors, and perform a comprehensive review of the literature related those conditions. The National Board of Chiropractic Examiners (NBCE) has gathered data about chiropractic practice in the U.S. through surveys performed in 1991, 1998, and 2003. The results have been collectively published in a series of three texts known as the Job Analysis of Chiropractic, the most recent version published in 2005.

The Job Analysis of Chiropractic data revealed that three muscular conditions are reported by clinicians as "often" seen in chiropractic practice (see below list) and that only one condition is "sometimes" seen, fibromyalgia syndrome. The three "often-seen conditions are:

- Muscular strain/tear
- Tendinitis/tenosynovitis
- Myofascitis

Chiropractors report that they treat the three conditions listed above, without the need for medical co-management, in about 75-80% of cases. In this regard, they act as the sole health care provider managing these cases. However, in the case of fibromyalgia syndrome, chiropractors report that they only see this condition "sometimes" and choose to co-manage this condition with another health care provider in about 64% of cases.

For the purposes of this soft tissue chapter, the three conditions listed above were collapsed into two categories of myofascial/muscular pain, and tendon pain. The rationale for this merging of categories was quite simple; a preliminary review of the online literature showed that the MESH terms "muscle" and "strain" did not bring up any unique citations that were not already found by using the keywords "tendinitis", "tendinopathy", "myofascial pain", "myofascitis", or "trigger point". It appeared that it would be redundant to perform a separate literature search on muscle tears/strains. Also, the Upper and Lower Extremity teams had much overlap with respect to the chiropractic management and treatment of muscle injuries in their respective literature searches.

Therefore, the Soft Tissue team performed comprehensive literature reviews on three general categories of soft tissue conditions: (1) Myofascial pain, (2) Fibromyalgia syndrome, and (3) Tendon pain. Each of these three categories required a separate and distinct approach to online literature searching, retrieval, and evidence ratings, which are described in the next section.

General Overview of Literature Search Procedures

The general approach to literature searching involved electronic, online database searches were performed by several of the soft tissue team members in each of the 3 previously noted categories as follows:

- Howard Vernon: Myofascial Pain literature
- Michael Schneider: Fibromyalgia literature
- Mark Pfefer: Tendon Pain literature

The keyword and search strategies for each of these three categories are described below:

1. Myofascial pain literature

The online search strategy for myofascial pain syndrome (MPS) was divided into three sections of relevance to chiropractic practice: Diagnosis and Assessment, Manual Treatments, and Other Conservative (non-manual) Treatments.

The inclusion criteria for the Diagnosis and Assessment search were: trigger points, myofascial pain syndrome (MESH headings: Musculoskeletal Manipulations, Myofascial pain syndrome (not exploded to Temporomandibular joint)); diagnosis, "Reproducibility of Results" [Mesh], "Validation Studies" [Mesh], 1965 to 2007; English, German; human studies. This search was conducted in Medline, Cinahl, ICL, Mantis, Embase, National Guidelines Clearinghouse, DARE and TRIP databases.

The inclusion criteria for the Manual Treatment search were: manual therapies, trigger points, myofascial pain syndrome (MESH headings: Musculoskeletal Manipulations, Myofascial pain syndrome (not exploded to Temperomandibular joint)); 1965 to 2007; English, German; human studies. This search was conducted in Medline, Cinahl, ICL, Mantis, Embase, the National Guidelines Clearinghouse, DARE and TRIP databases. After the primary search was conducted, a number of secondary searches were conducted based upon "related links", especially emphasizing systematic or clinical reviews, randomized clinical trials, chiropractic treatments (vs Musculoskeletal Manipulations only) as well as searches of additional works by the authors identified in the primary search.

The search strategy for Other Conservative (non-manual) Treatments was essentially the same as that for the above noted Manual Treatment search, utilizing the same databases. However, the inclusion criteria for this new search were: conservative therapies, laser, acupuncture, ultrasound, electro-therapy, naturopathy, trigger points, myofascial pain syndrome. Finally, citation reviews were conducted manually to identify any additional suitable studies for all three of these searches.

2. Fibromyalgia syndrome literature

The fibromyalgia syndrome (FMS) literature was searched for key systematic reviews of the literature by starting with a review of the Cochrane Database of Systematic Reviews (1996-2005) and for existing clinical guidelines by searching the National Guidelines Clearinghouse (NGC). The inclusion criteria for searching both of these databases were the keywords of "fibromyalgia", "fibrositis", and/or "fibromyalgia syndrome".

After reviewing these systematic reviews and practice guidelines, it was found that the most current FMS literature included in these studies was performed through the year 2002. Therefore, we manually performed additional searches with the same keywords and inclusion criteria of the following electronic databases for the years 2000-2006, limited to clinical trials: Medline, PubMed, CINAHL, AMED, EMBASE, DARE and TRIP. The year 2000 was chosen as a starting point for this search rather than 2002, in order to create some overlap and not miss any important citations.

In order to be complete, a separate search was conducted of the MANTIS and ICL databases which include an extensive listing of all the peer-reviewed and non-peer reviewed chiropractic journals and publications. These two databases were searched using the keywords "fibromyalgia", "fibrositis", and/or "fibromyalgia syndrome" without any restrictions on the type of article or journal of publication (peer reviewed or non-peer reviewed).

3. Tendon pain literature

The tendon pain literature review has not been completed at the time of this preliminary release (March 1, 2008) of the soft tissue chapter. More details about the search strategy and literature review will be posted with the final version of this chapter. Also, the upper and lower extremity chapters of the CCGPP best practices document may contain some overlapping information regarding the chiropractic management of tendon conditions in the extremities.

Table 1: List of Diagnosis Codes

Table 1 below is a compilation of the most commonly reported ICD9 codes utilized by chiropractors when submitting claims for the treatment of various soft tissue conditions. Please note that although myofascial pain syndrome (MPS) and fibromyalgia syndrome (FMS) are the two most commonly treated conditions by chiropractors, no specific diagnosis codes exist for either of these two conditions. The non-specific code 729.1 is frequently used to report both MPS and FMS. This can be very confusing, because MPS and FMS are considered two separate and distinct disorders with different treatment approaches. It is the opinion of this committee that the present ICD coding choices are inadequate with respect to these two diagnostic entities, and should be amended to include new codes for both MPS and FMS.

Table 1: Applicable ICD9-CM codes commonly reported for soft tissue conditions managed and treated by chiropractors.

Code	Official ICD9 Name
726.1	Rotator cuff syndrome of shoulder and allied disorders
726.12	Bicipital tenosynovitis
726.31	Medial epicondylitis
726.32	Lateral epicondylitis
726.33	Olecranon bursitis
726.90	Enthesopathy of specified site
727.3	Other bursitis
726.60	Enthesopathy of knee, unspecified
726.64	Patellar tendinitis
726.70	Enthesopathy of ankle/tarsus, unspecified
726.72	Tibialis tendinitis
726.8	Other peripeheral enthesopathies
729.1	Myalgia and myositis, unspecified [fibromyalgia syndrome]
729.4	Fasciitis, unspecified
840.4	Rotator cuff strain
840.3	Infraspinatus strain
840.5	Subscapularis strain
840.6	Supraspinatus strain
841.0	Unspecified strain elbow/forearm
842.00	Sprain/strain wrist and hand, unspecified site
844.9	Sprain/strain knee and leg, unspecified site

Rating Table for Myofascial Pain Syndrome and Fibromyalgia Syndrome

Table 2: Summary of Recommendations for Myofascial Pain and Fibromyalgia Syndrome

Topic	Conclusion and Strength of Evidence Rating	Page(s)
Myofascial Pain Syndrome (MPS)		
Evaluation	**RATING A**: **Pressure Algometry** There is strong evidence that pressure algometry has high reliability and validity in the assessment of the intensity of myofascial trigger points (MTrPs). **RATING B**: **Manual palpation** There is moderately strong evidence, that manual palpation has acceptably high reliability and validity in the assessment of the location and intensity of MTrPs.	**16**
Manipulation/ Mobilization	**RATING B: Short-term relief** There is moderately strong evidence to support the use of some manual therapies (manipulation, ischemic pressure) in providing immediate relief of pain at MTrPs. **RATING C – Long-term relief** There is limited evidence to support the use of some manual therapies in providing long-term relief of pain at MTrPs.	**26**
Conservative Adjunctive Therapies	**RATING A: Laser therapies** There is strong evidence that laser therapy (various types of lasers) is effective in the treatment of MTrPs and myofascial pain syndrome (MPS). **RATING B: TENS, Magnets & Acupuncture** There is moderately strong evidence that TENS is effective in the short-term relief of pain at MTrPs. There is moderately strong evidence that magnet therapy is effective in the relief of pain at MTrPs and in MPS. There is moderately strong evidence that a course of deep acupuncture to MTrPs is effective in the treatment of MTrPs and MPS for up to 3 months. **RATING C: Electrotherapies, Ultrasound** There is limited evidence for the effectiveness of Electrical Muscle Stimulation, High Voltage Galvanic Stimulation, Interferential Current and Frequency Modulated Neural Stimulation in the treatment of MTrPs and MPS. There is conflicting evidence that Ultrasound is no more effective than placebo or is somewhat more effective than other therapies in the treatment of MTrPs and MPS.	**33**
Fibromyalgia Syndrome (FMS)^^		
Evaluation	**RATING A: Pressure Algometry** There is strong evidence that pressure algometry has high reliability and validity in the assessment of the Tender Points (TePs) found in fibromyalgia syndrome. **RATING A: Fibromyalgia Impact Questionnaire (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 one systematic review that massage is helpful in improving sleep and reducing anxiety in chronic pain. **RATING C: Manipulation**. There is limited evidence consisting of one moderate sized and one small pilot chiropractic clinical trial that manipulation may relieve pain in FMS. The literature also contains two chiropractic and two osteopathic manipulation case reports/series.	
Exercise	**RATING A: Aerobic exercise**. There is strong evidence from multiple RCTs / systematic reviews that mild aerobic exercise in 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 three small RCTs that gentle body awareness exercise methods such as T'ai 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 beneficial effect of these therapies for FMS.	
Cognitive Behavioral Therapy	**RATING A: Cognitive Behavioral Therapy (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**	**RATING A:** The medications with the strongest evidence of effectiveness for FMS are the tricyclics (amitriptyline and cyclobenzaprine) used alone, or in combination with selective serotonin reuptake inhibitors (SSRIs). **RATING B:** Moderately strong evidence exists for SSRIs (used alone) and tramadol for the treatment of widespread pain in FMS. **RATING C:** Preliminary clinical trials show promising effectiveness for pain reduction with anticonvulsants, opioids, and serotonin- norepinephrine reuptake inhibitors (SNRIs). **RATING D:** The following medications have been demonstrated to be ineffective (used alone) for the pain of FMS: NSAIDs, steroids, benzodiazapines, guaifenesin.	
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**	**RATING B: Acupuncture.** There is one systematic review and one RCT that show moderate reduction of pain in FMS patients with acupuncture treatment.	

^^Note on FMS ratings: A large portion of these FMS ratings was adapted from the American Pain Society's 2005 guideline: Buckhardt, C. et al. Guideline for the management of fibromyalgia syndrome pain in adults and children, in clinical practice. Guideline number 4, American Pain Society. 2005: Glenview, IL. Our committee reviewed the complete APS guideline and found it to be very comprehensive with respect to its systematic review of the FMS literature, and inclusion of all the chiropractic RCTs on FMS. This APS rated highly on the AGREE protocol for rating of practice guidelines, and our committee considers this document to be the most comprehensive and generalizable FMS guideline published as of the date of completion of our FMS literature review (September 2006).

**Note of medications and acupuncture: Although prescription medications are outside the scope of chiropractic, their evidence ratings as determined. Chiropractors are likely to see many FMS patients who are taking these medications, many of which are inappropriately prescribed by primary care physicians and rheumatologist who are not conversant with the current literature. This information may serve a valuable role in the inter-professional dialogue between chiropractors and other medical physicians about the evidence basis for many commonly prescribed medications for FMS. The evidence rating for acupuncture is included in this table because some jurisdictions in North America permit the use of various types of acupuncture within the chiropractic scope of practice.

Definitions for evidence ratings

GRADE A:

Supported by good evidence from relevant studies. Must be included in evidence tables and as a reference(s) for best practices.

Explanation

- The evidence consists of results from studies based on appropriate research designs of sufficient strength to answer the questions addressed.
- The results are both clinically important and consistent with minor exceptions at most.
- The 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.

Examples

- Supporting evidence may consist of a systematic review of randomized controlled trials (RCT's) with comparable methodology and consistent results or the preponderance of evidence from several relevant RCT's with consistent results.
- For diagnostic tests - a systematic review of studies meeting standards of reporting diagnostic accuracy; or at least 1 study meeting standards of diagnostic accuracy, including cohort studies with good reference standards.
- For the question of natural history of a disorder, in the absence of evidence to the contrary, the evidence might be results from a single well done prospective cohort study.

GRADE B:

Supported by fair evidence from relevant studies. Must be included in evidence tables and as reference(s) for best practices.

Explanation

- The evidence consists of results from studies based on appropriate research designs of sufficient strength to answer the questions addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies, or because of minor doubts about generalizability, bias, and research design flaws, or adequacy of sample size.
- Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with major exceptions at most.

Examples

- Supporting evidence might consist of a several RCT's with differing results although overall the results support the conclusion.
- The evidence might also be the result of a single randomized controlled trial with a clinically significant conclusion but doubtful generalizability.
- Alternatively, the evidence might come from a systematic review of RCT's with similar methodologies but differing results.

- For diagnostic tests, exploratory cohort studies with good reference standards, or instrumentation studies of reliability and validity.
- For a question of harm or adverse events, the evidence might consist of 2 or more independent case control studies with similar conclusions and minimal bias and research design flaws.

GRADE C:

Supported by limited evidence from studies or reviews. Do not include in evidence tables but as reference(s) for best practices.

Explanation

- The evidence consists of results from studies of appropriate design for answering the question addressed, but there is substantial uncertainty attached to the conclusions because of inconsistencies among the results from different studies, or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size.
- Alternatively, the evidence consists solely of results from a limited number of studies or because of weak design for answering the question addressed.

Examples

- For a question of treatment efficacy or effectiveness, the evidence might consist of systematic or narrative reviews or RCT's with contradictory results and/or serious methodological flaws.
- From relevant cohort, case control, ecological studies, and outcomes research.
- Alternately, the evidence might consist of individual case series.
- For diagnostic studies, the evidence might consist of non-consecutive studies without appropriate reference standards and case control studies unconfirmed by other studies.
- For a question or harm, the evidence might consist of results from a single case control study, or case series.

GRADE I:

No recommendation can be made because of insufficient or non-relevant evidence. It should not be included in evidence tables or as reference(s) for best practices.

Explanation

- There is no evidence that directly pertains to the addressed question because either the studies have not been performed or published, or are non-relevant.

LITERATURE SYNTHESIS: MYOFASCIAL PAIN SYNDROME (MPS) and MYOFASCIAL TRIGGER POINTS (MTrPs)

The literature search and synthesis of the relevant articles was divided into four sections of relevance to chiropractic practice: (1) Introduction and Background, (2) Diagnosis and Assessment, (3) Manual Treatments and (4) Other Conservative Treatments.

1. INTRODUCTION

Background

The seminal work in originating the concepts related to myofascial pain and trigger points is from Janet Travell who, with S. Rinzler, wrote about "The myofascial genesis of pain" [1952]. In 1983, Travell and David Simons published their famous textbook "Myofascial Pain and Dysfunction: The Trigger Point Manual" [Baltimore MD: Williams and Wilkins, 1983]. They first identified the importance of myofascial pain and its localization in what they termed "trigger points" and provided the first classification of diagnostic criteria for TrP's. They also provided detailed maps of the pain referral patterns from TrPs in all the muscles of the body. They continued to publish trigger point manuals and other materials in 1990, 1992 and 1999.

As reviewed briefly below and in Section 3, a number of other authors contributed to the growth of this field in the period from 1980-2000, including Yunus, Wolfe, Smythe, Graff-Radford, Reeves, Gerwin, Hong and Harden.

Definitions:

The definition and characterization of myofascial trigger poins (MTrPs) and the myofascial pain syndrome (MPS) have changed remarkably little since they were first formulated by Travell and Simons [1983]. Hong [2004; all quotes from pg. 38] distinguishes two modes of MTrPs: (1) latent trigger points as: "tender, but not painful spontaneously" and located in "almost every normal skeletal muscle", and (2) active trigger points as: "painful spontaneously or in response to movement" and "secondary to a certain pathological lesion". These "lesions" are described as the primary cause of the activation of latent MTrP's, and are described as one or more of:

- radiculopathy
- joint sprain, synovitis or arthritis
- tendon lesion or enthesopathy
- facet joint lesion

Hong emphasizes that a critical aspect of the active MTrP is its capacity to provoke referred pain, particularly into patterns that have been described and validated by prior studies. Hong defines MPS as "a pain phenomenon due to activation of latent TrPs". The following summary definition of MPS is taken from the Beth Israel Medical Center, Dept. of Pain Medicine and Palliative Care (MedlinePlus):

"Myofascial pain syndrome is a chronic local or regional musculoskeletal pain disorder that may involve either a single muscle or a muscle group. The pain may be of a burning, stabbing, aching or nagging quality. Importantly, where the patient experiences the pain may not be where the myofascial pain generator is located. This is known as referred pain. The pathophysiology of myofascial pain remains somewhat of a mystery due to limited clinical research; however, based on case reports and medical observation, investigators think it may develop from a muscle lesion or excessive strain on a particular muscle or muscle group, ligament or tendon. It is thought that the lesion or the strain

prompts the development of a "trigger point" that, in turn, causes pain."
In addition to the local or regional pain, people with myofascial pain syndrome also can suffer from depression, fatigue and behavioral disturbances, as with all chronic pain conditions. Recognition of this syndrome is difficult and requires the physician to have a precise understanding of the body's anatomy. Trigger points can be identified by pain produced upon digital palpation (applying pressure with one to three fingers and the thumb). In diagnosing myofascial pain syndrome, four types of trigger points can be distinguished:

active trigger point -- an area of exquisite tenderness that is usually located in a skeletal muscle and is associated with local or regional pain;

latent trigger point -- a dormant area that can potentially behave like an active trigger point;

secondary trigger point -- a hyperirritable spot in a muscle that becomes active as a result of a trigger point and muscular overload in another muscle;

satellite myofascial point -- a hyperirritable spot in a muscle that becomes active because the muscle is located within the region of another trigger point.

Chiropractic history:
Interest in myofascial tenderness extends throughout the history of chiropractic. It might be said that local paraspinal tenderness, as part of the manifestations of the "subluxation", was a central feature of chiropractic thinking from its inception. Arguably, the work of Ray Nimmo represents the earliest and perhaps still most established thinking on this topic amongst chiropractors. Cohen and Gibbons describe his work as "a conceptual leap from moving bones to working with muscles that move bones". Schneider has provided a collection and review of all of Nimmo's works [1992, 2001]. Nimmo's explanations in the 1950's of the pathophyiology of trigger points are still regarded as accurate and highly sophisticated.

Other chiropractic authors who have written on this topic include: Schneider [1994, 1995], Perle [1989], Hains [2002a, 2002b], and Hammer [2007], whose seminal textbook, Hammer W. Functional Soft Tissue Examination & Treatment by Manual Methods, 3rd Ed. Jones & Bartlett, 2007, is now in its third printing. There are also numerous case reports and technical reports relating to various soft tissue techniques in chiropractic such as Graston technique, Myofascial Release Technique, and Active Release Technique. In this field, chiropractic is generally regarded as one of the complementary and alternative medical (CAM) therapies. CAM therapies are quite commonly used in the treatment of myofascial pain and trigger points. [Harris RE, Clauw DJ; 2002], and there is considerable overlap between chiropractic approaches and CAM therapies in this field.

Table 3: **Myofascial Pain Literature Review: Summary of all studies found for MPS diagnosis and assessment, manual and non-manual treatment methods.**

Study Type	Oxford Level	Number of studies
Systematic Reviews	1a	2
Sytematic Review Protocols		1
Practice Guidelines	1a	2
RCTs	1b	11
RCTs	2b	3
Case Series	4	3
Case Reports	5	17

Clinical Reviews (selected: 2000-2005)	5	6

2. DIAGNOSIS and ASSESSMENT

Literature Search Strategy

The search strategy for this section was limited to studies related to the diagnosis of MPS and TrPs. The inclusion criteria for this search were: trigger points, myofascial pain syndrome (MESH headings: Musculoskeletal Manipulations, Myofascial pain syndrome (not exploded to Temporomandibular joint)); diagnosis, "Reproducibility of Results" [Mesh], "Validation Studies" [Mesh], 1965 to 2007; English, German; human studies. This search was conducted in Medline, Cinahl, ICL, Mantis, Embase, National Guidelines Clearinghouse, DARE and TRIP databases. Citation reviews were conducted manually to identify any additional suitable studies.

The following exclusion criteria were applied to the results of the searches: studies on the prevalence of these conditions, the mechanisms underlying these conditions and on the validity of the concepts involved in these conditions (such as TrP counts/severity in patient groups vs controls) were not included; the diagnostic procedures systematically reviewed here were limited to manual trigger point assessment and pressure algometry. These procedures could involve any of the following parameters: location of TrPs, elicitation of intensity ratings, presence of referred pain and/or secondary signs. Finally, studies investigating the use of these procedures in any of the specifically defined body / complaint regions employed in the CCGPP (such as back pain, neck pain, etc.) were not included in this Chapter.

Literature search results: Systematic Reviews

Tough et al. [2007] reviewed the criteria used to diagnose TrPs in all published studies up to 2000. Ninety-three (93) studies were included in this review. The four most common criteria found in this group of studies were: (1) tender spot in the taut band of skeletal muscle, (2) patient pain recognition, (3) predicted pain referral pattern, and, (4) local twitch response. Criteria # 1 and #3 were employed in over half of these studies. Tough et al. called for greater precision and consistency in the criteria used by investigators for diagnosing TrPs.

Fernandez de las Penas et al. [2006] summarized the findings of 4 studies [SIGN rating = +] from 1992-1997 (Nice et al, 1992; Njoo et al., 1994; Wolfe et al. 1992; Gerwin et al., 1997) with respect to Kappa values for inter-rater reliability of the following criteria for TrP diagnosis (mean values are listed here):

- palpable taut band = 0.54
- tender spot in the taut band = 0.70
- local twitch response = 0.23
- referred pain pattern = 0.47
- jump sign = 0.70
- pain recognition = 0.59

A Cochrane Collaboration Protocol entitled “Non-invasive physical treatments of myofascial pain”, Kilkenny et al. [2006] was identified. This protocol has reviewed the extant literature on the epidemiology and characteristics of MPS and TrPs as well as the diagnostic procedures typically employed in clinical practice. The following studies pertaining to diagnostic procedures additional to those in Fernandez de las Penas et al. were included:

- Lew et al, 1997
- Sciotti et al, 2001
- Testa et al, 2003 (no original data)

Lew et al examined 58 asymptomatic subjects for TrPs in the upper trapezius area. Two different examiners manually palpated for taut bands with or without local or referred pain. Concordance between examiners was low: 10% for non-referring TrPs and 21% for referring TrPs.

Sciotti et al used four examiners to investigate the reliability of locating latent TrPs in 20 subjects. Using a 3-D camera for anatomic localization as well as patient feedback and algometry, they obtained reliability coefficients ranging from 0.83-0.92.

Literature search results: Practice Guidelines / National Consensus Documents
Only two practice guidelines were found during our literature search.

One guideline was published by the Institute for Clinical Systems Improvement (ICSI) entitled "Assessment and management of chronic pain". Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 which states the following:

"Myofascial pain is regional muscle soft tissue pain commonly involving the neck, shoulders, arms, low back, hips, and lower extremities. Trigger points refer pain. Myofascial pain is common in patients seen in pain clinics. Etiology, diagnosis, and management are controversial. Palpation for areas of spasm or tenderness and for identification of trigger points is useful".

Harden et al. [2000] surveyed American Pain society members obtaining 403 / 1663 responses (25%). More than 80% of respondents agreed on the following diagnostic criteria for MPS: regional location, presence of trigger points, normal neurologic examination, reduced pain on local anaesthetic treatment, taut bands, tender points, palpable nodules, muscle ropiness, decreased range of motion, pain exacerbated by stress, pain described as "dull", "achy" or "deep". The following signs were not endorsed by the majority of respondents: sensory or reflex abnormalities, scar tissue and "most test results".

Literature search results: Experimental Studies (clinical trials)
Additional clinical studies not included in the previously cited systematic reviews are briefly summarized below:

- Reeves et al. [1986] reported on two separate reliability studies. The first reported "high reliability" between and within examiners for pressure algometry ratings over tender spots. The second showed "significant between-examiner reliability" in locating tender points.

- Viikari-Juntura [1987] reported "good reliability" in "sensitivity tests for touch and pain" in the soft tissues of neck upon ratings by two independent examiners on neck pain patients.

- Levoska et al. [1993] found that the repeatability of manual examination for tender points was "poor" (reliability coefficients ranged from 0.15 to 0.62), but that the intra- and inter-examiner reliability of dolorimetry measurement of "found" points was high, with repeatability coefficients ranging from 0.65 to 0.87.

- Delaney and McKee [1993] studied the intra- and inter-rater reliability of pressure algometry over tender points in the trapezius muscle. They reported ICC values ranging from 0.80 to 0.92 for all tests. They concluded that the pressure threshold meter is highly reliable between and within examiners.

- Boline et al. [1993] studied manual palpation for spinal osseous and soft tissue tenderness in low back pain patients. Kappa coefficients for osseous pain ranged from 0.48 -0.90 and for soft tissue pain: 0.40 – 0.79. These were judged to be adequately high for clinical usage.

- Hubka and Phelan [1994] investigated the inter-examiner reliability of manual palpation for soft tissue pain in the neck. They obtained 76% agreement with the site of pain (Kappa – 0.68, $p < .001$).

- Tunks et al. [1995] studied both digital palpation and algometry in four clinical groups over 19 paired tender points and 8 paired control points. Three examiners independently evaluated these points. 75% agreement was obtained for the digital palpation. The inter-rater and test-re-test reliability scores for algometry were rated as "good".

- Nilsson [1995] reported that the use of the Total Tenderness Score system resulted in high inter- (Spearman's Rho = 0.88) and intra-examiner (Spearman's Rho = 0.85) reliability in assessing tenderness in the neck in neck pain patients.

- Bendtsen et al. [1996] studied the use of "pressure controlled palpation" with a "palpometer" (pressure sensitive film) in a study of TrPs in headache subjects. Tenderness was rated on a 4-point scale. Testers using the conventional manual technique differed significantly in their tenderness scores. Testers using the palpometer did not differ significantly in their ratings. TrP intensity ratings were shown to be consistent only when the palpometer was used.

- Al-Shenquiti et al. [1997] evaluated 58 patients with rotator cuff tendonitis. Intra-examiner reliability over 3 days was tested for (Kappa value): taut band (1.0), spot tenderness (1.0), jump sign (1.0), pain recognition (1.0), referred pain (0.79-0.88) and local twitch response (0.75-0.1).

- Pontinen PJ. [1998] Reliability, validity and reproducibility of algometry in the the diagnosis of active and latent tender spots and trigger points. J Musculoskel Pain, 1998;6:61-71. A review of the studies on pressure algometry concluding that it "showed good intra-rater and inter-rater correlation and reliability" in all age groups.

- Hsieh et al. [2000] studied the reliability of 5 different palpators for lumbar and leg TrPs in 26 back pain subjects and 26 controls. Palpators were considered as expert, trained or non-trained. Kappa values for taut bands, local twitch responses and referred pain ranged across examiners and groups from -0.01 to 0.43. They concluded that, among non-expert practitioners, TrP palpation was not reliable.

- Conti et al. [2002] studied the palpatory findings of 4 examiners on 16 TMD patients and 16 controls. Examiners palpated for TrP tenderness on a 0-3 scale of intensity. All concordance scores (Kendall's concordance test) were considered fair to excellent. Palpation of the sternocleidomastoid muscle showed the highest concordance at 0.84, while the lowest concordance was obtained for the masseter muscle at 0.56.

- Christensen et al. [2003] investigated the intra- and inter-observer reliability of manual palpation of anterior chest wall tenderness. They found inter-observer reliability coefficients of 0.22 – 0.31. They found intra-observer coefficients for day-to-day re-testing = 0.21 to 0.28 and for hourly re-testing = 0.44 to 0.49. They concluded that there was an important lack of consistency in this assessment between and within observers.

- Ylinen et al. [2007] found high group reliability coefficients in serial algometry in neck pain patients (ICC 0.78 to 0.93). However, individual coefficients of variation ranged from 10-22%. They concluded that algometry was sufficiently reliable for research purposes; however, they cautioned its use in individual clinical circumstances.

Literature search results: Clinical Reviews:
Although the following clinical reviews of the myofascial pain literature were not rated for quality and are not formally part of the evidence tables, selected clinical reviews will be highlighted here for their value in elucidating the nature of myofascial pain syndrome in a clinical context.

The original texts of Travell and Simons [1983] outline the initial protocols for identifying TrPs, including manual palpation for local tenderness, taut bands, twitch responses and referred pain and autonomic findings. Referred pain patterns were described and mapped for every muscular TrP.

Skootsky et al. [1989] reviewed 54 of 172 cases in an internal medicine practice who qualified for the diagnosis of myofascial pain. They opined that this condition was much more prevalent in internal medicine settings than was previously thought and they urged the use of standard diagnostic and therapeutic approaches to TrPs.

Yunus et al. [1988] provided one of the earliest descriptions of the differences in these two conditions and set out the criteria for TrP diagnosis.

Hans Krause is recognized as an important figure in the early development of this field. Along with Fischer, his "Diagnosis and treatment of myofascial pain" [1991] is considered a classic in the field.

Andrew Fischer can be considered the "father" of quantitative TrP testing, having introduced the pressure pain threshold meter into the field. Smythe [1986] had employed a similar device in his earlier work, but his device did not become as popularly used as Fischer's. Fischer's 1990 paper, "Application of pressure algometry in manual medicine" [1990], was a comprehensive review of the current protocols, most of which have, interestingly, remained in place to the present. He highlighted the use of thermography to identify "hot spots" which would then undergo manual palpation as well as algometry. He referred to the work of Reeves et al. in regard to the acceptable reliability of these procedures.

Fischer's other published work [1987,1998] included studies of normal and abnormal PPT measurements as well as the identification of a "clinically meaningful difference" either side-to-side

for the same TrP or over serial measurements on the same TrP. Typically, a 2 kg/sq.cm difference was considered clinically important. This had implications for the identification of clinically important TrPs as well as for the determination of clinically important change at a TrP in response to an intervention or even the natural history over time. Simons has published prolifically in this area. [1993, 2000]

Schneider [1995] reviewed and critiqued the extant literature on diagnostic classification and criteria of TrPs, and called for more clarity in the differential diagnosis of the myofascial trigger points (TrPs) found in myofascial pain, from the tender points (TePs) found in fibromyalgia syndrome.

Baldry's review [2002] provides a fascinating historical review of the concept of TrPs through the work of Lewis and Kellgren, and Sir William Osler. He reiterates the utility of the standard protocol of manual palpation. Cummings and Baldry [2007] summarized the clinical features and the reliability of the clinical procedures commonly used.

Wheeler AH. [2004] provides a comprehensive review of the whole field.

Gerwin has published prolifically in this area. His 2005 publication, "Differential diagnosis of trigger points". J Musculoskel Pain 2005;12:23-28 specifically focuses on the need to include a variety of etiologies in the differential diagnosis of TrPs.

McPartland JM [2002] reviews the standard approach to diagnosis of TrPs from an osteopathic perspective.

Graff-Radford [2004] provides a comprehensive review of the field.

Yap [2007] emphasized that TrPs are often underdiagnosed. He emphasized history taking as a means to identify perpetuating factors. Physical examination was endorsed as a means to identify the following components of myofascial pain: taut bands, trigger points, tender spots, sensitised spinal segments.

<u>Literature search results: Thermography and Ultrasonography</u>
Thermography was a popular procedure in the late 1980's and early 1990's, but has fallen out of favour in the recent decade. The following studies are listed for historical interest and comprehensiveness.

Diakow P. Thermographic imaging of myofascial trigger points. J Manip Physiol Ther. 1988.11:114-7. This report presented two cases of patients suffering with myofascial pain syndrome in which hot spots did correlate with TrPs.

Swerdlow B, Dieter JN. An evaluation of the sensitivity and specificity of medical thermography for the documentation of myofascial trigger points. Pain. 1992. 48:205-213. This study found no evidence that thermographic "hot spots" directly correlated with trigger points.

Diakow PR. Differentiation of active and latent trigger points by thermography. J Manip Physiol Ther 1992.15: 439-441.A retrospective file review was conducted identifying 65 cases of motor vehicle accident-injured patients. All patients had received thermographic evaluations in two modes: increased thermal emission over the TrP only vs increased thermal emission over the pain referral area.

Moderate agreement (Kappa – 0.44) was obtained between these modes. When areas of spinal segmental dysfunction were removed from the analysis, Kappa for agreement rose to 0.54 and the sensitivity and specificity values also rose.

Kruse RA, Christiansen JA. Thermographic imaging of myofascial trigger points: a follow-up study. Arch Phys Med Rehabil. 1992. 73:819-823. Active trigger points in 11 subjects with TrPs showed distinct thermographic emission temperature reduction over the TrP and in the pain referral zone upon digital compression of the TrP. Control subjects did not demonstrate this phenomenon.

Ultrasonography for the diagnosis of TrPs appears to be a very recent development with very little empirical evidence yet available. Only one citation was identified: Sciotti VM, Dishman JD, Woodward SP, Mittak VL, Ford L. The use of diagnostic ultrasound imaging in the verification of trigger point diagnosis: a blinded study. J Chirop Educ. 2002.16:48. No results from this study were published, only an abstract of the study design.

Tables 4 and 5: Myofascial pain literature review: Diagnosis and Assessment

Study Type	Oxford Rating	Number of studies retrieved
Systematic reviews	3a	1
Literature reviews	3a	1
Review protocols		1
Practice Guidelines	1a	2
Experimental Studies	2c	21
Clinical Reviews: 2000-2007	5	6

DIAGNOSTIC TEST	# Studies reporting adequate reliability (Kappa, Rho, etc > 0.40)	#Studies reporting poor reliability (<0.40)
Manual palpation	13	4
Algometry	7	0

3. MANUAL THERAPIES

Literature Search Strategy

The search strategy for this section of the Chapter was constrained by the need to identify only those studies of chiropractic treatments (manual therapy) which are not directed at clinical complaints associated with any of the specific body regions which have been designated as other Chapters in the CCGPP. In other words, no study was selected of the effect of a chiropractic treatment (manual therapy) specifically indicated for back pain, neck pain, upper limb pain (shoulder, elbow, wrist), lower limb pain (hip, knee, ankle and foot) of any kind (i.e., for any category of diagnosis). Only studies of chiropractic treatments for Myofascial Pain Syndrome (MPS) and trigger points (TrPs) were considered. Therefore, the inclusion criteria for this search were: manual therapies, trigger points, myofascial pain syndrome (MESH headings: Musculoskeletal Manipulations, Myofascial pain syndrome (not exploded to Temperomandibular joint)); 1965 to 2007; English, German; human

studies. This search was conducted in Medline, CINAHL, ICL, Mantis, Embase, National Guidelines Clearinghouse, DARE and TRIP databases.

After the primary search was conducted, a number of secondary searches were conducted based upon "related links", especially emphasizing systematic or clinical reviews, randomized clinical trials, chiropractic treatments (vs. Musculoskeletal Manipulations only) as well as searches of additional works by the authors identified in the primary search. Finally, citation reviews were conducted manually to identify any additional suitable studies. Selected publications were rated on the Oxford Rating Scale [2000] as well as the SIGN Checklist.

Literature search results: Systematic Reviews:
Two completed systematic review were identified; Fernandez de las Penas et al, 2005 and Rickards LD, 2006.

Fernandez de las Penas et al employed the following selection criteria for acceptable studies:

> "clinical or randomized controlled trials in which some form of manual therapy (strain/counterstrain, ischemic compression, transverse friction massage, spray and stretch, muscle energy technique) was used to treat (myofascial trigger points) MTrPs" [pg. 29].

Mobilization and manipulation were apparently not explicitly included. It should be noted that the criterion applied to the "clinical category" in this search was "MTrPs", although Myofascial Pain Syndrome (MPS) was referenced later in their review. No additional, more specific criteria related to clinical complaints in any of the body regions (i.e., back pain, neck pain, limb pain, etc) were employed. It would appear that this search strategy is consistent with the one required by this soft tissue chapter, as well as other chapters that deal with the chiropractic management of pain complaints specific to these body regions.

Fernandez de las Penas et al identified 7 acceptable trials, four of which obtained a sufficiently high quality score (>5 / 10 on the PEDro Scale).

- Gam et al. [1998] (PEDro score = 6/10)
- Jaeger and Reeves [1986] (2/10)
- Hanten et al. [2000] (3/10)
- Hong et al. [1993] (6/10)
- Hou et al. [2002] (5/10)
- Hanten et al. [1997] (5/10)
- Dardzinski et al. [2000] (1/10)

The interventions employed in these studies were (# studies):

- spray and stretch (2)
- soft tissue massage (2)
- ischemic compression (2)
- occipital release exercises (1)
- strain/counterstrain (1)
- myofascial release (1)

An important finding was:

> "Only 2 studies…test(ed) the specific efficacy (efficacy beyond placebo) of various manual therapies in the treatment of MPS (Gam et al., 1998 [massage] and Hanten et al., 1997 [occipital release]). These studies found no difference between interventions [pg. 30]".

Another important issue from this group of studies is the duration of treatment. Most of these studies (4) investigated only the immediate effects on pain and tenderness (Jaeger, 1986; Hanten et al., 1997; Hong et al., 1993; Hou et al., 2002). One study investigated the short-term treatment effects of ischemic compression vs exercises over five treatments (Hanten et al., 2000) while two investigated longer term effects (6 months) of a course of, in one case, massage added to ultrasound therapy [Gam et al., 1998] and, in the other case, strain/counterstrain in addition to exercises [Dardzinski et al., 2000]. In both of the latter studies of a course of therapy, the manual therapy employed (massage or strain/counterstrain) was included among other therapies, making it impossible to identify the distinct contribution of the manual therapy to the reported outcomes.

Fernandez de las Penas et al. conclude that there are very few randomized controlled studies of any type of manual therapy in the treatment of MTrP (MPS) and, as a result, "the hypothesis that manual therapies have specific efficacy beyond placebo in the management of MPS caused by MTrPs is neither supported or refuted by the research to date" [pg. 33]. They do acknowledge that there is some evidence for improvement in some groups within these trials, and that this warrants further research.

In Rickards' review [2006], the inclusion criteria included RCT's of a conservative (in this section: manual only) therapy for active TrPs, not latent TrPs, in which a patient-related pain outcome was used and in which an explicit diagnosis of TrP was made including at least local tenderness and a taut muscle band. Studies were rated on a 20-point scale; however, no cut-off score was used for inclusion. Rickards included the following studies:

- Chatchawan et al. [2005]
- Fernandez de las Penas et al. [2006]
- Hanten et al. [1997]
- Hou et al. [2002]
- Edwards and Knowles. [2003]

For the purposes of the present review, the following comments apply to this group of studies: (1) the Chatchawan et al study of massage therapies clearly identified the target group as chronic low back pain and should be included in the Chapter on Low Back Pain; (2) the Fernandez de las Penas et al study is included below; (3) the Hanten et al and Hou et al studies are included in the review by Fernandez de las Penas et al summarized above; and (4) the Edwards and Knowles' trial did not include a manual therapy (only active stretching and dry needling were investigated). Therefore, for manual therapies, Rickard's review does not add anything substantially new to the present review.

A Cochrane Collaboration Protocol entitled "Non-invasive physical treatments of myofascial pain" by Kilkenny et al (2006) was identified. This protocol currently contains no results. However, it was used as a source of additional references, particularly on published clinical trials and systematic reviews.

Literature search results: Practice Guidelines

Our search of the National Guidelines Clearinghouse identified the following two Practice Guidelines, which do not appear to be particularly useful to the chiropractic profession:

- The Institute for Clinical Systems Improvement (ICSI). Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005. This guideline states "No recommendation for physical (manual) therapies in the treatment of MPS or TrPs."

- The Work Loss Data Institute. Pain (chronic). Corpus Christi (TX): Work Loss Data Institute; 2006. The only relevant section of this reference states "Myofascial pain syndrome, physical therapy: 14-21 days"

Literature search results: Randomized Clinical Trials

The previously noted systematic review by Fernandez de las Penas covered a large amount of the myofascial pain literature, however we performed an additional search of the literature to look for any clinical trials that potentially were not included in that systematic review. A total of 14 RCTs were retrieved. Quality scores ranged widely for the 7 trials reviewed by Fernandez de las Penas et al.Ten (10) of fourteen (14) trials we identified involved only immediate changes in TrP or tender point ratings. Two other trials reported outcomes for short courses of treatments over 3-5 days (Greene et al., Hanten et al., 2000) while two others reported outcomes at 6 months (Gam et al., Dardzinski et al.).

3 RCTs studied the effect of spinal manipulation on local paraspinal muscular tenderness in the dorsal spine (Terret and Vernon, 1984), cervical spine (Vernon et al, 1990) and lumbo-pelvic area (Cote et al, 1994). All three studies investigated only the immediate effect of the interventions on local muscular pain thresholds; electrical stimulus in Terret and Vernon and pressure stimulus in Vernon et al and Cote et al. Immediate and statistically significant increases in pain thresholds were found for spinal manipulation as compared to mobilization in the cervical and dorsal paraspinal muscles, but not in the lumbo-pelvic soft tissues.

We identified one study by Vicenzino et al. (1996) who reported on the immediate effect of a cervical mobilization on pressure pain threshold of tender points on the lateral epicondyle in patients with "tennis elbow". Only the mobilization (described as "manipulation" in this study) resulted in statistically significant increases in lateral epicondyle pressure pain thresholds vs placebo and control conditions.

Greene et al (1990) investigated the effect of four different treatments given three times over three days on skin resistance levels. Subjects with thoracic TrPs were randomized to receive osteopathic manipulative treatment (OMT), laser treatment, OMT plus laser and sham laser. No significant differences in effects were noted between these groups.

Atienza Meseguer et al (2006) studied 54 subjects with trapezius TrP treated with classical strain/counterstrain (SCS), modified SCS and control. Both treatment groups showed immediate improvement in pressure pain threshold vs. controls, but not vs. each other.

Fryer and Hodgson (2005) compared manual pressure release to sham myofascial release in 37 subjects with upper trapezius myofascial trigger points. A statistically significant increase in pressure pain threshold (PPT) was obtained immediately after the intervention in the manual pressure group vs. controls which was found to be due to a change in tissue sensitivity.

Fernandez-de-Las-Penas et al. (2006) compared ischemic compression to transverse friction massage in 40 subjects with myofascial trigger points in the upper trapezius muscle. Both groups obtained significant improvement in PPT within 2 minutes. No difference was found between the groups.

The outcomes of the "immediate" trials can be summarized as demonstrating effectiveness in reducing tenderness for spinal manipulation (2 out of 3 trials), spray and stretch (2 trials), ischemic compression (3 trials), transverse friction massage (1 trial) and strain / counterstrain (1 trial). One trial of mobilization failed to show any significant changes in tenderness scores vs. controls. We conclude that there is moderately strong evidence to support the use of some manual therapies in the immediate relief of TrP tenderness.

The two trials of short-term effects (3-5 days) demonstrated the effectiveness of osteopathic manipulation and ischemic compression, respectively in reducing TrP tenderness. One long term trial reported that strain / counterstrain demonstrates clinically important changes in TrP tenderness and general pain over 6 months, while the other showed that massage produced limited effect. However, there is only limited evidence to support the use of manual therapies over longer courses of treatment in the management of TrPs and MPS.

Literature search results: Case Reports and Clinical Reviews

The CCGPP protocol considers case reports and clinical reviews as part of the overall literature review, however these are considered the lowest quality of evidence and were therefore not formally rated. We have listed these articles with summaries in Table…..

Seventeen (17) case reports in the chiropractic literature were identified from ICL or MANTIS. These reports covered trigger point treatments in patients with hand pain, low back pain due to a trigger point in the quadratus lumborum muscle, wrist pain, fibromyalgia, upper quarter syndrome, myofascial pain syndrome and general trigger points.

Several current clinical reviews [Harden, 2006; Hong, 2005; Gerwin, 2004, Simons, 2002; Alvarez and Rockwell, 2002] by noted experts in the field of myofascial pain have endorsed the use of a variety of manual therapies in the treatment of TrPs and MPS.

Harden [2006] notes that the principle aims of therapy for MPS are: relief of pain and inflammation, prevention of further injury, reducing spasm, correcting abnormal postures and improving circulation. He endorses the following therapeutic modalities for accomplishing these aims:

- in the acute stage:
    - ice
    - iontophoresis
    - ultrasound
    - splinting
- postural and ergonomic education
- massage
- myofascial release
- exercises and postural correction
- laser therapy: efficacy undetermined
- acupuncture: efficacy undetermined

Hong [2005] recommends that the first principle of treatment for MPS is the identification and treatment of the presumed primary lesion. Only after this has been done, and if there is persistence of pain from the active TrPs, should direct treatment to the TrPs be performed. He further suggests that, at this point in the therapeutic process, release of muscle tightness is the first objective. He identifies 7 steps in the treatment process for the active TrPs themselves:

i. Pain recognition: Treating the active TrPs not the latent ones.
ii. Identify the key TrP: among active TrPs, one will be the most painful and most provocative of referred pain.
iii. Conservative vs aggressive treatment: This principal applies to the treatment of the primary lesion as well as the key TrP. Treatment should begin with what he describes as "non-invasive treatment including physiotherapy" and progress toward more invasive forms of therapy.
iv. Acute vs chronic TrPs: Distinguishing these helps guide therapy in the acute vs chronic stages of pain.
v. Superficial vs Deep TrPs: Different therapeutic modalities are needed the more deeply located is the TrP.
    a. Superficial: deep pressure massage
    b. Deep: stretch, ultrasound, laser, acupuncture, acupressure or local injection
vi. Individual preference: Each patient may have levels of comfort and familiarity with various forms of treatment which should then be tailored to this need.
vii. Other considerations: cost, time, etc.

Hong places considerable importance on manual therapies for TrPs. He indicates the following as important aspects of manual therapy [pg. 40]:

- stretching of shortened muscles (or taut band)
- improving local circulation
- counter-irritation
- other reflex effects

Gerwin [2004] also endorses the treatment protocol which separately addresses therapies for the local TrP vs therapies for the perpetuating factors. In the former category, he specifically endorses manual trigger point compression for focal TrP release, followed by myofascial release techniques for local stretching and then "therapeutic stretch" for the longer-range elongation of the body segments. In the case of perpetuating factors, he includes correction of postural faults as well as joint dysfunction. This should be followed by an active program of physical conditioning, stretching and endurance, including preventative strategies. Unfortunately, no studies were provided as evidence for this approach.

Simons [2002] reviews the mechanisms of TrP formation and perpetuation in order to guide the appropriate treatment approach. The therapies endorsed in his review are:

- post-isometric relaxation and release
- trigger point (manual) pressure release
- combinations of the above two therapies
- trigger point massage.

Only the work of Lewit [1986], who advocates post-isometric relaxation in combination with other methods of muscular facilitation and inhibition is cited as support for this approach. Other non-invasive therapies which Simons merely mentions as additional to the approach described above include: facilitatory techniques, acupuncture, strain/counterstrain, microcurrent, ultrasound and laser.

Alvarez and Rockwell's review [2002] only provides a list of non-invasive treatment modalities which include: acupuncture, osteopathic manual medicine techniques (sic), massage, acupressure, ultrasound, heat, ice, diathermy, transcutaneous electrical nerve stimulation, and "spray and stretch" techniques. For these modalities, no clinical trial evidence was provided. The only support was a reference to the authoritative work described in Travell and Simons' trigger point manual [1983]. Lavelle et al. [2007] endorse the following treatments as efficacious: spray & stretch, TENS, physical therapy and massage.

All of the six most current clinical reviews (2001-2006) endorsed manual therapies for the treatment of myofascial trigger points in MPS. None of these reviews provided a single reference to a randomized clinical trial to support this position. None of the RCTs that we reviewed above was cited in any of these clinical reviews. As such, there is discordance, even at the level of renowned experts' reviews, between the apparent consensus on the use and types of manual therapies in treating TrPs vs. the evidence from the published literature. Most of the conclusions drawn by the authors of these six clinical reviews regarding manual therapies appear to be based mostly upon expert opinion rather than evidence from clinical trials.

With respect to the clinical reviews regarding non-manual therapies, only Harden cites the clinical trial of Esenyel et al. [2000] (ultrasound + stretching vs dry needling + stretching vs stretching alone) and the case series of Simunovic [1996] (laser therapy) as clinical studies of these sorts of therapies as well as the review of laser therapy by Gam et al. [1993]. The other reviews provide no support in the form of any clinical study for their recommendation on non-invasive therapies for TrPs.

Table 6: Myofascial pain literature review: randomized clinical trials of manual therapies

RCT	Time	Manual Therapy	Outcome
Terret and Vernon, 1986	Immediate	Spinal manipulation	Spinal manipulation > mobilization
Jaeger and Reeves, 1986	Immediate	Spray and stretch	Significant intra-group effects
Greene et al., 1990	3 days	Osteopathic manipulative therapy	No difference between OMT with or without laser and vs control
Vernon et al., 1992	Immediate	Spinal manipulation	SMT > control
Hong et al., 1993	Immediate	Spray and stretch, Deep manual pressure	Deep pressure massage was more effective than comparison modalities
Cote et al., 1994	Immediate	Spinal manipulation	Spinal manipulation = control
Hanten et al., 1997	Immediate	Manual mobilization	No sig diff bet mobilization, exercise and control
Gam et al., 1998	6 months	Massage	No sig diff bet massage with real or sham ultrasound or control

Hanten et al., 2000	5 days	Ischemic compression	Ischemic compression > exercise for pain and tenderness
Dardzinski et al., 2000	6 months	Strain / counterstrain	Clinically important intra-group changes
Hou et al., 2002	Immediate	Ischemic compression	Ischemic compression > control
Fryer and Hodgson, 2005	Immediate	Manual pressure release vs sham control	Manual pressure release > control
Fernandez-de-Las_Penas et al., 2006	Immediate	Ischemic compression & transverse friction massage	Ischemic compression = transverse friction massage
Atienza Meseguer et al., 2006	Immediate	Strain / counterstrain	Strain / counterstrain > control

4. OTHER NON-MANUAL CONSERVATIVE THERAPIES

Literature Search Strategy

The search strategy for this section was identical to that described in the previous manual therapy section. Only studies of chiropractic treatments for Myofascial Pain Syndrome (MPS) and trigger points (TrPs) were considered. Therefore, the inclusion criteria for this search were: conservative therapies, laser, acupuncture, ultrasound, electrotherapy, naturopathy, trigger points, myofascial pain syndrome. We used the MESH headings: Musculoskeletal Manipulations, Myofascial pain syndrome (not exploded to Temporomandibular joint); 1965 to 2007; English, German; human studies. This search was conducted in Medline, Cinahl, ICL, Mantis, Embase, National Guidelines Clearinghouse, DARE and TRIP databases.

After the primary search was conducted, a number of secondary searches were conducted based upon "related links", especially emphasizing systematic or clinical reviews, randomized clinical trials, conservative treatments (vs. Musculoskeletal Manipulations only) as well as searches of additional works by the authors identified in the primary search. Finally, citation reviews were conducted manually to identify any additional suitable studies.

Literature search results: Systematic Reviews

Two published systematic reviews of the literature were identified for treatment methods other than manual therapies [Rickards, 2006; Cummings and White, 2001].

In Rickards' review [2006], the inclusion criteria included RCTs of a conservative therapy for active TrPs, not latent TrPs, in which a patient-related pain outcome was used and in which an explicit diagnosis of TrP was made including at least local tenderness and a taut muscle band. Studies were rated on a 20-point scale; however, no cut-off score was used for inclusion. Rickards included the following 18 studies (5 other studies on "physical therapies" were reviewed in the previous section):

Laser therapy: 6 studies
Electrotherapy: 5 studies
Magnet therapy: 3 studies
Ultrasound therapy: 4 studies

It should be noted that no trials for acupuncture were included in this systematic review (see below).

A total of 18 trials listed above were included in this review. Rickards' conclusions were based on the following schema:

- Significant evidence: consistent findings in multiple high quality RCT's
- Moderate evidence: consistent findings in multiple lower quality evidence and/or a single high quality RCT
- Limited evidence: a single low quality RCT
- Unclear evidence: inconsistent or conflicting results from multiple RCT's
- No evidence: no evidence identified
- Evidence of adverse effect: RCT's with lasting negative changes

Rickards' conclusions for each therapy were:

Laser: Significant evidence that laser may be effective in the short term. Type, dose and frequency of treatments require additional research.

TENS: Evidence (unqualified?) that TENS may be effective in providing immediate relief at TrPs.

Other Electrotherapies: Limited evidence for the effectiveness of FREMS, HVGS, EMS and IFC.

US: Moderate evidence that US is no more effective than placebo.

Magnets: Preliminary evidence that magnets may be effective.

It was noted that the majority of trials involved either immediate or short-term effects and that much more research, especially on the longer term effects was needed.

Cummings and White [2001] reviewed all trials up to 2000 of "Needling Therapies" for myofascial pain. Three of these trials involved what could be described as "standard" acupuncture typical of the type used by some chiropractors. This is distinguished from deep dry needling and any injection-type therapies which would not be standard chiropractic treatment approaches. For the present review, any trials that specifically identified one of the regional complaint areas in the other CCGPP chapters (i.e., low back pain, neck pain) without specifying the treatment of TrPs were excluded.

Cummings and White concluded that marked improvements were demonstrated in most treatment groups. However, dry needling techniques alone did not appear to be superior to other treatments in the treatment of myofascial trigger points. As well, they could not find evidence for a specific efficacy of these techniques beyond placebo. They called for more placebo-controlled trials.

A Cochrane Collaboration Protocol entitled "Non-invasive physical treatments of myofascial pain", Kilkenny et al. [2006] was identified. This protocol currently contains no results. However, it was used as a source of additional references, particularly on published clinical trials and systematic reviews.

Literature search results: Randomized Clinical Trials

In order to be complete with our literature synthesis, we performed an additional online literature search to find potential RCTs that were not included in the two previously noted systematic reviews by both Rickards [2006] and Cummings and White [2001]. These two systematic reviews employed specific inclusion and exclusion criteria which resulted in the exclusion of numerous studies, either because they were not RCT's or for various methodologic reasons. These excluded trials will not be listed or reviewed here, as that would both duplicate and undermine the methods and conclusions of these reviews.

As a result of our additional online literature searching, including searches of the MANTIS and ICL databases, several additional trials were identified that have either been published since these previous systematic reviews, or were not identified at all by the Rickards or Cummings/White reviews. This additional literature includes studies published in the following areas:

Acupuncture: There is some additional evidence that a course of deep acupuncture to trigger points is effective in the treatment of myofascial pain for up to 3 months, as noted in 5 additional clinical trials; Ceccherelli et al [2006], Itoh et al [2004], Ceccherelli et al [2002], Goddard et al [2002], Ceccherelli et al [2001].

Laser: Greene et al.'s study [1990] of laser vs osteopathic manipulation (OMT) alone vs OMT + laser vs sham laser to thoracic paraspinal muscle trigger points over 3 days involved measuring only local skin resistance. No measures of pain or tenderness response were made. This study would not have qualified for Rickards' review and does not, as well, for the present review.

Olavi et al. [1989] compared infrared laser to placebo laser over various active trigger points located throughout the body. Pressure pain thresholds were measured immediately after and then 15 minutes after treatment. A statistically significant difference favoring the laser group was found, especially at 15 minutes.

Electrotherapy: No additional studies.

Exercise: No additional studies not already included in Rickards under "physical therapies".

Spray and stretch: The study by Hou et al. was included in the previous section and was included in both Fernandez de las Penas et al and Rickards' systematic reviews. This is because the majority of treatment groups received ischemic compression with or without a variety of other physiologic therapies. One of these therapies was "spray and stretch", making Hou et al the only published clinical trial to investigate this therapy. Hou et al found that the addition of spray and stretch to ischemic compression provided immediate benefit in reducing trigger point sensitivity.

There are no other published clinical trials of "spray and stretch" therapy for management of pain from TrP's. Notwithstanding, it is often cited by clinical experts as a valuable treatment for TrPs.

Table 7: Myofascial pain literature review: Other non-manual conservative therapies

Study	Treatments	Outcomes
Laser therapy		
Gur et al. [2004]	Laser vs placebo	Laser > placebo
Snyder-Mackler et al. [1989]	Laser vs placebo	Laser > placebo
Ceccherelli et al. [2001]	Laser vs placebo	Laser > placebo
Hakguder et al. [2003]	Laser and stretching Vs Placebo and stretching	Laser > placebo
Ilbuldu et al. [2003]	Laser vs dry needling vs placebo	Laser > dry needling Laser > placebo
Altan et al. [2003]	Laser + exercise + stretching vs. Placebo + exercise + stretching	Laser = Placebo (other treatments thought to contribute to improvement)
Electrotherapy		
Graff-Radford et al. [1986]	A: TENS mode A B: TENS mode B C: TENS mode C D: TENS mode D E: Placebo TENS	B > C, D > A, E (B = 100 Hz, 250us)
Farina et al. [2004]	FREMS vs TENS	FREMS = TENS
Hsueh et al. [1997]	A : placebo electrotherapy B : TENS C : EMS	TENS > EMS, placebo
Ardic et al. [2002]	A: TENS + stretching B: EMS + stretching C: stretching	A = B > C
Tanrikut et al. [2003]	A: HVGS + exercise B: placebo HVGS + exercise C : exercise	A > B, C
Magnet therapy		
Brown et al. [2002]	Magnets vs placebo	Magnets > placebo
Smania et al. [2005]	A: Repetitive Magnetic Stimulation (RMS) B: TENS C: Placebo US	A > B > C
Smania et al. [2003]	A: RMS B: Placebo RMS	A > B
Ultrasound		
Gam et al. [1998]	A: US + massage + exercise B: Placebo US + massage + exercise C: control	A = B = C
Maljesi et al. [2004]	A: High power US B: Conventional US	A > B

Lee et al. [1997]	A: placebo US B: US C: electrotherapy D: US + electrotherapy	C > A
Esenyel et al. [2000]	A: US + stretching B: TrP injection + stretching C: stretching	A, B > C
Acupuncture		
Birch and Jamison [1998] (neck pain)	A: superficial acupuncture + IP cords + heat B: wrong point superficial acupuncture C: NSAID	At 3 months: A > B, C
Johansson et al. [1991] (facial pain or headache)	A: acupuncture B: occulusal splint C: no treatment control	At 3 months: A = B > C
Kisiel and Lindh [1996] (neck pain)	A: manual acupuncture B: physiotherapy	At 6 months: A = B
Ceccherelli et al. [2006] (neck pain)	A: Somatic acupuncture B: Somatic acupuncture + auricular acupuncture	At 1 & 3 months: A = B (both = positive effect on pain)
Itoh et al. [2004] (low back pain)	A: Acupuncture at traditional points B: Superficial acupuncture at trigger points C: Deep acupuncture at trigger points	At 3 months: A > B, C (not statistically significant)
Ceccherelli et al. [2002] (low back pain)	A: superficial acupuncture to trigger point B: deep acupuncture to trigger point	At 3 months: B > A
Goddard et al. [2002] (jaw pain)	A: acupuncture B: sham acupuncture	Immediately: A = B
Ceccherelli et al. [2001] (shoulder)	A: superficial acupuncture to trigger point B: deep acupuncture to trigger point	At 1 and 3 months: B > D

<u>MYOFASCIAL PAIN REFERENCES</u>:

Alvarez DJ, Rockwell PG. Trigger points: diagnosis and management. Am Fam Phys 2002;65:653-60.

Al-Shenqiti AM, Oldaham JA. Test-retest reliability of myofascial trigger point detection in patients with rotator cuff tendonitis. Clin Rehabil 2005;19:482-487.

Altan L, Bingol U, Aydae M, Yurtkuran M. Investigation of the effect of GA AS laser therapy on cervical myofascial pain syndrome. Rheumatol Int 2003;25:23-27.

Anderson RU, Wise D, Sawyer T, Chan C. Integration of myofscial trigger point release and paradoxical relaxation training treatment of chronic pelvic pain in men. J Urol 2005 Jul;174(1):155-60.

Ardic F, Sarhus M, Topuz O. Comparison of two different techniques of electrotherapy on myofascial pain. J Back Musculoskel Rehabil 2002;16:11-16.

Atienza Meseguer A, Fernandez de las Penas C, Navarro-Poza JL, Rodriguez-Blanco, C, Bosca Gandia JJ. Immediate effects of the strain/counterstrain technique in local pain evoked by tender points in the upper trapezius muscle. Clin Chirop 2006;9:112-118.

Baldry P. Management of myofascial trigger point pain. Acup Med 2002;20:2-10.

Bendtsen L, Jensen R, Jensen NK, Olesen J. Pressure-controlled palpation: a new technique which increases the reliability of manual palpation. Cephalalgia 1995;15:205-210.

Birch S, Jamison RN. Controlled trial of Japanese acupuncture for chronic myofascial neck pain: assessment of specific and nonspecific effects of treatment. Clin J Pain 1998;14:248-255.

Boline PD, Haas M, Meyer JJ, Kassak K, Nelson C, Keating JC. Interexaminer reliability of eight evaluative dimensions of lumbar segmental abnormality: Part II. J Manip Physiol Ther 1993;16:363-374.

Brewer G, Kampschroeder F, Moore L. Trigger point and transverse frictional massage: a case report. Chiropr 1990;6:40-42.

Brown CS, Ling FW, Wan JY, Pilia AA. Efficacy of static magnetic field therapy in chronic pelvic pain: a double-blind pilot study. Am J Obstet Gynecol 2002;187:1581-1587.

Ceccherelli F, Altafini L, Lo Castro G, Avila A, Ambrosio F, Giron GP. Diode laser in cervical myofascial pain: a double-blind study versus placebo. Clin J Pain 1989;5:301-304.

Ceccherelli F, Bordin M, Gagliardi G, Caravello M. Comparison between superficial and deep acupuncture in the treatment of shoulder myofascial pain : a randomized and controlled study. Acupunct Electrother Res 2001;26:229-238.

Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L. Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study. Clin J Pain 2002;18:149-153.

Ceccherelli F, Tortora P, Nassimbeni C, Casale R. Gagliardi G, Giron G. The therapeutic efficacy of somatic acupuncture is not increased by auriculotherapy : a randomised, blind control study in cervical myofascial pain. Complemt Ther Med 2006;14:47-52.

Chatchawan U, Thinkhamrop B, Kharmawan S, Knowles J, Eungpinichpong W. Effectiveness of traditional Thai massage versus Swedish massage amont patients with back pain associated with myofascial trigger points. J Bodywork Mov Ther 2005;9:298-309.

Christensen HW, Vach W, Manniche C, Haghfelt T, Hartvigsen L, Hoilund-Carlsen PF. Palpation for muscular tenderness in the anterior chest wall: an observer reliability study. J Manip Physiol Ther 2003;26:469-475.

Cohen JH, Gibbons RW. Raymond L. Nimmo and the evolution of trigger point therapy, 1929-1986. J Manip Physiol Ther 1998;21:167-172.

Conti PC, dos Santos CN, Lauris JR. Interexminer agreement for muscle palpation procedures: the efficacy of a calibration program. Cranio 2002;20:289-294.

Cote P, Mior SA, Vernon H. The short-term effect of a spinal manipulation on pain/pressure threshold in patients with chronic mechanical low back pain. J Manipul Physiol Ther. 1994.17(6):364-8.

Crawford JS, Simpson J, Crawford P. Myofascial release provides symptomatic relief from chest wall tenderness occasionally seen following lumpectomy and radiation in breast cancer patients. Int J Radiat Oncol Biol Phys. 1996.15;34(5):1188-9.

Cummings TM, White AR. Needling therapies in the management of myofascial trigger point pain: a systematic review. Arch Phys Med Rehabil 2001;82:986-992.

Cummings M, Baldry P. Regional myofascial pain: diagnosis and management. Best Pract Res Clin Rheumatol 2007;21:367-387.
Daniells E, Wood T. Chiropractic care protocol versus stretching in the treatment of active trigger point in the extensor muscles of the hand and fingers. Toronto, ON: Proceedings of the World Federation of Chiropractic, 7th Biennial Congress, 2003:311-312.
Dardzinski JA, Ostrov BE, Hamann LS. Myofascial pain unresponsive to standard treatment. Successful use of strain and counterstrain technique in physical therapy. J Clin Rheum 2000;6:169-174.
Davies C. Trigger point therapy for carpal tunnel syndrome: self-applied massage of the forearms and scalenes. J Am Chiropr Assoc 2002;39:18-23. c/r
Delaney GA, McKee AC. Inter- and intra-rater reliability of the pressure threshold meter in the measurement of myofascial trigger point sensitivity. Am J Phys Med Rehabil 1993;72:136-139.
De Franca G, Levine L. Quadratus lumborum and low back pain. J Manip Physiol Ther.1991;14:142-9.
Diakow P. Thermographic imaging of myofascial trigger points. J Manip Physiol Ther 1988;11:114-7.
Diakow PR. Differentiation of active and latent trigger points by thermography. J Manip Physiol Ther 1992;15: 439-441.
Edwards J, Knowles N. Superficial dry needling and active stretching in the treatment of myofascial pain – a randomised controlled trial. Acupunct Med 2003;21:80-86.
Esenyel M, Caglar N, Aldemir T. Treatment of myofascial pain. Am J Phys Med Rehabil 2000;79:48-52.
Farina S, Casarotto M, Bennelle M, Tinazzi M, Fiaschi A, Goldoni M, et al. A randomised controlled study on the effect of two different treatments (FREMS and TENS) in myofascial pain syndrome. Eur Medicophys 2004;40:293-301.
Fernandez de las Penas C, Sohrbeck Campo M, Fernandez Carnero J, Miangolarra Page JC. Manual therapies in myofascial trigger point treatment: a systematic review. J Bodywork Move Ther 2005;9:27-34.
Fernandez de las Penas C, Alonso-Blanco C, Fernandez-Carnero J, Miangolarra-Page JC. The immediate effect of ischemic compression technique and tranverse friction massage on tenderness of active and latent myofascial trigger points : a pilot study. J Bodywork Move Ther 2006;10:3-9.
Fischer AA. Pressure algometry over normal muscles. Standard values, validity and reproducibility of pressure threshold. Pain 1987;30:115-126.
Fischer AA. Application of pressure algometry in manual medicine Man Med,1990;5(4):145-150.
Fischer AA. Algometry in the diagnosis of musculoskeletal pain and the evaluation of treatment outcome: an update. J Musculoskel Pain 1998;6:5-32.
Fryer G, Hodgson L. The effect of manual pressure release on myofascial trigger points in the upper trapezius muscle. J Bodywork Move Ther 2005;9:248-255.
Gam AN, Warming S, Larsen LH, Jensen B, Hoydalsmo O, Allon I, Andersen B, Gotzsche NE, Petersen M, Mathiesen B. Treatment of myofascial trigger points with ultrasound combined with massage and exercise: a randomized controlled trial. Pain 1998;77:73-79.
Gerwin RD, Shannon S, Hong CZ, Hubbard D, Gervitz R. Interrater reliability in myofascial trigger point examination. Pain 1997;69:65-73.
Gerwin RD. Myofascial pain syndromes in the upper extremity. J Hand Ther 1997;10:130136.
Gerwin RD, Shannon S. Interexaminer reliability and myofascial trigger points. Arch Phys Med Rehabil 2000;81:1257-1258.
Gerwin RD. Classification, epidemiology and natural history of myofascial pain syndrome. Curr Pain Headache Pre 2001;5:412-420.

Gerwin RD. A review of myofascial pain and fibromyalgia – factors that promote their persistence. Acupunct Med 2005;23:121-134.
Gerwin R. Differential diagnosis of trigger points. J Musculoskel Pain 2005;12:23-28.
Goddard G, Karibe H, McNeill C, Villafuerte E. Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients. J Orofac Pain 2002;16:71-76.
Graff-Radford SB, Reeves JL, Jaeger B. Management of head and neck pain: the effectiveness of altering perpetuating factors in myofascial pain. Headache 1986;27:186-190.
Graff-Radford SB. Myofascial pain: diagnosis and management. Curr Pain Headache Rep 2004;8:463-467.
Greene C, Debias D, Helig D, Nicholas A, England K, Ehrenfeuchter W, Young W. The effect of helium-neon laser and osteropathic manipulation on soft-tissue trigger points. J Amer Osteop Assoc 1990;90:638-639.
Grobli C, Dejung B. Non-medical therapy of myofascial pain. Schmerz 2003;17:475-480. c/s
Gur A, Sarac AJ, Cevik R, Altindag O, Sarac S. Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myfascial pain in the neck: a double-blind and randomized controlled trial. Lasers Surg Med 2004;35:229-235.
Hains G. Locating and treating low back pain of myofascial origin by ischemic compression. J Can Chirop Assoc 2002a;46:257-64.
Hains G. Chiropractic management of shoulder pain and dysfunction of myofascial origin using ischemic compression techniques. J Can Chirop Assoc 2002b; 46:192-200.
Hakguder A, Birtane M, Gurcan S, Kokino S, Turan FN. Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation. Lasers Surg Med 2003;33:339-343.
Hammer W. Functional Soft Tissue Examination & Treatment by Manual Methods, 3rd Ed. Jones & Bartlett, 2007.
Han SC, Harrison P. Myofascial pain syndrome and trigger point management. Reg Anaesth 1997;22:89-101.
Hanten W, Olson S, Butts N, Nowicki A. Effectiveness of a home program of ischemic pressure followed by sustained stretch for treatment of myofascial trigger points. Phys Ther 2000;80:997-1003.
Hanten W,P, Barret M, Gillespie-Plesko M, Jump KA, Olson SL. Effects of active head retraction with retraction/extension and occipital release on the pressure pain threshold of cervical and scapular trigger points. Phys Theory Pract 1997;13:285-291.
Harden RN, Bruehl SP, Gass S, Niemiec C, Barbick B. Signs and symptoms of the myofascial pain syndrome: a national survey of pain management providers. Clin J Pain 2000;16:64-72
Harden RN. Muscle pain syndromes. Am J Phys Med Rehabil 2007;86(Suppl):S47-S58.
Harris RE, Clauw DJ. The use of complementary medical therapies in the management of myofascial pain disorders. Curr Pain Headache Rep 2002;6:370-374
Hong CZ, Chen YC, Pon CH, Yu J. Immediate effects of various physical medicine modalities on pain threshold of an active myofascial trigger point. J Musculoskel Pain 1993;1:37-53.
Hong C. Specific sequential myofascial trigger point therapy in the treatment of a patient with myofascial pain syndrome associated with reflex sympathetic dystrophy. Australas Chiropr and Osteop 2000;9:7-11. c/r
Hong CZ. Myofascial Pain Therapy. J Musculoskel Pain 2004;12:37-43.
Hou CR, Tsai LC, Cheng KF, Chung KC, Hong CZ. Immediate effects of various physical therapy modalities on cervical myofascial pain and trigger point sensitivity. Arch Phys Med Rehabil 2002;83:1406-1414.

Howitt SD,Wong J,Zabukovec S. The conservative treatment of Trigger Thumb using Graston Technique and Active Release Techniques®. J Can Chiropr Assoc 2006;50:249-254. c/r
Hsieh H, Hong C. Effect of chiropractic manipulation on the pain threshold of myofascial trigger point: a pilot study. Proceedings of: International Conference on Spinal Manipulation, 1990:359-363.
Hsieh CY, Hong CZ, Adams AH, Platt KJ, Danielson CD, Hoehler FK, Tobis JS. Interexaminer reliability of the palpation of trigger points in the trunk and lower limbs. Arch Phys Med Rehabil 2000;81:258-264.
Hsueh TC, Cheng PT, Kuan TS, Hong CZ. The immediate effectiveness of electrical nerve stimulation and electrical muscle stimulation on myofascial trigger points. Am J Phys Med Rehabil 1997;76:471-476.
Hubka MJ, Phelan SP. Interexaminer reliability of palpation for cervical spine tenderness. J Manip Physiol Ther 1994;9:591-595.
Hunter G. Specific soft tissue mobilization in the management of soft tissue dysfunction. Man Ther 1998;3:2-11.
Hyde, T. (2003). Graston Technique: A soft tissue treatment for athletic injuries. DC Tracts. Fall 2003.
Ilbuldu E, Cakmak A, Disci R, Aydin R. Comparison of laser, dry needling and placebo laser treatments in myofascial pain syndrome. Rheumatol Int 2003;25:23-27.

Itoh K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients -- a blinded RCT. Acupunct Med 2004;22:170-177.
Jaeger B, Reeves JL. Quantification of changes in myofascial trigger point sensitivity with the pressure algometer following passive stretch. Pain 1986;27:203-210.
Johannson A, Wenneberg B, Wagersten C, Haraldson T. Acupuncture in treatment of facial muscular pain. Acta Odontol Scand 1991;49:153-158.
Kasunich NJ. Changes in low back pain in a long distance runner after stretching the iliotibial band. J Chiropr Med 2003;2:37-40.
Kaye MJ. Evaluation and treatment of a patient with upper quarter myofascial pain syndrome. J Sports Chiropr Rehabil 2001;15:26-33.
Kilkenny MB, Deane K, Smith KA, Eyre S. Non-invasive physical treatments of myofascial pain (Protocol). Cochrane Library, 2007, Issue 1.
Kisiel C, Lindh C. Smartlindring med fysikalsk terapi och manuell akupnktur vid myofasciella nackoch skuldersmartor. Sjukgymnasten 1996;12 Suppl:24-31.
Krause H, Fischer AA. Diagnosis and treatment of myofascial pain. Mt Sinai J Med 1991;58:235-239.
Kruse RA, Christiansen JA. Thermographic imaging of myofascial trigger points: a follow-up study. Arch Phys Med Rehabil 1992;73:819-823.
Lavelle ED, Lavelle W, Smith HS. Myofascial trigger points. Med Clin North Am 2007;91:229-239.
Leahy P. Improved Treatments for Carpal Tunnel and Related Syndromes. Chiro Sports Med 1995;9(1): 6-9.
Leahy, PM. Active Release Techniques: Soft tissue management system for the upper extremity. Colorado Springs, CO: Self-published, 1996.
Leahy, PM, Mock LE. Myofascial release technique and mechanical compromise of peripheral nerves of the upper extremity. Chirop Sports Med 1992;6: 139-150.
Levoska S, Keinanen-Kiukaanniemi S, Bloigu R. Repeatability of measurement of tenderness in the neck-shoulder region by a dolorimeter and manual palpation. Clin J Pain 1993;9:229-235.
Lee JC, Lin Dt, Hong C. The effectiveness of simultaneous thermotherapy with ultrasound and electrotherapy with combined AC and DC current on the immediate pain relief of myofascial trigger points. J Musculoskel Pain 1997;5:81-90.

Lew PC, Lewis J, Story J. Inter-therapist reliability in locating latents myfascial trigger points using palpation. Man Ther 1997;2:87-90.
Maljesi J, Unalan H. High power pain threshold ultrasound technique in the treatment of active myofascial trigger points: a randomized, double-blind case-control study. Arch Phys Med Rehabil 2004;85:833-836.
McPartland JM. Getting to the Point: an osteopathic appreciation of Janet Travell. J Osteop Med 2002;5:73-79.
Melham TJ, Sevier TL et al. Chronic ankle pain and fibrosis successfully treated with a new noninvasive augmented soft tissue mobilization technique (ASTM): a case report. Med Sci in Sports Exer 1998; 30(6): 801-4.
Mock LE. (1997) Myofascial Release Treatment of specific muscles of the upper extremity. Part 1. Clin Bull Myofasc Ther. 2(1):5-23.1997
Mock LE. (1997) Myofascial Release Treatment of specific muscles of the upper extremity. Part 2. Clin Bull Myofasc Ther. 2(2/3):5-22.1997
Mock LE. (1997) Myofascial Release Treatment of specific muscles of the upper extremity. Part 3. Clin Bull Myofasc Ther. 2(4):51-69.1997
Mock LE. (1998) Myofascial Release Treatment of specific muscles of the upper extremity. Part 4. Clin Bull Myofasc Ther. 3(1):71-93.
Mulcahy R, Johnson J, Witt R. Treatment of myofascial pain utilizing an activator instrument on trigger points. Chiropractic 1994;9:45-46.
Nice D, Riddle DL, Lamb RL. Intertester reliability of judgments of the presence of trigger points in patients with low back pain. Arch Phys Med Rehabil 1992;73:893-898.
Nilsson N. Measuring cervical muscle tenderness: a study of reliability. J Manip Physiol Ther 1995;18:88-90.
Nimmo, RL. The development of chiropractic through the perspective of Dr. Raymond Nimmo [videorecording]. Pasadena, TX: Texas Chiropractic College, 1984.
Nimmo, RL. The receptor-tonus method, Pasedena TX: Texas Chiropractic College, 1992.
Nimmo, RL. The Receptor-Tonus method: directory 1962. Self-published.
Nimmo, RL. The Receptor-Tonus method: directory 1967. Self-published.
Njoo KH, Van der Does E. The occurrence and inter-rater reliability of myofascial trigger points in the quadratus lumborum and gluteus medius: a prospective study in non-specific low back pain patients and controls in general practice. Pain 1994;58:317-323.
Olavi A, Pekka G, Pertti K, Pekka P. Effects of infrared laser therapy at treated and non-treated trigger points. Acupunct Electrother Res 1989;14:9-14.
Perle SM. Understanding trigger points: key to relieving myotogenous pain. Chirop J 1989;3:17.
Perle SM. Myofascial trigger points. Chirop Sports Med;9:106-108.
Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M. Levels of Evidence. Oxford, UK: Oxford Centre for Evidence-based Medicine, 2001.
Pontinen PJ. Reliability, validity and reproducibility of algometry in the the diagnosis of active and latent tender spots and trigger points. J Musculoskel Pain, 1998;6:61-71.
Reeves JL, Jaeger B, Graff-Radford SB. Reliability of the pressure algometer as a measure of myofascial trigger point sensitivity. Pain 1986;24:313-321.
Rickards LD. The effectiveness of non-invasive treatments for active myofascial trigger point pain: a systematic review of the literature. Int J Osteop Med 2006;9:120-136.
Sackett DL, Straus SE, Richardson et al. Evidence –Based Medicine : How to practice and teach EBM. Guidelines. Edinburgh, Scotland: Churchill Livingstone, 2000.
Schneider MJ. Snapping hip syndrome in a marathon runner: treatment by manual trigger point therapy – a case study. Chiropr Sports Med 1990;4:54-58.

Schneider, MJ. Principles of manual myofascial therapy. Pittsburgh, Pa.: self published, 1992.
Schneider M. Receptor-Tonus technique Assessment. Chirop Tech 1994;6:156-159.
Schneider M. Tender points / Fibromyalgia vs Trigger points / Myofascial pain Syndrome: A need for clarity in terminology and differential diagnosis. J Manip Physiol Ther 1995;18:398-406.
Schneider M, Cohen J, Laws S. The collected writings of Nimmo and Vannerson : pioneers of chiropractic trigger point therapy. Pittsburgh, Pa.: self-published, 2001
Sciotti VM, Mittak VL, DiMarco L, Ford LM, Plezbert J, Santipadri E, Wigglesworth J, Ball K. Clinical precision of myofascial trigger point location in the trapezius muscle. Pain 2001;93:259-266.
Sciotti VM, Dishman JD, Woodward SP, Mittak VL, Ford L. The use of diagnostic ultrasound imaging in the verification of trigger point diagnosis: a blinded study. J Chirop Educ 2002;16:48.
Simons DG. Examining for myofascial trigger points. Arch Phys Med Rehabil 1993;74:676-677.
Simons DG. Myofascial pain syndromes: trigger points. J Musculoskel Pain 2000;8:105-112.
Simons DG. Understanding effective treatments of myofascial trigger points. J Bodywork Move Ther 2002;6:81-88.
Simunovic Z, Trobonjaca T, Trobonjaca Z. Treatment of media land lateral epicondylitis – tennis and golfer's elbow – with low level laser therapy : a multicentre double-blind, placebo-controlled clinical study on 324 patients. J Clin Laser Med Surg 1998;16:145-151.
Smania N, Corato E, Fiaschi A, Pietropoli P Aglioti SM, Tinazzi M. Therapeutic effects of peripheral repetitive magnetic stimulation on myofascial pain syndrome. Clin Neurophysiol 2003;114:350-358.
Smania N, Corato E, Fiaschi A, Pietropoli P Aglioti SM, Tinazzi M. Repetitive magnetic stimulation: a novel approach for myofascial pain syndrome. J Neurol 2005;252:307-314.
Skootsky SA, Jaeger B, Oye RK. Prevalence of myofascial pain in general internal medicine. West J Med 1989;151:157-160.
Smythe H. Referred pain and tender points. Am J Med. 1986 Sep 29;81(3A):90-2.
Smythe HA, Buskila D, Gladman D. Performance of scored palpation, a point count, and dolorimetry in assessing unsuspected nonarticular tenderness. J Rheumatol. 1993 Feb;20(2):352-7.
Snyder-Mackler L, Barry AJ, Perkins AI, Soucek MD. The effects of helium-neon laser irradiation on skin resistance and pain in patients with trigger points in the neck or back. Phys Ther 1989;69:336-341.
Srbely J, Dickey JP. Stimulation of myofascial trigger points causes systemic physiologic effects [abstract]. J Can Chiropr Assoc 2005;49:75.
Swerdlow B, Dieter JN. An evaluation of the sensitivity and specificity of medical thermography for the documentation of myofascial trigger points. Pain 1992;48:205-213.
Such GW. Manual care of the hyoid complex. Top Clin Chirop 2002;9:54-62. c/r
Tanrikut A, Ozaras N, Ali Kaptan H, Guven Z, Kayhan O. High voltage galvanic stimulation in myofascial pain syndrome. J Musculoskel Pain 2003;11:11-15.
Terrett AC, Vernon H. Manipulation and pain tolerance. A controlled study of the effect of spinal manipulation on paraspinal cutaneous pain tolerance levels. Am J Phys Med. 1984. 63(5):217-25.
Testa M, Barbero M, Gherlone E. Trigger points: update of clinical aspects. Europ Medicophys 2003;39:37-43.
Tough EA, White AR, Richards S, Campbell J. Variability of criteria used to diagnose myofascial trigger point pain syndrome – evidence from a review of the literature. Clin J Pain 2007;23:278-286.
Travell J, Rinzler S. The myofascial genesis of pain. Postgrad Med 1952;11:425-434.

Travell J, Simons DG. Myofascial Pain and Dysfunction: The Trigger Point Manual. Baltimore MD: Williams and Wilkins, 1983.
Tunks E. McCain GA, Hart LE, Teasell RW, Goldsmith C, Rollman G, McDermid A, DeShane PJ. The reliability of examination for tenderness in patients with myofascial pain, chronic fibromyalgia and controls. J Rheumatol 1995;22:944-952.
Vernon HT, Aker P, Burns S, Viljakaanen S, Short L. Pressure pain threshold evaluation of the effect of spinal manipulation in the treatment of chronic neck pain: a pilot study. J Manip Physiol Ther. 1990;13(1):13-6.
Vicenzino B, Collins D, Wright A. The initial effects of a cervical spine manipulative physiotherapy treatment on the pain and dysfunction of lateral epicondylalgia. Pain 1996;68:69-74
Viikari-Juntura E. Interexaminer reliability of observations in physical examinations of the neck. Phys Ther 1987;67:1526-1532.
Walsh MJ, Wise P. Chiropractic treatment of fibromyalgia: two case studies. Chiropr J Aust 2001;31:42-46.
Wheeler AH. Myofascial pain disorders : theory to therapy. Drugs 2004;64:45-62. Wolfe F, Simons DG, Fricton JR, Bennett RM, Goldenberg DL, Gerwin R, Hathaway D, McCain GA, Russell IJ, Sanders HO. The fibromyalgia and myofascial pain syndromes: a preliminary study of tender points and trigger points in persons with fibromyalgia, myofascial pain syndrome and no disease. J Rheum 1992;19:944-951.
Yap EC. Myofascial pain—an overview. Ann Acad Med Singapore 2007;36:43-38.
Ylinen J, Nykanen M, Kautiainen H, Hakkinen A. Evluation of repeatability of pressure algometry on the neck muscles for clinical use. Man Ther 2007;12:192-197.
Yunus MB, Kalyan-Raman UP, Kalyan-Raman K. Primary fibromyalgia syndrome and myofascial pain syndrome: clinical features and muscle pathology. Arch Phys Med Rehabil 1988;69:451-4.

FIBROMYALGIA SYNDROME (FMS): LITERATURE SYNTHESIS

Introduction and background

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's syndrome, bruxism, atypical patterns of sensory dysethesia, and other symptoms. 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 auto-immune disorder of the peripheral tissues.

The diagnosis of FMS has been burdened by a controversial and problematic history since its inception in 1990, with a disturbing trend toward over-diagnosis in recent years. 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 indeed the case. The primary symptoms of FMS, 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, and many other conditions.

The issue of over-diagnosis or mis-diagnosis is 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 two vague criteria. One of these criteria is chronic widespread pain and the other is the presence of a specific number of tender points (TePs). Although a diagnosis of FMS is predicated upon the presence of TePs, the etiology of these areas of superficial tenderness is not known. The FMS literature contains biopsy studies of these TePs that have failed to show any specific soft tissue abnormality. It is clear that TePs are not areas of soft inflammation, which explains the established fact that the pharma-ceutical literature has shown conclusively that no anti-inflammatory medication (steroidal or non-steroidal) has any significant effect on reducing the painful TePs in FMS patients.

The hallmark symptom of FMS is pronounced tenderness to even the mildest palpation. This extreme tenderness to subthreshold stimuli fits the definition of allodynia, i.e. the perception of pain to a non-painful stimulus. 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. The presence of allodynia typically infers 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 (MRI) and positron emission tomography brain scans of patients with FMS5 receiving innocuous sensory stimulation.

The diagnosis of FMS can be traced back to a consensus conference by the American College of Rheumatology (ACR) in 1989, which resulted in a landmark article published in 1990 by Wolfe et. al. entitled "The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: Report of the Multicenter Criteria Committee". It was this publication that laid out the following two diagnostic criteria for inclusion of a FMS patient for research purposes:

1. History of chronic (> 3 months) widespread Pain – defined as:

a) Pain on both sides of body.
b) Pain above and below the waist.
c) Axial skeletal pain is present.

2. Presence of at least 11 of 18 tender points – "tenderness" defined as less than 4 kg of manual pressure causing the patient to express verbal or non-verbal pain communication. The 18 pre-determined anatomical sites for tender point examination are the nine bilateral regions noted below:

Occiput	Lateral epicondyle
Gluteal muscles	Trapezius
Greater trochanter	Anterior lower cervical region
Supraspinatus	Medial knee
Anterior second rib	

As noted above, biopsy evidence failed to show any specific soft tissue abnormality in these 18 pre-determined anatomical sites, leading current researchers to consider the TeP phenomenon to merely be the peripheral manifestation (widespread allodynia) of a central nervous system dysfunction.

Several additional consensus conferences have addressed the issue of FMS diagnosis and treatment since the publication of the original 1990 ACR criteria. All have concluded that the patient with classic FMS presents with many other symptoms besides the original two ACR criteria listed above. It has been well established in the literature that patients with FMS are predominantly female (female/male ratio, 10-20:1), typically report non-refreshing sleep, general fatigue, 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's phenomenon, exercise intolerance, cognitive deficit, and other symptoms suggestive of autonomic nervous system or neuroendocrine dysregulation.

The most recent consensus conference noted in our literature search (through mid-2005) was a working clinical case definition of FMS for practitioners with updated diagnostic and treatment protocols; the result of a Canadian consensus conference published in 2003. These "updated" protocols still recommend the same two ACR criteria as being mandatory for making an FMS diagnosis, along with a laundry list of additional clinical symptoms and signs which include neuro-cognitive 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. This consensus conference concluded with remarks and recommendations about the need for FMS researchers to start looking 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 has been challenged by the more recent evidence. As this Canadian consensus conference concluded, FMS is likely to be a syndrome or cluster of symptoms that may have a number of different etiologies, which requires a number of different treatment approaches. The literature synthesis as performed by our committee is consistent with this emerging idea of FMS as being composed of numerous subsets. As the reader reviews the following evidence rating tables, practice guidelines and literature synthesis 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.

Systematic Reviews and Meta-Analyses of the FMS Literature

We began our literature review by searching for systematic reviews and meta-analyses of fibromyalgia syndrome (FMS) on the Cochrane Database of Systematic Reviews (1996-2005) using keywords "fibromyalgia", "fibrositis", and "fibromyalgia syndrome" brought up a total of 26 references in this database. After reviewing the abstracts, we found that only 11 of these studies were directly related to the subject of FMS or widespread pain. There were 8 systematic reviews and 3 meta-analyses of the FMS literature which are summarized in Table 8.

A consistent theme that emerges from these systematic reviews is that there is no known cause or etiological agent(s) responsible for the development of the symptom complex known as FMS. All treatment options are directed toward amelioration of the major symptoms of widespread pain and fatigue. The majority of systematic reviews have concluded that three 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 anti-depressant medications.

Karjalainen[83] et al performed an electronic search of multidisciplinary rehabilitation for FMS and widespread musculoskeletal pain. They searched MEDLINE from 1966, PsycLIT from 1967 and EMBASE from 1980 to April 1998. The Cochrane Musculoskeletal Group Trials Register and the Cochrane Controlled Trials Register were searched as well. They found that behavioral treatment and stress management appear to be important components to the management of FMS. Education combined with physical training showed some positive effects in long term follow up. These authors concluded that there appeared to be little scientific evidence for the effectiveness of multidisciplinary rehabilitation for these musculoskeletal disorders.

Berman[84] et al performed a systematic review of acupuncture treatment for FMS. MEDLINE (from 1966 to 1997), EMBASE, MANTIS, the specialised register of the Cochrane Complementary Medicine Field, the University of Maryland's CAMPAIN database, CISCOM, and the database of the National Institutes of Health Office of Alternative Medicine were searched using the keywords 'acupuncture' and 'fibromyalgia'. The search was supplemented with conference abstracts, citation lists, and letters to pertinent institutions or individuals. Studies reported in any language were considered.

7 studies were included in the review. There were 3 RCTs (n=168), 3 uncontrolled studies (n=126) 2 prospective and 1 retrospective, and 1 non-randomised uncontrolled study. There was a limited amount of high-quality evidence available. This evidence suggested that real acupuncture is more effective than sham acupuncture for relieving pain, increasing pain thresholds, improving global ratings, and reducing morning stiffness of FMS. However, some patients reported no benefit, while a few reported an exacerbation of their FMS-related pain with acupuncture. The results from lower-quality studies were consistent with these findings. The duration of benefit after cessation of the acupuncture treatments is unknown, because the only high-quality RCT did not provide follow-up data.

Rossy[87] et al performed a systematic review and meta-analysis of the literature that evaluated the efficacy of pharmacological and non-pharmacological treatments for FMS. The databases searched were: MEDLINE from 1966 to November 1996; PsycINFO from 1967 to October 1996; CINAHL

from 1982 to September 1996; and Dissertation Abstracts from 1861 to September 1996. The 'Reference' sections of all of the retrieved studies and major review papers were searched manually. Manual searches of the 1995 and 1996 issues of four key journals, and the abstracts from three key journals over the past 4 years, were conducted. Primary authors were contacted for copies of other outcome studies that they had conducted, published or unpublished. Only studies or abstracts written in English were included in the review.

The designs of the included studies were unclear. A total of 49 studies were included: 33 of pharmacological treatments and 16 of non-pharmacological treatments. The optimal intervention for FMS would include non-pharmacological treatments, specifically exercise and cognitive-behavioral therapy, in addition to appropriate medication management as needed for sleep and pain management.

Hadhazy[90] et al performed a systematic review of the literature that assessed the effectiveness of mind-body therapy (MBT) in persons with FMS. They searched 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. 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.

They concluded that 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. The authors state that MBT should be used early in the course of fibromyalgia and that MBT may augment the effect of other treatments. 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 patients' ability to use MBT and to improve compliance.

O'Malley[92] et al performed a systematic review and meta-analysis of the literature regarding antidepressant medications for the treatment of FMS. Their search was of the literature in English language, randomized, placebo-controlled trials. Studies were obtained from searching MEDLINE, EMBASE, and PSYCHLIT (1966-1999), the Cochrane Library, unpublished literature, and bibliographies. 16 randomized, placebo-controlled trials were identified, of which 13 were appropriate for data extraction. Overall the quality of the studies was good. Anti-depressants improved sleep, fatigue, pain, and well-being, but not tender points. They concluded that antidepressants are efficacious in treating many of the symptoms of FMS. Patients were more than 4 times as likely to report overall improvement, and reported moderate reductions in individual symptoms, particularly pain. They stated that whether this effect is independent of depression needed further study.

Arnold[91] et al also performed a systematic review and meta-analysis of the literature regarding antidepressant medications for the treatment of FMS. Randomized, controlled trials of antidepressant medication for the treatment of FMS were reviewed by methodology, results, and potential predictors of response. Twenty-one controlled trials, 16 involving tricyclic agents, were identified; 9 of these 16 studies were suitable for meta-analysis. Effect sizes were calculated for measurements of physician and patient overall assessment, pain, stiffness, tenderness, fatigue, and sleep quality.

They found that compared with placebo, tricyclic agents were associated with effect sizes that were substantially larger than zero for all measurements. The largest improvement was associated with measures of sleep quality; the most modest improvement was found in measures of stiffness and

tenderness. They concluded that further studies were needed utilizing randomized, double-blind, placebo-controlled, parallel designs with antidepressants administered at therapeutic dose ranges, using standardized criteria for fibromyalgia and systematically assessed for co-occurring psychiatric illness.

Sim[88] et al conducted a systematic review of all randomized trials for non-pharmacological interventions for FMS. 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.

Strong evidence did not emerge for any single intervention, although there was preliminary support of moderate strength, based on 3 studies, for aerobic exercise. 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. Studies that used a combination approach showed greater improvements than those with a single intervention. They suggested that FMS may be better managed by a multimodal approach, incorporating aerobic exercise and education to address physical, functional and psychological aspects of FMS.

Nezu[89] et al conducted a systematic review of the literature regarding cognitive behavioral therapy (CBT) for the treatment of medically unexplained symptoms. The authors' objective was to review the existing literature regarding CBT for medically unexplained symptoms and three related disorders: chronic fatigue syndrome (CFS), fibromyalgia syndrome (FMS) and noncardiac chest pain (NCCP). PsycLIT and MEDLINE were searched and the reference lists of retrieved articles were checked for additional citations. The search terms were reported.

The authors stated that CBT was found to be effective in significantly improving the medical status of the patients reviewed. However, the findings of the review do not provide unequivocal support for CBT in these indications. The authors stated that more research evaluating the efficacy of a wide range of CBT strategies is needed. Such research should include adequate control groups, use manualised protocols, include treatment integrity measures, use more multimodal assessment procedures for outcome measurement, and describe in detail the population under study. They suggested that research should delineate specific treatment strategies, and provide for an assessment of the specific impact of a particular intervention on a given hypothesized mechanism of action and its resulting impact on changes in physical symptoms.

Richards[99] et al conducted a systematic review of the literature regarding the effects of massage in acute and critical care of pain, sleep and relaxation. Although this systematic review did not specifically address FMS, it is included in our chapter since massage is a common treatment for FMS. MEDLINE, CINAHL, and PsycINFO were searched from January 1980 to April 1999 for full-length articles, using the terms ‘massage’, ‘massage and sleep’ and ‘back massage’. 22 articles were included in the review: 1 meta-analysis, 2 systematic reviews, and 19 original research studies (n=802). Of the 19 original research studies, 10 were level III, 6 were level II, and 3 were level I evidence. The authors concluded that massage is an effective treatment for providing relaxation and reducing pain. They suggest that massage may also be an effective treatment for sleep disturbances related to anxiety and pain, but further research is needed to test its efficacy.

Busch[86] et al performed a systematic review of the literature regarding exercise training as a treatment for FMS. Their search strategy included 6 electronic bibliographies for studies of exercise training in FMS: MEDLINE (1966-12/2000), CINAHL (1982-12/2000), HealthSTAR (1990-12/2000), Sports Discus (1975-05/2000), EMBASE (1974-05/2000) and the Cochrane Controlled Trials Register (2000,

issue 4). They also reviewed the reference lists from identified articles, including other systematic reviews and meta-analyses of treatment studies.

The authors found 16 relevant clinical trials involving a total of 724 participants. 7 studies were high quality training studies: 4 aerobic training, 1 mixture of aerobic, strength and flexibility training, 1 strength training, and 2 with exercise training as part of a composite treatment. They concluded that supervised aerobic exercise training has beneficial effects on physical capacity and FMS symptoms. Strength training may also have benefits on some FMS symptoms. They suggested that further studies on muscle strengthening and flexibility are needed, and that additional research on the long-term benefit of exercise for FMS is also needed.

Finally, the most recent systematic review of the FMS literature that is relevant to chiropractic practice was published by Holdcraft[85] et al in 2003, and was further updated and expanded into a clinical practice guideline document[96] published by the American Pain Society in 2005. Holdcraft et al performed a systematic review of the literature that assessed the effectiveness of complementary and alternative medicine (CAM) for people with fibromyalgia syndrome (FMS). 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, and the keywords were stated.

They reviewed a large number of studies, encompassing a wide variety of various non-pharmacological therapies including the following:

Acupuncture (8 studies including 2 RCTs with 130 patients) There was strong evidence of the effectiveness of acupuncture. All 8 studies showed that acupuncture improved symptoms of FMS.

Chiropractic (1 RCT with 19 patients).

Magnesium (2 crossover RCTs with 39 patients)

SAMe (one 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,

Dietary modifications (1 RCT with 78 patients, quality score 11)

They concluded that the vast majority 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 SAMe, and limited evidence for the remaining CAM therapies listed above.

Published Guidelines found on the National Guideline Clearinghouse

The next step of the FMS literature review involved a search for relevant practice guidelines on website of The National Guidelines Clearinghouse (NGC), a comprehensive database of evidence-based clinical practice guidelines and related documents. NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. NGC was originally created by AHRQ in partnership with the American Medical Association and the American Association of Health Plans (now America's Health Insurance Plans [AHIP]). A search of the NGC database produced a total of five published guidelines on the management of FMS. These 5 guidelines and summaries of their recommendations are listed in Table 2.

The most current of these FMS guidelines was authored by Buckhardt[96] et al and published by the American Pain Society (APS) in 2005. This guideline is very extensive and well written. It basically offers recommendations for the management of FMS according to the three most strongly evidence based therapies described in the majority of the Cochrane systematic reviews, i.e. low dose anti-depressant medications, aerobic exercise, and cognitive behavioral therapy.

The 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. NSAIDs and steroids are not recommended as primary medications for the treatment of FMS.

2. Use cognitive-behavioral training (CBT) to reduce pain and psychological 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 two 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 non-pharmacologic techniques.

7. Treat anxiety and depression aggressively with both pharmacologic and non-pharmacologic approaches.

In this APS guideline authored by Buckhardt[96] et al, the systematic review of the FMS literature and committee consensus lead to the following evidence ratings:

Best or Strong Evidence
Aerobic exercise
Cognitive-behavioral therapy (CBT)
Amitriptyline (Elavil)
Cyclobenzaprine (Flexeril)
Multi-component therapy (Exercise, CBT, and patient education)

Moderate Evidence
Selective serotonin reuptake inhibitors (SSRI) in combo w/ tricyclics
Tramadol
Muscle-strength training
Balneotherapy (Spa/water)
Patient education alone
Hypnotherapy
Biofeedback
Massage

Preliminary or Mixed Evidence
Acupuncture
Chiropractic
Growth hormone
Melatonin
Anticonvulsants (gabapentin, Neurontin)
SSRIs alone
Serotonin Norepinephrine reuptake inhibitors (SNRI)
Dietary modifications (vegetarian diet)
Supplements and herbs (magnesium, malic acid, chlorella pyrenoidosa)
S-adenosyl-L-methionine (SAMe)
Movement and body awareness therapies (qigong, t'ai chi)
Trigger point injections

No Evidence of Effectiveness
NSAIDs (demonstrated as ineffective when used alone)
Prednisone (demonstrated as ineffective)
Benzodiazapines (demonstrated as ineffective for pain)
Guaifensesin (demonstrated as ineffective)

The next most current guideline for the management of FMS was authored by Goldenberg[97] et al and published in the JAMA in 2004. This guideline was the result of an independent panel of experts who convened under the sponsorship of the American Pain Society and performed a comprehensive review of the FMS literature. They produced a consensus document/guideline based upon the best available evidence, which came to the following conclusions:

- There is strong evidence to support the use of low-dose tricyclic medications, such as amitriptyline and cyclobenzaprine, as well as cardiovascular exercise, cognitive behavioral therapy (CBT), patient education, or a combination of these for the management of fibromyalgia syndrome (FMS).
- There is moderate evidence that tramadol, selective serotonin reuptake inhibitors (SSRIs), serotonin and epinephrine reuptake inhibitors (SNRIs), and certain anticonvulsants are effective, but the complete results of some trials are not available and systematic reviews have not been reported.
- Moderate evidence exists for the efficacy of strength training exercise, acupuncture, hypnotherapy, biofeedback, massage, and warm water baths (balneotherapy).
- Weak evidence exists for chiropractic, manual and massage therapy; electrotherapy, ultrasound.
- No evidence exists for tender (trigger) point injections or flexibility exercise.

This guideline concluded that many of the commonly used FMS therapies have not been carefully evaluated. Based on their literature evaluation and consensus conference, the independent panel recommended the following stepwise FMS management approach:

Step 1

- Confirm the diagnosis.
- Explain the condition.
- Evaluate and treat comorbid illness, such as mood disturbances and primary sleep disturbances.

Step 2

- Trial with low-dose tricyclic antidepressant or cyclobenzaprine.
- Begin cardiovascular fitness exercise program.
- Refer for cognitive behavior therapy or combine that with exercise.

Step 3

- Specialty referral (e.g., rheumatologist, physiatrist, psychiatrist, pain management).
- Trials with selective serotonin reuptakes inhibitors, serotonin and norepinephrine reuptake inhibitors, or tramadol.
- Consider combination medication trial or anticonvulsant.

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 to consider initially are low doses of tricyclic antidepressants or cyclobenzaprine. Some SSRIs, 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 CBT or stress reduction with relaxation training. A multidisciplinary approach combining each of these modalities may be the most beneficial. Other 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.

One guideline exists regarding FMS and work related injury, from the Washington State Department of Labor and Industries[93]. 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, but such treatment is limited to physical therapy, low dose anti-depressant and muscle relaxant medication, and spinal manipulations. Trigger point injections, methotrexate, opioids, and NSAIDs are not approved for the treatment of FMS by the Department.

One FMS clinical guideline was found on the NGC website that was published in 2004 by Intracorp[95], a public for profit organization that had their internal medical technology and quality assurance committees review the FMS literature. They generated the following recommendations regarding the clinical management of FMS:

- ALWAYS RECOMMENDED
    - Exercise program – gradual
    - Education
    - Support
- RECOMMENDED
    - Low-dose antidepressants, muscle relaxants
    - Acetaminophen in combination with tramadol (Ultracet)
    - Analgesics (aspirin) or modest doses of nonsteroidal anti-inflammatory drugs (NSAID) (e.g., Advil, Motrin)
    - Heat to the tender areas and gentle massage
- FAILURE TO PROGRESS
    - Consultation with psychiatrist, physiatrist, psychopharmacologist, sleep laboratory
    - Medication to improve sleep: amitriptyline, cyclobenzaprine
    - Injections of local anesthetic
    - Intensive pain management
    - Psychotherapy
    - Manipulation
    - Acupuncture
- TREATMENTS NOT RECOMMENDED
    - Narcotics
    - Corticosteroids

The University of Texas, School of Nursing published a guideline[94] for the treatment of FMS in 2005 that suggests a step-wise approach as summarized below:

Step 1 - Patient and Family Education

1. Validate the diagnosis. Patients need to understand their illness before any medications can be prescribed. They must be reassured that fibromyalgia is a "real" illness.
2. Educate about prognosis, pathophysiology, and treatment principles. Lectures, group discussions, and written materials improved outcomes including pain, sleep, fatigue, self efficacy, and quality of life.

3. Fibromyalgia Impact Questionnaire (FIQ). FIQ is a tool to quantitate fibromyalgia's impact over several dimensions of the patient's life, such as function, pain level, fatigue, sleep deprivation, and psychological distress.

Step 2 - Pharmacological Treatment

1. Adequate sleep. Low levels of serotonin and norepinephrine are related to depression, muscle pain, and fatigue. Amitriptyline 25-50 mg 2 to 3 hours before bedtime, allowing peak sedative effect with minimal carry-over effect. Cyclobenzaprine can be used as an alternative to amitriptyline because of its structural similarity to TCA compounds.
2. Treat fatigue and depression. If no response with amityiptyline or cyclobenzaprine, consider adding selective serotonin reuptake inhibitor (fluoxetine) in the morning. Since people with fibromyalgia already have decreased levels of serotonin; it is believed that fluoxetine increases the levels of serotonin to the brain. One research study completed in 2002 found there is a synergistic effect between fluoxetine and amitriptyline due to the pharmacokinetic interaction between the 2 drugs. Using them together may be more effective for the patient's symptoms than using them alone.
3. Treat muscle spasms. Cyclobenzaprine or low dose benzodiazepines (clonazepam) are used to treat muscle spasms.
4. Adequate pain control. The pain component of fibromyalgia is thought to be abnormal CNS processing of pain signals. It is thought that the pain is caused by a complex interaction between neurotransmitter release, external stressors, patient behavior, hormones, and the CNS system. Tramadol 50-100 mg every 4 to 6 hours is recommended for pain control. Non-steroidal anti-inflammatory agents are not recommended because fibromyalgia is not an anti-inflammatory process. Opioids are not recommended due to adverse side effects and regulatory concerns, and no increased benefit has been noted in research studies.

Step 3 - Non-pharmacological Treatment

Exercise & Massage. Tender point thresholds are increased with exercise and external muscle stimulation via massage. Exercise has also been shown to decrease the perception of central pain, which is also increased in fibromyalgia patients. The following are recommended methods of exercise and pain control.

- Cardiovascular fitness training (Gowans & deHueck, 2004)
- Muscle strengthening/stretching (Gowans & deHueck, 2004)
- Balneotherapy (Evcik, Kizilay, & Gokcen, 2002)
- Massage (Hadhazy et al., 2005)
- Biofeedback (vanSanten et al., 2002)

Step 4 - Procedures There have been very few studies of tender point or trigger point injection demonstrating its effectiveness. However, due to the complicated nature of pain management in some patients, it should not be ruled out as an alternative means of treatment. Further studies are warranted.

Step 5 - Referrals. (for consideration). Referrals may be helpful for patients with severe symptoms and comorbid psychosocial issues, along with those who are non-compliant or who have not received adequate relief with medication therapy and management. These referrals may be to: sleep centers, mental health professionals, or pain/rehabilitation clinics.

One additional reference on guidelines for the clinical management of FMS was published in 2003, that was the summary of a Canadian consensus conference on the clinical management of FMS[98]. This publication proposes some diagnostic and treatment protocols for clinicians regarding the management of FMS patients as summarized below:

1. Diagnostic Protocol

Case Definition = Compulsory HISTORY of widespread pain and compulsory PAIN ON PALPATION at 11 of 18 TeP sites. Additional clinical signs and symptoms are clinically important; 2 or more are found in most cases of FMS.

Application of Case Definition:

a) Assess patient's total illness and symptom cluster as FMS
b) Identify aggravating factors and 2° symptoms
c) Quantify severity of symptoms and impact on ADLs

Clinical Observations of FMS:

a) Pain and neurological manifestations
b) Neurocognitive manifestations
c) Fatigue
d) Sleep dysfunction
e) Autonomic and/or neuroendocrine dysfunctions
f) Other signs: postural faults, mm imbalance patterns, etc.

Clinical Evaluation of FMS:

a) Complete History and Systems Review
b) Physical Exam - TrP scan, autonomic/neuroendocrine, CNS, vitals
c) Lab and Diagnostic testing - to rule out other disorders
d) Differential diagnosis– systemic arthrides, CNS diseases, malignancy, endocrine, chronic fatigue syndrome or myofascial pain syndrome

2. Treatment Protocol

Goals & Therapeutic Principles:

a) Individualized treatment plans: Empower the patient to understand the illness.
b) Treating physician and Rehab personnel must understand FMS.
c) Fluctuating symptoms and activity boundaries must be respected.
d) Treatment Program must reflect the total illness burden of the patient.

Self-Help Therapies:

e) Patient education: FMS and sleep, exercise, diet, stress reduction, etc.
f) Self-Development: strategies to improve the above aggravating factors.
g) Self-powered Exercise Program: low intensity and pacing.

Pharamacological Treatments:

h) Sleeping Disturbance
i) Anxiety
j) Depression

CAM Approaches:

a) Needling Techniques: Dry needling, prolotherapy, Botox, Acupuncture
b) Chiropractic

c) PT, Massage
d) Magnets
e) Craniosacral, Reiki
f) TENS
g) EEG & EMG Biofeedback
h) Bright light therapy
i) Aromatherapy

Supplements and Herbs:

a) Vitamins and Minerals
b) b) Supplements
c) c) Herbal Remedies

Table 8 – Systematic Reviews, Meta-Analyses, Practice Guidelines: These 17 references were found upon searching the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), and ACP Journal Club, for the years 1996-2005, and the National Guidelines Clearinghouse.

Type of treatment addressed	**Type of article**				Totals
	Systematic Literature Review	Meta-Analysis	Practice Guideline	Consensus Document	
total	8	3	5	1	17
Acupuncture [83]	1				1
Multi-disciplinary Rehabilitation [84]	1				1
Complementary & Alternative Medicine therapies [85]	1				1
Exercise [86]	1				1
Pharmacological vs. Non-pharmacological therapies [87]		1			1
Non-pharmacological therapies [88]	1				1
Cognitive Behavioral Therapy [89]	1				1
Mind-Body therapies [90]	1				1
Anti-depressant medications [91-92]		2			2
FMS treatment and management [93-98]			5	1	6
Massage [99]	1				1

Additional controlled clinical trials not included in previous systematic reviews, meta-analyses, or practice guidelines

A manual review of the reference lists of the Cochrane systematic reviews and meta-analyses, and the NGC practice guidelines found that the most recent publications had searched the FMS literature through 2002. We therefore performed our own additional manual searches for additional controlled trials using the keyword “fibromyalgia” between the years 2000-2006 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 previously reviewed, in order to update the FMS literature for this soft tissue chapter.

Our search strategy yielded an additional 44 studies that are listed in Table 2. Of these 44 studies, the largest number of RCTs (n=14) were of various exercise interventions for FMS symptoms, 7 of which were included in prior systematic reviews. Since exercise is already an established treatment for FMS, the additional 7 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. There were 5 trials on vitamins, nutritional and dietary interventions, however all of these studies were included in the previous systematic reviews and practice guidelines. A total of 20 studies within the 44 found during our search were previously included in the reference sections of prior systematic reviews or practice guidelines.

The 24 studies that we found which were not previously considered in the prior systematic reviews or practice guidelines are also listed in Table 2. The studies that have potential relevance to chiropractic practice are listed below:

- Osteopathic manipulation (one small pilot RCT)
- Massage therapy (two small RCTs)
- Laser therapy (one small RCT)
- Spa/water therapy/Balneotherapy (one moderate sized RCT)
- Ultrasound and interferential current (one small RCT)

The results of our manual search for clinical trials from 2000-2006 basically confirmed the previously summarized findings and conclusions of the Cochrane systematic reviews and meta-analyses, as well as the most recently published practice guidelines. The few additional RCTs listed above that were not previously reviewed are considered preliminary, fair quality, and had small sample sizes.

Table 9 – Additional Clinical Trials: These 44 references were found upon additional searches of the Medline, PubMed, CINAHL, AMED, EMBASE, DARE and TRIP databases for years 2000-2006. This represents 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[96] and systematic review[97] of the FMS literature. No additional chiropractic trials were found on any of these medical databases.

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=20)
total	44	44	
Chiropractic	-	-	
Osteopathic manipulation [39]	1	1	
Exercise [40-53]	14	14	Schacter[51], van Santen[53] Hakkinen[41,] Jones[42], King[44],Mannerkorpi[45,46] Citera[55], Merchant[58], Kaartinen[57], Azad[54], Edwards[56] Anderberg[59] Kendall[65]
Vitamins and diet therapy [54-58]	5	5	
Medications [59-64]	6	6	
Body awareness and Qi Gong [65]	1	1	
Laser therapy [66]	1	1	
Education [67-68]	2	2	

Massage [69-70]	2	2	
Spa/water therapy (balneotherapy) [71-72, 82]	3	3	Buskila[71] Evcik[72]
Magnet therapy [73]	1	1	Alfano[73]
Meditation and Qi Gong [74]	1	1	Astin[74]
Ultrasound & interferential current [75]	1	1	
T'ai Chi [76]	1	1	Taggart [76]
Exercise and cognitive behavioral therapy (combination therapy) [77-78]	2	2	
Cognitive behavioral therapy [79]	1	1	Soares[79]
Multidisciplinary approaches [80-81]	2	2	

Additional studies found on MANTIS and ICL databases, including observational case reports

In addition to searching the standard online databases such as MEDLINE, we specifically performed yet another comprehensive manual search of the MANTIS and ICL databases, which are more inclusive of the chiropractic and alternative therapy literature. We used several search strategies on these databases. First, we performed a wide search using the term "fibromyalgia" without any restrictions in journal type but restricted the year of publication from 1990-2006, which produced a total of 661 citations of which 21 were considered relevant. 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 American College of Rheumatology (ACR) criteria for diagnosis of fibromyalgia syndrome. Our second search strategy was to use the keywords "fibromyalgia AND chiropractic", and limited the year of publication from 1950-2006. This second search strategy produced a total of 50 citations of which 17 were considered relevant.

Therefore, we found a total of 38 relevant articles produced from our search of the MANTIS and ICL databases using the keywords "fibromyalgia" and "fibromyalgia AND chiropractic". We found that the all of the citations produced from the ICL database were included in our search from the MANTIS database. These 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.

We carefully cross-referenced all 38 of these studies with the reference sections of all the previously published systematic reviews, meta-analyses, and practice guidelines. Only 3 of the studies found from our MANTIS and ICL searches were included in the most recent systematic review[97] of the FMS literature and FMS practice guideline[96] (Blunt[1], Deluze[9], Abraham[18]). Therefore, 35 articles were found that represent unique and separate contributions to the FMS literature. Expanded summaries of all these studies are listed in TABLE 4. Regarding chiropractic treatment of FMS, we found one additional RCT[2], one case-series report[35], and one single-case report[36]. The RCT describing chiropractic treatment for FMS[2] was published in the World Federation of Chiropratic 7th biennial congress conference proceedings, and had a very scant description of the study and results. A hand search for a detailed peer-reviewed version of this publication was not found.

The conclusion from our search of the MANTIS and ICL databases does not provide any strong new evidence to recommend any one specific type of CAM therapy, including chiropractic care or spinal manipulation. Most of the articles retrieved for these and other therapies were previously included in the most recent systematic reviews and practice guidelines. As noted after the FMS summary rating/recommendation table on pages 6-7, our committee believes that the 2005 American Pain Society FMS Guideline is comprehensive and inclusive of the pertinent chiropractic literature. We recommend that clinicians consult this guideline for the most current evidence synthesis and best practices document regarding FMS.

Table 10 – Additional studies from MANTIS and ICL searches: These 38 references were retained from literature searches of the MANTIS and Index to Chiropractic Literature (ICL) databases from 1950 to 2006. The two databases are not restricted to peer-reviewed, indexed journals. Only three of these studies were included in the most recent systematic review[97] of the FMS literature and FMS practice guideline[96] (Blunt[1], Deluze[9], Abraham[18])

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) [1-2, 35-36]	2			1	1	4
Osteopathic manipulation [3-4]				2		2
Exercise [5-8]	4					4
Acupuncture [9-10]	2					2
Multi-disciplinary rehab [11-12]	2					2
Body awareness and Qi Gong [13]	1					1
Bright light therapy [14]	1					1
Therapeutic touch [15]				1		1
Craniosacral therapy and muscle energy technique [16]				1		1
Microcurrent stimulation [17]				1		1
Dietary interventions [18-20]				3		3
Prolotherapy [21]				1		1
Homeopathy [22-25]	3			1		4
Eye movement desensitization [26]				1		1
Educational programs [27]				1		1
Cognitive behavioral therapy [28]			1			1
Hair analysis [29]			1			1

Surface EMG [30]			1		1
Thyroid hormone [31]	1				1
Water therapy [32]	1				1
Chiropractic manipulation and cranial electrical stimulation [33]				1	1
Acupuncture and diet [34]				1	1
Survey of CAM therapies used by FMS patients referred to Mayo clinic [37]		1			1
Psychological profile of FMS attending private chiropractic clinics [38]		1			1

TABLE 11: Additional Studies of Various FMS Treatments: Expanded summaries of results of literature search on MANTIS and ICL databases using the keywords "fibromyalgia" (1990-2006) and "fibromyalgia AND chiropractic" (1950-2006).

Clinical Trials	Title	Summary
Bell[22]	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
Blunt[1]	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
DaCosta[6]	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
Faull[32]	A pilot study of the comparative effectiveness of two water-based treatments for fibromyalgia syndrome: Watsu and Aix massage	Non-randomized clinical trial; n=13 Watsu did better than Aix, but no control group and small sample size make findings equivocal
Harris[10]	Treatment of fibromyalgia syndrome with formula acupuncture	Single blind RCT; n=114 comparing 4 types of acupuncture traditional/non-traditional needle placement with/with-out electrical stimulation; No control group; All 4 types were effective
Lemstra[11]	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.
Mannerkorpi[13]	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

Pearl[14]	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 sig diff bet. groups. Very small sample size and no control group make findings equivocal
Sencan[7]	A study to compare the therapeutic efficacy of aerobic exercise and paroxetine in fibromyalgia syndrome	N=60; RCT comparing 3 groups; aerobic exercise (AE) on a bike, paroxetine, placebo TENS; AE group had less analgesic usage, AE and paroxetine groups had better outcomes than the placebo TENS group.
Wigers[8]	Effects of aerobic exercise versus stress management treatment in fibromyalgia: A 4.5 year prospective study	N=60; RCT comparing 14 wks of treatment with either aerobic exercise(AE),stress management (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
Wise[2]	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.
Zijlstra[12]	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 ½ weeks of treatment at a spa resort with treatment as usual; spa therapy reduced pain at 3 months, but not at 6 or 12 months
Case Reports and/or Case Series	**Title**	**Summary**
Abraham[18]	Management of fibromyalgia: Rationale for the use of magnesium and malic acid	N=15 case series of patients
Denison[15]	Touch the pain away: New research on therapeutic touch and persons with fibromyalgia syndrome	Case series; no specific number of subjects reported.
Friedberg[26]	Eye movement desensitization in fibromyalgia	N=6 patients who had two treatment sessions.
Gemmell[25]	Homeopathic Rhus Toxicondendron in the treatment of fibromyalgia	N=3 case series of patients; no sig effects found
Hains[35]	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
Harte[33]	Clinical forum: Fibromyalgia syndrome	Single case report
Henriksson[27]	Evaluation of four outpatient educational programmes for patients with longstanding fibromyalgia	N=191; survey data comparing four educational programs that varying in total length of time and number of staff/patient contact hours. No diffs bet groups.
Leach[30]	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
Lo[3]	Osteopathic manipulative treatment in fibromyalgia syndrome	N=19 patients treated with OMT; most had a favorable outcome with intervention
Lukaczer[19]	A pilot trial evaluating Meta050, a	N=54 patients with "rheumatic disease";

	proprietary combination of reduced iso-alpha acids, rosemary extract and oleanolic acid in patients with arthritis and fibromyalgia	osteoarthritis, rheumatoid arthritis, and/or fibromyalgia syndrome
McMakin[17]	Cytokine changes with microcurrent treatment of fibromyalgia associated with cervical spine trauma	N=54 consecutive patients
Michalsen[20]	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
Silva[16]	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
Stotz[4]	The effects of osteopathic manipulative treatment on the tender points associated with fibromyalgia	N=18; case series of patients
Tyers[34]	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
Wise[36]	Chiropractic treatment of fibromyalgia: Two case studies	N=2 case reports
Survey Research	**Title**	**Summary**
Jamison[38]	A psychological 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.
Wahner-Roedler[37]	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.
Case-Control Study	**Title**	**Summary**
Ng[29]	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; signif higher amts of calcium and mag in FMS group
Goldenberg[28]	A controlled study of a stress-reduction, cognitive-behavioral treatment program in fibromyalgia.	N=121; 79 FMS pts completed a 10 wk stress reduction, cognitive behavioral meditation program. Control group was 42 FMS pts on wait list. CBT group

		showed superior outcomes to controls.

FIBROMYALGIA REFERENCES:

[1-39][40-89][90-99]

1. Blunt, K.L., M. Rajwani, and R. Guerriero, *The effectiveness of chiropractic management of fibromyalgia patients: a pilot study.* J Manip Physiol Ther, 1997. **20**(6): p. 389-99.
2. Wise, P., M. Walsh, and G. Littlejohn, *Effectiveness of chiropractic treatment on fibromyalgia syndrome: a randomized controlled trial.* WFC 7th Biennial Congress Conference Proceedings, 2003. **7th edition**: p. 374-5.
3. Lo, K., et al., *Osteopathic manipulative treatment in fibromyalgia syndrome.* J Amer Osteopath Assoc, 1992. **92**(9): p. 1177.
4. Stotz, A. and R. Kappler, *The effects of osteopathic manipulative treatment on the tender points associated with fibromyalgia.* J Amer Osteopath Assoc, 1992. **92**(9): p. 1183.
5. Cook, D.B., et al., *Exercise and cognitive performance in chronic fatigue syndrome.* Med Sci Sports Exer, 2005. **37**(9): p. 1460-7.
6. DaCosta, D., et al., *A randomized clinical trial of an individualized home-based exercise programme for women with fibromyalgia.* Rheumatology, 2005. **44**(11): p. 1422-27.
7. Sencan, S., et al., *A study to compare the therapeutic efficacy of aerobic exercise and paroxetine in fibromyalgia syndrome.* J Back Musculoskel Rehabil, 2004. **17**(2): p. 57-61.
8. Wigers, S.H., T.C. Stiles, and P.A. Vogel, *Effects of aerobic exercise versus stress management treatment in fibromyalgia: A 4.5 year prospective study.* Scand J Rheumatol. 1996.**25**(2):77-86.
9. Deluze, C., et al., *Electroacupuncture in Fibromyalgia: Results of a controlled trial.* BMJ, 1992. **305**(6864): p. 1249-52.
10. Harris, R., et al., *Treatment of fibromyalgia syndrome with formula acupuncture: Investigation of needle placement, needle stimulation, and treatment frequency.* J Altern Complement Med, 2005. **11**(4): p. 663-671.
11. Lemstra, M. and W.P. Olsvnski, *Effectiveness of multidisciplinary rehabilitation in the treatment of fibromyalgia: A randomized controlled trial.* Clin J Pain, 2005. **21**(2): 166-174.
12. Zijlstra, T., et al., *Spa treatment for primary fibromyalgia syndrome: A combination of thalassotherapy, exercise and patient education improves symptoms and quality of life.* Rheumatology, 2005. **44**(4): p. 539-46.
13. Mannerkorpi, K. and M. Arndorw, *Efficacy and feasibility of a combination of body awareness therapy and qigong in patients with fibromyalgia: A pilot study.* J Rehabil Med, 2004. **36**(6): p. 279-81.
14. Pearl, S., et al., *The effects of bright light treatment on the symptoms of fibromyalgia.* J Rheumatol, 1996. **23**(5): p. 896-902.
15. Denison, B., *Touch the pain away: New research on therapeutic touch and persons with fibromyalgia syndrome.* Holistic Nurs Pract, 2004. **18**(3): p. 142-151.
16. Silva, M., J. Barrett, and J. Williams, *A retrospective review of outcomes of fibromyalgia patients following physical therapy treatments.* J Musculoskel Pain, 2004. **12**(2): p. 83-92.
17. McMakin, C., W. Gregory, and T. Phillips, *Cytokine changes with microcurrent treatment of fibromyalgia associated with cervical spine trauma.* J Bodywork Movement Ther, 2005. **9**(3): p. 169-176.
18. Abraham, G.E. and J.D. Flechas, *Management of fibromyalgia: Rationale for the use of magnesium and malic acid. .* J Nutr Med, 1992. **3**(49-59).

19. Lukaczer, D., et al., *A pilot trial evaluating Meta050, a proprietary combination of reduced iso-alpha acids, rosemary extract and oleanolic acid in patients with arthritis and fibromyalgia.* Phytotherapy Res, 2005. **19**(10): p. 864-9.
20. Michalsen, A., et al., *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.* BMC Complementary Alternative Med, 2005. **5**(22).
21. Reeves, K., *Treatment of consecutive severe fibromyalgia patients with prolotherapy.* J Orthop Med, 1994. **16**(3): p. 84-9.
22. Bell, I., et al., *Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo.* Rheumatology, 2004. **43**(5): p. 577-82.
23. Bell, I.R., et al., *Individual differences in response to randomly assigned active individualized homeopathic and placebo treatment in fibromyalgia: implications of a double-blinded optional crossover design.* J Altern Compl Med, 2004. **10**(2): p. 269-83.
24. Bell, I.R., et al., *Electroencephalographic cordance patterns distinguish exceptional clinical responders with fibromyalgia to individualized homeopathic medicines.* J Altern Compl Med, 2004. **10**(2): p. 285-99.
25. Gemmell, H., B. Jacobson, and K. Banfield, *Homeopathic Rhus Toxicondendron in the treatment of fibromyalgia.* Chirop J Austr, 1991. **21**(1): p. 2-6.
26. Friedberg, F., *Eye movement desensitization in fibromyalgia.* Complementary Therapies in Nurs Midwifery., 2004. **10**(4): p. 245-9.
27. Henriksson, C., et al., *Evaluation of four outpatient educational programmes for patients with longstanding fibromyalgia.* J Rehabil Med, 2004. **36**(5): p. 211-9.
28. Goldenberg, D., et al., *A controlled study of a stress-reduction, cognitive-behavioral treatment program in fibromyalgia.* J Musculoskel Pain, 1994. **2**(2): p. 53-66.
29. Ng, S., *Hair calcium and magnesium levels in patients with fibromyalgia: A case center study.* J Manip Physiol Ther, 1999. **22**(9): p. 586-93.
30. Leach, R. and R. Hosek, *Clinical and myoelectric observations on fibromyalgia: a prospective descriptive clinical series.* Proceedings of the International Conference on Spinal Manipulation, 1994. **June**: p. 13-14.
31. Lowe, J., *Triiodothyronine (T3) treatment of euthyroid fibromyalgia: a small-n replication of a double-blind placebo-controlled crossover study.* Clin Bull of MyofascThera, 1997. **2**(4): p. 71-88.
32. Faull, K., *A pilot study of the comparative effectiveness of two water-based treatments for fibromyalgia syndrome: Watsu and Aix massage.* J Bodywork Movement Ther, 2005. **9**(3): p. 202-210.
33. Harte, E., *Clinical forum: Fibromyalgia syndrome.* Integrative Med, 2003. **2**(4): p. 50-54.
34. Tyers, S. and R.B. Smith, *A comparison of cranial electrotherapy stimulation alone or with chirorpractic therapies in the treatment of fibromyalgia.* The American Chiropractor, 2001. **23**(2): p. 39-41.
35. Hains, G. and F. Hains, *Combined ischemic compression and spinal manipulation in the treatment of fibromyalgia: A preliminary estimate of dose and efficacy.* J Manip Physiol Ther, 2000. **23**(4): p. 225-30.
36. Wise, P. and M. Walsh, *Chiropractic treatment of fibromyalgia: Two case studies.* Chirop J Austr, 2001. **31**(2): p. 42-6.
37. Wahner-Roedler, D., et al., *Use of complementary and alternative medical therapies by patients referred to a fibromyalgia treatment program at a tertiary care center.* Mayo Clinic Proceedings, 2005. **80**(1): p. 55-60.

38. Jamison, J.R., *A psychological profile of fibromyalgia patients: a chiropractic case study.* J Manip Physiol Ther, 1999. **22**(7): p. 454-7.
39. Gamber, R.G., et al., *Osteopathic manipulative treatment in conjunction with medication relieves pain associated with fibromyalgia syndrome: results of a randomized clinical pilot project.* J Amer Osteop Assoc, 2002. **102**(6): p. 321-5.
40. Gowans, S.E., et al., *Effect of a randomized, controlled trial of exercise on mood and physical function in individuals with fibromyalgia.* Arthritis & Rheum, 2002. **45**(6): p. 519-29.
41. Hakkinen, A., et al., *Strength training induced adaptations in neuromuscular function of premenopausal women with fibromyalgia: comparison with healthy women.* Ann Rheum Dis, 2001. **60**(1): p. 21-6.
42. Jones, K.D., et al., *A randomized controlled trial of muscle strengthening versus flexibility training in fibromyalgia.* J Rheumatol, 2002. **29**(5): p. 1041-8.
43. Karper, W.B. and S.C. Stasik, *A successful, long-term exercise program for women with fibromyalgia syndrome and chronic fatigue and immune dysfunction syndrome.* Clin Nurse Specialist, 2003. **17**(5): p. 243-8.
44. King, S.J., et al., *The effects of exercise and education, individually or combined, in women with fibromyalgia.* J Rheumatol, 2002. **29**(12): p. 2620-7.
45. Mannerkorpi, K., M. Ahlmen, and C. Ekdahl, *Six- and 24-month follow-up of pool exercise therapy and education for patients with fibromyalgia.* Scand J Rheumatol, 2000. **31**(5): 306-10.
46. Mannerkorpi, K., et al., *Pool exercise combined with an education program for patients with fibromyalgia syndrome. A prospective, randomized study.* J Rheumatol, 2000. **27**(10): 2473-81.
47. Meiworm, L., et al., *Patients with fibromyalgia benefit from aerobic endurance exercise.* Clin Rheum, 2000. **19**(4): p. 253-7.
48. Meyer, B.B. and K.J. Lemley, *Utilizing exercise to affect the symptomology of fibromyalgia: a pilot study.* Med Science Sports Exer, 2000. **32**(10): p. 1691-7.
49. Peters, S., et al., *A randomized controlled trial of group aerobic exercise in primary care patients with persistent, unexplained physical symptoms.* Fam Pract, 2002. **19**(6): 665-74.
50. Ramsay, C., et al., *An observer-blinded comparison of supervised and unsupervised aerobic exercise regimens in fibromyalgia.* Rheumatology, 2000. **39**(5): p. 501-5.
51. Schachter, C.L., et al., *Effects of short versus long bouts of aerobic exercise in sedentary women with fibromyalgia: a randomized controlled trial.* Phys Ther, 2003. **83**(4): p. 340-58.
52. Valim, V., et al., *Aerobic fitness effects in fibromyalgia.* J Rheumatol, 2003. **30**(5): p. 1060-9.
53. van Santen, M., et al., *High or low intensity aerobic fitness training in fibromyalgia: does it matter?* J Rheumatol, 2002. **29**(3): p. 582-7.
54. Azad, K.A., et al., *Vegetarian diet in the treatment of fibromyalgia.* Bangladesh Med Research Council Bull, 2000. **26**(2): p. 41-7.
55. Citera, G., et al., *The effect of melatonin in patients with fibromyalgia: a pilot study.* Clin Rheum, 2000. **19**(1): p. 9-13.
56. Edwards, A.M., et al., *Food supplements in the treatment of primary fibromyalgia: a double-blind, crossover trial of anthocyanidins and placebo.* J Nutr Environ Med, 2000. **10**(3): p. 189-199.
57. Kaartinen, K., et al., *Vegan diet alleviates fibromyalgia symptoms.* Scand J Rheumatol, 2000. **29**(5): p. 308-13.
58. Merchant, R.E., C. Andre, and C. Wise, *Nutritional supplementation with Chlorella pyrenoidosa for fibromyalgia syndrome: a double-blind, placebo-controlled crossover study.* J Musculoskel Pain, 2001. **9**(4): p. 37-54.

59. Anderberg, U.M., I. Marteinsdottir, and L. von Knorring, *Citalopram in patients with fibromyalgia - a randomized, double-blind, placebo-controlled study.* Eur J Pain, 2000. **4**(1): p. 27-35.
60. Erhan, E., et al., *Fluoxamine versus amitriptyline in the treatment of fibromyalgia.* Agri, 2000. **12**(1): p. 32-36.
61. Farber, L., et al., *Efficacy and tolerability of tropisetron in primary fibromyalgia - a highly selective and competitive 5-HT3 receptor antagonist.* Scand J Rheumatol, 2000. **113**(Supplement): p. 49-54.
62. Graven-Nielsen, T., et al., *Ketamine reduces muscle pain, temporal summation, and referred pain in fibromyalgia patients.* Pain, 2000. **85**(3): p. 483-91.
63. Haus, U., et al., *Oral treatment of fibromyalgia with tropisetron given over 28 days: influence on functional and vegetative symptoms, psychometric parameters and pain.* Scand J Rheumatol, 2000. **113**(Supplement): p. 55-8.
64. Russell, I.J., et al., *Efficacy of tramadol in treatment of pain in fibromyalgia.* Journal of Clin Rheumatol, 2000. **6**(5): p. 250-257.
65. Kendall, S.A., et al., *A pilot study of body awareness programs in the treatment of fibromyalgia syndrome.* Arthr Care Res, 2000. **13**(5): p. 304-11.
66. Gur, A., et al., *Efficacy of low power laser therapy in fibromyalgia: a single-blind, placebo-controlled trial.* Lasers in Med Science, 2002. **17**(1): p. 57-61.
67. Cedraschi, C., et al., *Fibromyalgia: a randomized, controlled trial of a treatment programme based on self-management.* Ann Rheum Dis, 2004. **63**(3): p. 290-6.
68. Fors, E.A. and K. Gotestam, *Patient education, guided imagery and pain related talk in fibromyalgia coping.* Eur J Psychiatry, 2000. **14**(4): p. 233-240.
69. Field, T., J. Delage, and M. Hernandez-Reif, *Movement and massage therapy reduce fibromyalgia pain.* J Bodywork Movement Ther, 2003. **7**(1): p. 49-52.
70. Field, T., et al., *Fibromyalgia pain and substance P decrease and sleep improves after massage therapy.* J Clin Rheum, 2002. **8**(2): p. 72-76.
71. Buskila, D., et al., *Balneotherapy for fibromyalgia at the Dead Sea.* Rheum International, 2001. **20**(3): p. 105-8.
72. Evcik, D., B. Kizilay, and E. Gokcen, *The effects of balneotherapy on fibromyalgia patients.* Rheum International, 2002. **22**(2): p. 56-9.
73. Alfano, A.P., et al., *Static magnetic fields for treatment of fibromyalgia: a randomized controlled trial.* J Altern Compl Med, 2001. **7**(1): p. 53-64.
74. Astin, J.A., et al., *The efficacy of mindfulness meditation plus qigong movement therapy in the treatment of fibromyalgia: a randomized controlled trial.* J Rheumatol, 2003. **30**(10): p. 2257-62.
75. Almeida, T.F., et al., *The effect of combined therapy (ultrasound and interferential current) on pain and sleep in fibromyalgia.* Pain, 2003. **104**(3): p. 665-72.
76. Taggart, H.M., et al., *Effective treatment of chronic fatigue syndrome and fibromyalgia - A randomized, double-blind, placebo-controlled, intent-to-treat study.* Orthop Nurs, 2003. **22**(5): p. 353-60.
77. Redondo, J.R., et al., *Long-term efficacy of therapy in patients with fibromyalgia: a physical exercise-based program and a cognitive-behavioral approach.* Arthr Rheum. 2004.**51**(2):84-92
78. van Santen, M., et al., *A randomized clinical trial comparing fitness and biofeedback training versus basic treatment in patients with fibromyalgia.* J Rheumatol, 2002. **29**(3): p. 575-81.
79. Soares, J. and G. Grossi, *A randomized, controlled comparison of educational and behavioural interventions for women with fibromyalgia.* Scand J Occup Ther, 2002. **9**(1): p. 35-45.

80. Teitelbaum, J.E., et al., *Effective treatment of chronic fatigue syndrome and fibromyalgia - A randomized, double-blind, placebo-controlled, intent-to-treat study.* J Chronic Fatigue Synd, 2001. **8**(2): p. 3-28.
81. Worrel, L.M., et al., *Treating fibromyalgia with a brief interdisciplinary program: initial outcomes and predictors of response.* Mayo Clinic Proceedings, 2001. **76**(4): p. 384-90.
82. Neumann, L., et al., *The effect of balneotherapy at the Dead Sea on the quality of life of patients with fibromyalgia syndrome.* Arthr Care Res, 2001. **13**(5): p. 291-5.
83. Karjalainen, K., et al., *Multidisciplinary rehabilitation for fibromyalgia and musculoskeletal pain in working age adults.* Cochrane Database of Systematic Reviews, 2004. **4**.
84. Berman, B.M., et al., *Is acupuncture effective in the treatment of fibromyalgia?* . J Fam Pract, 1999. **48**(3): p. 213-218.
85. Holdcraft, L.C., N. Assefi, and D. Buchwald, *Complementary and alternative medicine in fibromyalgia and related syndromes.* Best Pract Res Clin Rheumatol, 2003. **17**(4): p. 667-683.
86. Busch, A., et al., *Exercise for treating fibromyalgia syndrome.* Cochrane Database of Systematic Reviews, 2006. **4**.
87. Rossy, L.A., et al., *A meta-analysis of fibromyalgia treatment interventions.* Ann Behav Med, 1999. **21**(2): p. 180-191.
88. Sim, J. and N. Adams, *Systematic review of randomized controlled trials of nonpharmacological interventions for fibromyalgia.* Clin J Pain, 2002. **18**(5): p. 324-36.
89. Nezu, A.M., C. Maguth Nezu, and E. Lombardo, *Cognitive-behavior therapy for medically unexplained symptoms: a critical review of the treatment literature.* . Behav Ther, 2001. **32**(3): p. 537-583.
90. Hadhazy, V.A., et al., *Mind-body therapies for the treatment of fibromyalgia: a systematic review.* J Rheumatol, 2000. **27**(12): p. 2911-2918.
91. Arnold, L.M., P. Keck, and J. Welge, *Antidepressant treatment of fibromyalgia. A meta-analysis and review.* Psychosomatics, 2000. **41**: p. 104-13.
92. O'Malley, P.G., et al., *Treatment of fibromyalgia with antidepressants: a meta-analysis.* J Gen Int Med, 2000. **15**(9): p. 659-66.
93. *Fibromyalgia*. 2002: Washington State Department of Labor and Industries, Olympia, WA.
94. *Fibromyalgia Treatment Guideline*. 2005: University of Texas, School of Nursing, Family Nurse Practitioner Program, Austin, TX.
95. *Fibromyalgia.* 2004: Intracorp, Philadelphia, PA.
96. Buckhardt, C., et al., *Guideline for the management of fibromyalgia syndrome pain in adults and children*, in *Clinical practice guideline; no. 4, American Pain Society*. 2005: Glenview, IL.
97. Goldenberg, D., C. Burckhardt, and L.J. Crofford, *Management of Fibromyalgia Syndrome.* JAMA 2004. **292**(19): p. 2388-2395.
98. Jain, A.K., et al., *Fibromyalgia Syndrome: Canadian clinical working case definition, diagnostic and treatment protocols - a consensus document.* Journal of Musculoskeletal Pain., 2003. **11**(4): p. 3-107.
99. Richards, K.C., R. Gibson, and A. Overton-McCoy, *Effects of massage in acute and critical care.* AACN Clinical Issues, 2000. **11**(1): p. 77-96.