Fibromyalgia (FM) is an often debilitating chronic syndrome of widespread pain in muscles and other connective tissues associated with characteristic soft tissue tender points, sleep disorder, general fatigue, and other systemic manifestations. Tender points differ from trigger points. Trigger points have palpable localized spasm and edema along with tenderness, referred pain, and twitch response. Tender points are reported as painful by the patient but there are no other local signs. Associated clinical features may include but are not limited to: chronic fatigue, non-restorative sleep, irritable bowel syndrome (IBS), muscle stiffness (especially in the morning), headaches, and depression. Approximately 3-4% of the general population in Europe and the US are affected, 9 times more prevalent in women than men.\(^2\)\(^-\)\(^3\)

Roughly one-quarter of people with fibromyalgia are work-disabled.\(^4\) There is a higher risk for fibromyalgia if other rheumatic disease is present. These include osteoarthritis, lupus, rheumatoid arthritis, or ankylosing spondylitis. FM is also often confused with chronic fatigue syndrome and the distinction is often difficult to ascertain, with up to 70 percent of patients meeting the diagnosis for both.\(^5\)

Recent research indicates that an interdisciplinary approach to FM treatment creates better outcomes.\(^6\)\(^-\)\(^7\) Non-pharmacological treatments involving active participation of patients seem to be more effective than those that involve passive physical measures. Empiric approaches to treatment are recommended. It is highly recommended that practitioners take the time to explore what has been tried previously and build on the successes or failures of that work. Patients with FM tend to use more complementary and alternative medicine (CAM) and it can be very effective at relieving symptoms.\(^8\)\(^-\)\(^9\)\(^,\)\(^11\)\(^,\)\(^12\)\(^,\)\(^13\)\(^,\)\(^14\) Those who use CAM have been shown to have lower insurance expenditures than those who do not use CAM.\(^15\) It is important to clarify successes and failures of past treatments as often there is only temporary improvement with therapeutic approaches that can add to patient and provider frustration.

**Diagnosis**

American College of Rheumatology (ACR) preliminary diagnostic criteria for FM was updated in 2010.\(^16\) The older requirement of a tender point exam has been omitted and replaced with a symptom checklist.\(^16\)\(^,\)\(^17\) The diagnosis is separated into two parts. The first part is called the Widespread Pain Index (WPI) in which the patient (and/or the clinician) endorses any of the 19 body regions of pain. The second part of the score is a Symptom Severity score (SS score) in which the patients other symptoms are evaluated. Using both scores takes into consideration the pain as well as other bothersome symptoms. The researchers and authors of the study state: “This criteria set has been approved by the American College of Rheumatology (ACR) Board of Directors as
Provisional. This signifies that the criteria set has been quantitatively validated using patient data, but it has not undergone validation based on an external data set. All ACR-approved criteria sets are expected to undergo intermittent updates.”

<table>
<thead>
<tr>
<th>Criteria Needed for a Fibromyalgia Diagnosis</th>
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<tr>
<td>1. Pain and symptoms over the past week, based on the total of:</td>
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<tr>
<td>Number of painful areas out of 19 parts of the body</td>
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<tr>
<td>Plus level of severity of these symptoms:</td>
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<tr>
<td>• Fatigue</td>
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<tr>
<td>• Waking unrefreshed</td>
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<tr>
<td>• Cognitive (memory or thought) problems</td>
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<tr>
<td>Plus number of other general physical symptoms</td>
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<tr>
<td>2. Symptoms lasting at least three months at a similar level</td>
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<tr>
<td>3. No other health problem that would explain the pain and other symptoms</td>
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</table>

Source: American College of Rheumatology, 2010

The tender points are as follows: around the neck, shoulder, chest, hip, knee, and elbow regions. The finger pressure that must be applied to these areas during an exam is just enough to cause the nail bed to blanch.

Other scales for FM diagnosis are currently being investigated to help improve and expand the understanding of this complex condition.18

The Fibromyalgia Network has a Criteria Survey based on the new 2010 guidelines. (neuro.memorialhermann.org/uploadedFiles/_Library_Files/MNII/NewFibroCriteriaSurvey.pdf), You can also take the survey online here: http://www.surveymonkey.com/s/HXZYTBM

**Subjective Findings and History**
- Diffuse muscular and bilateral axial pain
- Sleep disturbance(s)
- Exercise intolerance-increased aching with excessive physical exercise
- Migraine headaches
- Temporomandibular disorder (TMJ)
- Problems with memory or clear thinking
The condition is more common in women

Digestive issues (Irritable Bowel Syndrome) or gastroesophageal reflux disease (GERD)

As with other chronic pain conditions, co-morbid mood and anxiety disorders commonly occur in FM (29% and 27%, respectively) and a lifetime diagnosis of a major mood disorder has been observed in as many as 74% of FM patients.

A variety of symptoms and signs may accompany FM. The prevalence of frequently observed symptoms and signs in FM include (% of patients):

- Widespread pain with tender points (100)
- Generalized weakness, myalgias, arthralgias (80)
- Nonrestorative sleep (80)
- Fatigue (70)
- Stiffness (60)
- Tension headache (53)
- Dysmenorrhea (40)
- Irritable colon, functional bowel disease (40)
- Subjective numbness, swelling, tingling (35)
- Livedo reticularis or skin hyperaemia (30)
- Complaints of fever (20)
- Complaints of swollen glands (20)
- Complaints of dry eyes (20)
- Subjective significant cognitive dysfunction (20)
- Significant psychopathology (5-20)
- Nocturnal myoclonus, restless legs syndrome (15)
- Female urethral syndrome (12)
- Vulvodynia or vaginismus (10)
- Concomitant reflex sympathetic dystrophy (5)

Psychiatric co-morbidity and a lack of objective evidence of FM have led to the inaccurate belief that FM is a somatization disorder. In the past decade, innovative research inspired by advances in neuroscience and pain have greatly contributed to a better understanding of the pathophysiology of the condition (e.g., altered pain processing and a deficiency in an important central analgesic system resulting in diminished diffuse noxious inhibitory control (DNIC). This knowledge has resulted in new ways of conceptualizing FM and its treatment.

**Objective Findings**

- Complaints tend to be out of proportion to the paucity of objective findings
- Physical exam, lab, x-rays, and EMG studies may be normal. Sleep and muscle oxygenation studies may be abnormal. There is no specific test to confirm diagnosis.
- Minimal to no muscle hypertonicity
- ROM is often within normal limits
- Traditional Chinese Medicine (TCM) tongue, pulse, abdominal and meridian assessment findings will vary. There is no singular TCM presentation.
- As noted above, examination for tender points is not required to confirm the diagnosis.
Assessment
It is important to consider other clinical entities that present with similar symptomatology. The list for differential diagnosis includes: infections, muscle disorders, malignancies, autoimmune disease, hypermobility disorders, rheumatoid variants, substance abuse, and endocrinopathies such as diabetes and adrenal disorders. Other entities to be considered in the differential diagnosis include subclinical hypothyroidism, inappropriate thyroid replacement medication dosage, vitamin and mineral deficiencies, inappropriate nutraceutical usage, and adverse effects of medication such as hormone replacement therapy (HRT). Often patients will present already having had sufficient testing to allow for this differentiation. A therapeutic trial of treatment appropriate for FM with reasonable outcomes might suffice in lieu of a battery of further diagnostic testing. There appears to be a close relationship between the diagnosis of FM and chronic fatigue syndrome (CFS). The majority of patients with CFS meet the tender point criteria for FM and approximately 70 percent of patients with FM meet the criteria for CFS.30,31

Plan
FM is managed as a chronic condition. Patient education and a prioritization of the obstacles to response for each individual, as well as evaluating for patient acceptance of various options are seen as essential steps in creating an effective treatment plan.32 Healthcare professionals should be empathetic and not demonstrate negative attitudes. Certain guidelines recommend that “a therapeutic alliance would facilitate shared decision-making between the health care professional and the FMS-patient.”33,34 Patients should be active participants in their treatment plans.

Active interventions may include:
- Improving sleep through sleep hygiene and pharmacological and non-pharmacological interventions. (see below for more information)
- Aerobic exercise to tolerance (consider yoga, tai chi, qigong, water aerobics, or walking). Consistency and moderation are critical. The patient may need assistance in setting achievable goals.35-37 A number of recent reports suggest that water exercises may be an effective form of therapy in FM38,39
- Tai chi has shown to improve quality of life (QOL) and significant improvements in the FIQ score.40-41
- Cardiovascular fitness training has had positive effects on pain, global well-being and physical function. There is some evidence for strength training. One recent report found comparable benefits comparing muscle strength training to an aerobic exercise program42-44
- Resistance training45
- Increasing patient control of the condition through education is an important part of treatment. Goals for education include information and resources that will help the patient understand the complexity of their symptoms, be more proactive with their condition and avoid the stigma that may accompany their condition.46-48
- Cognitive behavioral therapy (CBT) on a group or individual basis has compelling evidence to support its use.47,48,49-50,51,52,53-54,55
- Guided imagery and meditation can be effective adjunctive treatments.61, 56, 57, 58,59, 60
- Relaxation techniques, such as biofeedback and progressive muscle relaxation (PMR) may be beneficial.52,54-62, 63, 64, 65,66, 67, 68, 69, 70, 71, 72, 73
- Optimize nutrition through Traditional Chinese Medicine (TCM) or conventional nutritional counseling, dietary assessment, or supplementation. Be aware of anti-nutritional agents such as preservatives, nicotine and alcohol use, or toxic exposure.

Passive modalities and provider-based interventions may complement, but not replace, patient self-management.

**Modalities to consider include:**
- Massage therapy to break the pain cycle. Patient tolerance must be considered and technique will need to be modified according to where the patient is in the FM continuum of remission and exacerbation.\(^{35,74,75}\)
- Hydrotherapy may be an effective intervention.\(^{76,44}\)

Manipulative therapies focusing on increasing functional capacity and patient independence. A thorough postural and biomechanical assessment and correction through short-term manipulative therapy is important. Reliance on passive care and manipulation of hypermobile areas must be avoided. Manipulative treatment should be paced concurrently with increasing self-directed exercise. Self-manipulation should be discouraged.\(^{77}\) A recent MT protocol was shown to be effective for improving pain intensity, widespread pressure pain sensitivity, impact of FMS symptoms, sleep quality, and depressive symptoms in individuals with FMS.\(^{78}\)

- Acupuncture and moxibustion accompanied by other TCM modalities.\(^{79}\) Acupuncture is helpful in decreasing the central pain mechanism, improving sleep, increasing circulation and muscle relaxation, and in improving neuroendocrine function. Acupuncture is effective in dealing with symptoms that often are associated with FM such as depression, fatigue, stiffness, tension headache, dysmenorrhea, irritable bowel syndrome, and subjective numbness.\(^{80,80,81}\)
- Prescription and OTC pharmaceuticals (see below)
- Support and counseling for psychological issues, such as cognitive behavioral therapy (CBT).\(^{77}\)
- Clarification of the medications and supplements the patient has or is using. Help the patient to determine what is appropriate and/or effective. Assist in future treatment planning.
- Coordination of co-treatment or interdisciplinary care

There may be some utility in treatments such as:
- Trigger point injections
- Homeopathy\(^{44,82}\)
- Electrical muscle stimulation - Transcranial direct current stimulation (tDCS)
- Microcurrent therapy
- Ion pumping cords
- Intravenous micronutrient therapy (IVMT)\(^{83,84}\)
- Balenotherapy (spa therapy)\(^{85}\)
- Further research is warranted for these interventions.
Multi-disciplinary Treatment
There is strong evidence for the effectiveness multidisciplinary interventions that combine cardiovascular exercise, cognitive behavioral therapy (CBT), and patient education. The ExPRESS (Exercise, Psychiatric comorbidity, Regaining function, Education, Sleep hygiene, Stress management) is a treatment approach acronym to help clinicians better recall the six domains that should be addressed in every patient visit, if possible.

Sleep Hygiene:
- Lengthy wind down period before bedtime
- Reduce television viewing before bedtime
- Regularity of sleep cycle
- Ergonomically optimal sleep positions
- Avoidance of stimulants
- Relaxation techniques and breathing exercises
- Regular exercise, at least 3 hours before expected bedtime

Nutraceuticals:
- Nutritional considerations for sleep hygiene:
  - Magnesium
  - B complex, particularly thiamin, B-6, B-12, folate
  - SAME (S-adenosylmethionine)
  - Foods high in tryptophan
  - Consider 5-Hydroxytryptophan (5-HTP) as a concentrated tryptophan source, one biochemical step removed from serotonin
  - Malic acid
  - Selenium
- Herbal therapy considerations:
  - Kava sp.
  - Hypericum sp.
  - Ginseng
  - Valerian sp.
  - Passiflora sp.
  - Chlorella pyrenoidosa
  - Chinese herbs
- Hormonal considerations:
  - Melatonin
  - Calcitonin
  - DHEAS
  - Growth hormone (GH)
- Pharmacological Agents (not an exhaustive list):
  - Patients with FM are frequently treated with analgesics, including opioids, despite an absence of evidence of their efficacy.
  - FDA approved specifically for fibromyalgia:
    - Duloxetine (Cymbalta)
    - Milnacipran (Savella)
    - Pregabalin (Lyrica)
- Gabapentin (Neurontin)
  - For symptoms:
    - Tricyclic antidepressants such as amitryptiline (Elavil) and desipramine
    - Other SSRIs, SNRIs, and dual reuptake inhibitors, such as venlafaxine (Effexor), fluoxetine (Prozac), paroxetine (Paxil) or sertraline (Zoloft)
    - Cyclobenzaprine (Flexeril) (a central acting muscle relaxant)
    - NSAIDs and analgesics, such as ibuprofen (Advil, Motrin) or naproxen (Aleve, Anaprox), acetaminophen (Tylenol) and tramadol (Ultram) (other opioids are not recommended and have not been shown to be effective in FMS).

- Drug/Nutraceutical Interactions (not an exhaustive list)
  - Possibility of Serotonin syndrome with SSRIs and Hypericum sp. and/or 5HTP.
  - Potential excessive CNS sedation from the additive effects of tricyclic antidepressants and sedating herbs such as Kava sp. and Valerian sp.

### Resources for Clinicians

The Fibromyalgia Impact Questionnaire ([http://www.myalgia.com/FIQ/fiq.pdf](http://www.myalgia.com/FIQ/fiq.pdf)) is a useful tool in assessing functional abilities in daily life and measures patient status, progress, and outcomes. It is a self-administered instrument that is composed of 10 items and can be completed in about 10 minutes.


### Clinical Pathway Feedback
CHP desires to keep our clinical pathways customarily updated. If you wish to provide additional input, please use the e-mail address listed below and identify which clinical pathway you are referencing. Thank you for taking the time to give us your comments.

Chuck Simpson, DC, CHP Vice President, Clinical Affairs: csimpson@chpgroup.com

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