2012 Canadian Guidelines for the diagnosis and management of fibromyalgia syndrome: Executive summary

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BACKGROUND: Recent neurophysiological evidence attests to the validity of fibromyalgia (FM), a chronic pain condition that affects >2% of the population.

OBJECTIVES: To present the evidence-based guidelines for the diagnosis, management and patient trajectory of individuals with FM.

METHODS: A needs assessment following consultation with diverse health care professionals identified questions pertinent to various aspects of FM. A literature search identified the evidence available to address these questions; evidence was graded according to the standards of the Oxford Centre for Evidence-Based Medicine. Drafted recommendations were appraised by an advisory panel to reflect meaningful clinical practice.

RESULTS: The present recommendations incorporate the new clinical concepts of FM as a clinical construct without any defining physical abnormality or biological marker, characterized by fluctuating, diffuse body pain and the frequent symptoms of sleep disturbance, fatigue, mood and cognitive changes. In the absence of a defining cause or cure, treatment objectives should be patient-tailored and symptom-based, aimed at reducing global complaints and enhancing function. Healthy lifestyle practices with active patient participation in health care forms the cornerstone of care. Multimodal management may include nonpharmacological and pharmacological strategies, although it must be acknowledged that pharmacological treatments provide only modest benefit. Maintenance of function and retention in the workforce is encouraged.

CONCLUSIONS: The new Canadian guidelines for the treatment of FM should provide health professionals with confidence in the complete care of these patients and improve clinical outcomes.

Key Words: Clinical care; Fibromyalgia; Pain; Practice guidelines

Although fibromyalgia (FM) has been recognized as a clinical syndrome for the past two decades, recent neurophysiological evidence of pain dysregulation has provided scientific validation. The controversy surrounding FM stems from the subjective nature of complaints and lack of any defining abnormal biological findings (1,2). This newer understanding has prompted clinical study and exploration of newer treatment options. In this spirit, the 2012 Canadian Guidelines for the diagnosis and management of FM syndrome were developed to provide directions for optimal patient care that align with the best available evidence (3). The clinical challenge remains because the cause of, the ideal treatment and any potential cures for FM are unknown. In addition, diagnosis is entirely dependent on patient report of symptoms and functional impairment, without any defining physical or laboratory abnormality.

In addition to the pivotal symptom of chronic widespread pain, FM syndrome often includes fatigue, nonrestorative sleep, cognitive dysfunction and mood disorder, as well as variable somatic symptoms (4). Canadian prevalence rates are in the order of 2% to 3%, with females...
Grades of recommendation

A Consistent level 1 studies
B Consistent level 2 or 3 studies, or extrapolations from level 1 studies
C Level 4 studies or extrapolations from level 2 or 3 studies
D Level 5 evidence or troublingly inconsistent or inconclusive studies of any level
Consensus Opinion supported by entire Canadian Fibromyalgia Guidelines Committee

Level may be graded down on the basis of study quality, imprecision, indirectness, inconsistency between studies, or because the absolute effect size is very small; level may be graded up if there is a large or very large effect size. Adapted from reference 10
is the fallacy associated with the tender point examination, a mainly subjective technique that is not supported by sound scientific basis and has been fraught with controversy. Therefore, contrary to previous beliefs, examination of tender points should not be used to either confirm or validate a diagnosis of FM (2). There is a strong call for the reduction of both excessive investigation and referrals to multiple specialists. Only simple laboratory tests should be performed, consistent with routine good health care, to ensure that some other, easily identifiable condition is not overlooked. The guidelines also acknowledge that criteria for the diagnosis of FM, developed by the American College of Rheumatology in 1990 and revised in 2010, were primarily intended for research purposes and should not be used to confirm a clinical diagnosis in an individual patient.

The clinical evaluation combined with simple blood tests will rule out most conditions that can present with body pain such as endocrine disease (hypothyroidism), rheumatic conditions (early inflammatory arthritis or polymyalgia rheumatica), neurological disease (myopathy or multiple sclerosis) or drug-induced conditions (lipid-lowering agents, aromatase inhibitors). Any additional testing should be specifically driven by the clinical findings, but with prudence.

Therefore, these guidelines recommend a paradigm shift whereby the responsibility for the diagnosis and management of FM is moved away from the specialist, with care concentrated in the primary care setting (12). Early diagnosis will avoid unnecessary investigations, a cause for patient uncertainty that prolongs health care behaviours and fosters medicalization (13-15). Attention can then be focused toward symptom management, attainment of optimal health, and maintenance or improvement of function. New symptoms in a patient with a previous diagnosis of FM should be evaluated according to good clinical standards, with the understanding that FM patients may eventually develop other illnesses unrelated to FM.

An elementary understanding of the neurophysiological concepts present in FM will reassure health care professionals of the validity of this condition and will also help guide rational treatment choices. Abnormalities in pain processing have been identified at various levels in the peripheral, central and sympathetic nervous systems, as well as the hypothalamo-pituitary-adrenal axis stress-response system, but these findings remain in the research domain and are not available for routine patient care (16-18).

The cause of FM is unknown. Familial studies have identified the possibility of genetic predisposition, with up to one-quarter of relatives of FM patients reporting chronic widespread pain (19,20). While no individual gene has been associated with FM, there is increasing evidence of a polygenic effect, with genes affecting serotonergic, catecholaminergic and dopaminergic systems likely playing a role (21,22). Genetic factors may, therefore, predispose some individuals to a dysfunctional stress response via the hypothalamo-pituitary axis, and may be the setting whereby a triggering event may initiate clinical symptoms (23). Psychosocial distress, as well as early life adversity including abuse, have been shown to predict the onset of chronic, widespread pain (24,25). Primed by genetic factors, a physical or psychological trigger, as reported for nearly one-quarter to one-third of individuals, may lead to clinical expression of FM (26). Therefore, the expression of FM may be explained by a biopsychosocial model in which predisposition, triggering and other factors, such as depression, maladaptive coping or fear-avoidance behaviour, contribute to chronicity.

The management of patients with FM

In the absence of a cure for FM, treatment recommendations should be directed at reduction of symptoms and fostering optimal function, with patient outcome goals clearly defined. Symptom-based management, taking into consideration the heterogeneous nature of this condition, can help to direct a patient-tailored, multimodal approach (27). Ideal management requires active patient participation in health-related practices and will centre on nonpharmacological strategies. Pharmacological treatments may be helpful for some patients, but with a need to evaluate efficacy and side effect profile (28). With average responses to therapy mainly modest at best, the essence of current evidence is that there is no ‘gold standard’ of treatment. Self-efficacy, attention to psychological distress and adherence to global treatment recommendations, strategies that may be augmented by cognitive behavioural therapy, will favourably influence outcome (29). Patients should be encouraged to be self-sufficient, develop good coping skills and pursue as normal a life pattern as possible.

Regular physical activity should form the cornerstone of treatment and received the highest grade of recommendation. To facilitate adherence, exercise of the patient’s choice is encouraged and should be adjusted according to the individual patient’s ability. This may take the form of an aerobic, strengthening, water, home-based or group program, depending on availability for an individual patient. Although many patients with FM are using various complementary and alternative medicines, in the absence of evidence, none can be recommended, but disclosure by the patient should be encouraged.

Symptom-based treatment represents a rational approach to pharmacological choices, with drugs impacting more than one symptom adding an advantage (16,27). There is a notion that the ideal treatment for FM is likely a combination of treatments, often in lower doses than reported in the study setting, with potential benefits of adherence. Although the traditional pharmacological treatment paradigm begins with the use of simple analgesics and tricyclic antidepressants, other agents that may be used include other antidepressants, gabapentinoids, dopaminergic agents and sleep modifiers. Once a drug treatment has been initiated, attention should be devoted to efficacy as well as the development of side effects, many of which can mimic symptoms of FM. Fatigue may be aggravated by gabapentinoids, antidepressants or analgesics; depression may be exacerbated by opioids and cannabinoids; gastrointestinal symptoms may be affected by non-steroidal anti-inflammatory agents, opioids and antidepressants; and sleep disturbance may be aggravated by opioids and antidepressants.

Although care in a multidisciplinary setting may be desirable, this is not realistic, nor is it necessary for most patients (30). Access to a health care team member who is knowledgeable about FM can provide support, and may help the patient to develop coping strategies. Nursing support has been shown to reduce waiting time to consultation and increase patient satisfaction, but is still underused (31). Finally, public education and social marketing will help demystify FM and promote health.

Patient trajectory and outcome in FM

Ideal care of individuals with FM will be in the primary care setting; there is no clear advantage of care by a specialist (32-35). Because the primary care physician has the best knowledge of the patient from the biopsychosocial perspective and is likely to have been managing the patient over time, the primary care setting must be the focal point of management. The need for education in this regard is imperative to provide confidence in management.

The health care community should discourage passive health-related practices and excessive dependence on health care professionals. Although clinic visits may be more frequent at treatment initiation, reduction of unnecessary health care contact when the patient is on a stable trajectory is mandatory. Clinical response may be reliably measured by a simple assessment of patient global status, rather than recourse to cumbersome questionnaires (36,37). Documenting patient goals and their levels of achievement is a strategy that has concrete meaning for a patient (38). Measurement of tender points is not a clinically relevant or reliable outcome measurement and should not be used to monitor patients (39). Every effort should be made to maintain individuals with FM in the workforce. Their work ability is often contentious, with up to 35% receiving work disability benefits (40). Work modification that may include pacing may be an avenue to help retain individuals in the workforce. Although the physical and psychological demands of a job influence employment, the life situation, attitude and motivation, and ability to influence work parameters are additional contributing factors (41). Although return to work is perceived as an ideal health
FM is a condition associated with considerable direct and indirect health care costs. A positive diagnosis may reduce costs by reducing tests, imaging, medication use, specialist referrals and primary care visits (14). In the United States, the cost for service utilization in an individual FM patient was more than US $2,000 in 1997, with reports in the order of CAD $4,000 per year per patient for Canada and Europe (6,43-45). While nonpharmacological therapies have been demonstrated to be an effective and necessary component of treatment, they do, however, incur costs that are threefold greater than for pharmacological therapies. Comorbidities, such as depression, have also been shown to increase costs, warranting attention (44). Education and improved knowledge translation will enable health care professionals to diagnose and manage individuals with FM more effectively with associated cost containment.

Limitations
These recommendations should serve as a template for the care of adult FM patients, with the understanding that each patient is unique and treatments should be individualized. Evidence to support many aspects of these guidelines was either scanty or lacking, with reliance often placed on clinical experience and consensus of the participating health care professionals. Because access to care is not equal across all geographical regions of Canada, differences in care will be evident, with a need to harmonize treatments to the clinical setting. Although no cost analysis for the implementation of these guidelines has been performed, development of simple, clinically useful tools is in process. The full guideline document available on both the CPS and Canadian Rheumatology Association websites is extensive and should, therefore, serve as a reference, rather than a tool for day-to-day clinical practice.

We acknowledge that these guidelines propose fairly considerable changes in the way FM patients will be managed in the future. These suggestions may, at first, appear discomforting, but we believe that the translation will enable health care professionals to diagnose and manage individuals with FM more effectively with associated cost containment.

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Education and knowledge
10. In caring for individuals with FM, health care professionals should be educated regarding the pathogenesis of FM (level 5, consensus), should be empathetic, open and honest, should not demonstrate negative attitudes and should practice shared decision-making (level 3, grade D) (55-57).
11. Health care professionals should be knowledgeable that objective neurophysiological abnormalities have been identified in patients with FM in the research setting, but are not available in clinical practice for either the diagnosis or care of individuals with FM (level 5, grade D) (16,18).
12. Patients and health care professionals should acknowledge that genetic factors as well as previous adverse events may have contributed to the development of FM, but focusing excessively on a triggering event could compromise patient care and should, therefore, be discouraged (level 5, grade D) (22,26,58).

Practice recommendations for FM: Section 2

Management

Treatment overview
13. A treatment strategy for patients with FM should incorporate principles of self-management using a multimodal approach (level 1 (27,28), grade A). It is recommended that attention should be devoted to individual symptoms in a patient-tailored approach, with close monitoring and regular follow-up, particularly in the early stages of management (level 5, grade D) (27).
14. Patients should be encouraged to identify specific goals regarding health status and quality of life at the initiation of treatment, with re-evaluation of goals during follow-up (level 5, grade D) (64).

Nonpharmacological overview
15. Nonpharmacological strategies with active patient participation should be an integral component of the therapeutic plan for the management of FM (level 1 (28,59), grade A). Encouraging self-efficacy and social support will facilitate the practice of health promoting lifestyles (level 3 (60,61), grade D).
16. Individuals with FM should be encouraged to pursue as normal a life pattern as possible, using pacing and/or graded incremental activity to maintain or improve function (level 4, grade D) (62,63).

Psychological interventions
17. The attainment of effective coping skills and promotion of self-management can be facilitated by multicomponent therapy (level 5, grade D) (59).
18. Interventions that improve self-efficacy should be encouraged to help patients cope with symptoms of FM (level 1, grade A) (64).
19. Psychological evaluation and/or counseling may be helpful for persons with FM in view of the associated psychological distress (level 5, consensus), and patients should be encouraged to acknowledge this distress when present and be informed about the negative impact this may have on well-being (level 3, grade D) (65).
20. Cognitive behavioural therapy, even for a short time, is useful and can help reduce fear of pain and fear of activity (level 1 (66,67), grade A).

Physical activity
21. Individuals with FM should participate in a graduated exercise program of their choosing to obtain global health benefits and probable effects on FM symptoms (level 1, grade A) (68-74).

Complementary and alternative medicine
22. Patients should be informed that there is currently insufficient evidence to support the recommendation of complimentary and alternative medicine treatments for the management of FM symptoms because they have mostly not been adequately evaluated regarding benefit (level 1, grade A) (75-77).
23. Patients should be encouraged to disclose use of complimentary and alternative medicines to the health care professional, who should be understanding and tolerant of this disclosure and should provide information on current evidence-based understanding of efficacy and risks where available (level 5, consensus).

Pharmacological overview
24. Physicians should identify the most bothersome symptom(s) to help direct pharmacological treatments according to a symptom-based approach. An ideal pharmacological choice may address multiple symptoms simultaneously and may require a combination of medications, in which case attention must be paid to drug interactions (level 5 (16,27), grade D).
25. Pharmacological treatments should be initiated in low doses with gradual and cautious upward titration to reduce medication intolerance (level 5, grade D) (27) with regular evaluation regarding continued efficacy and side effect profile, with the knowledge that drug side effects may appear similar to symptoms of FM (level 5, consensus).
26. Physicians prescribing medications for FM should be open-minded and aware of the broader spectrum of agents available to treat symptoms, and should not confine treatments to a single category of medications (level 5, consensus).

Traditional pain-relieving therapies
27. Consistent with the WHO step-up analgesic ladder, acetaminophen may be useful in some patients, but with attention to safe dosing (level 5, consensus).
28. In the event that nonsteroidal anti-inflammatory drugs are prescribed, particularly for associated conditions such as osteoarthritis, they should be used in the lowest dose and for the shortest possible period of time, in view of potential serious adverse events (level 5, grade D) (78,79).
29. A trial of opioids, beginning with a weak opioid, such as tramadol, should be reserved for treatment of patients with moderate to severe pain that is unresponsive to other treatment modalities (level 2, grade D) (80,81).
30. Strong opioid use is discouraged, and patients who continue to use opioids should show improved pain and function. Health care professionals must monitor for continued efficacy, side effects or evidence of aberrant drug behaviours (level 5, grade D) (82).

Nontraditional pain-relieving therapies
31. A trial of a prescribed pharmacological cannabinoid may be considered in a patient with FM, particularly in the setting of important sleep disturbance (level 3, grade C) (83-85).
32. The pain-modulating effects of antidepressant medications should be explained to patients with FM to dispel the concept of a primarily psychological complaint (level 5, grade D) (86).
33. All categories of antidepressant medications including tricyclic antidepressants, selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors may be used for treatment of pain and other symptoms in patients with FM (level 1, grade A) (87,88), with choice driven by available evidence for efficacy, physician knowledge, patient characteristics and attention to side effect profile (level 5, consensus).
34. Anticonvulsant medication use should be explained as having pain-modulating properties and treatment should begin with the lowest possible dose followed by up-titration, with attention to adverse events (level 1, grade A) (89-91).
35. Physicians should be aware that only pregabalin and duloxetine have Health Canada approval for management of FM symptoms and all other pharmacological treatments constitute ‘off label use’ (level 5, consensus).
**Practice recommendations for FM: Section 3**

**The outcome**

**Patient follow-up**

36. Clinical follow-up should be dependent on the judgement of the physician or health care team, with more frequent visits likely during the initial phase of management or until symptoms are stabilized (level 5, consensus).

37. In the continued care of a patient with FM, the development of a new symptom requires clinical evaluation to ensure that symptoms are not due to some other medical illness (level 5, consensus).

38. Patients should be informed that the outcome in many individuals is favourable even if symptoms of FM tend to increase and decrease over time (level 3, grade B) (92-94).

39. Patients who have experienced previous adverse lifetime events that have impacted on psychological well-being and have not been effectively addressed should be offered appropriate support to facilitate attaining health-related outcome goals (level 5, consensus).

40. Physicians should be alert that factors such as passivity, poor internal locus of control and prominent mood disorder may have a negative influence on outcome (level 5, consensus).

**Outcome tools**

41. Outcome can be measured by narrative report of symptom status or patient global impression of change, without need for more complex questionnaires (level 3, grade C) (36,37).

42. Tender point examination should not be used as an outcome measure (level 3, grade C) (39).

43. Patient goals and their levels of achievement should be recorded as a useful strategy to follow outcome (level 5, consensus).

44. Physicians should encourage patients to remain in the workforce and, if necessary, may provide recommendations that could help maintain optimal productivity because outcome is generally more favourable for those who are employed (level 3, grade C) (95).

45. Patients with FM on a prolonged sick leave should be encouraged to participate in an appropriate rehabilitation program with focus on improving function, including return to work if possible (level 5, grade D) (42).

46. In persons with FM, other comorbid conditions including depression should be recognized and addressed to reduce health care costs (level 3, grade C) (86,97).

**REFERENCES**


95. 2012 Canadian Fibromyalgia Guidelines