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REVIEW ARTICLE

Fibromyalgia diagnosis and diagnostic criteria

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Abstract

Criteria for fibromyalgia developed from the conceptualization and hypotheses of Smythe and Moldofsky in 1977 and gradually evolved to a set of classification criteria endorsed by the American College of Rheumatology that emphasized tender points and widespread pain, measures of decreased pain threshold. In 2010, American College of Rheumatology fibromyalgia diagnostic criteria were published that abandoned the tender point count and placed increased emphasis of patient symptoms. The 2010 criteria also contained severity scales and offered physicians the opportunity to assess polysymptomatic distress on a continuous scale. This enabled physicians who were opposed to the idea of fibromyalgia to also assess and diagnose patients using an alternative nomenclature.

Key words: *Criteria, diagnosis, fibromyalgia*

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There are several approaches to the diagnosis and classification of fibromyalgia (chronic widespread pain without organic disease sufficient to explain observed symptoms): 1) One may rely on the 1990 American College of Rheumatology (ACR) classification criteria that emphasize pain (tenderness) on pressure at specific anatomical sites (1) (Figure 1); 2) One may utilize the ACR 2010 criteria that depend on patient report of the location and extent of pain together with distress symptoms (2); 3) One may consider fibromyalgia as a manifestation of a group of functional somatic syndromes (FSS) (3), bypassing the concept of fibromyalgia entirely; 4) Finally, one may refuse to diagnose fibromyalgia, considering it to be a non-disease, an illegitimate disorder, and assess and treat symptoms without a formal diagnosis. Recent advances in fibromyalgia criteria and assessment (2) allow different approaches to this controversial syndrome.

The development of the fibromyalgia concept

Fibromyalgia and fatigue-like illnesses can be identified as early as the nineteenth century (4–7), and sporadic descriptions of fibromyalgia (8–11) can be found through the 1960s. The modern concept of fibromyalgia syndrome arose in the 1970s to characterize a common group of patients, mostly middle-aged women, who had high levels of pain, multiple complaints, sleep disturbance, psychiatric symptoms, and a generally decreased threshold to painful stimuli. Such patients are common in general medicine and represent about 2% of the general population (12). Scientific investigations of fibromyalgia first began in the early 1980s. At that time fibromyalgia was variously proposed as a psychiatric disorder (‘psychogenic rheumatism’), a muscle disorder, a sleep disorder, and a generally hyperirritable state.

The modern construct of fibromyalgia arose from a single article in 1977 by Smythe and Moldofsky entitled ‘Two contributions to the understanding of the “fibrositis” syndrome’ (13), although a similar description had been published previously (9). Moldofsky and Smythe identified the characteristics of the syndrome, then called ‘fibrositis’, and proposed criteria based on what they saw as its key features: non-refreshing sleep and tender points.

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Key messages

- The 1990 American College of Rheumatology criteria for the classification of fibromyalgia depended primarily on the physical examination of tender points.
- The 2010 American College of Rheumatology preliminary diagnostic criteria, which abandoned the tender point count, is based on the number of painful body regions and the presence and severity of fatigue, unrefreshed sleep, cognitive difficulty, and the extent of somatic symptoms.
- The 2010 criteria contains a symptom severity scale that allows quantification of fibromyalgia-type symptom severity that can also be used in lieu of a fibromyalgia diagnosis for those uncomfortable with the fibromyalgia concept.

Tender points were defined as pre-specified points on the body that, in persons with the syndrome, were particularly sensitive to pressure. The presence of 'widespread aching for longer than three months' and 'disturbed sleep with morning fatigue and stiffness' was also a requirement in these criteria. Decreased pain threshold was measured by a count of tender points.

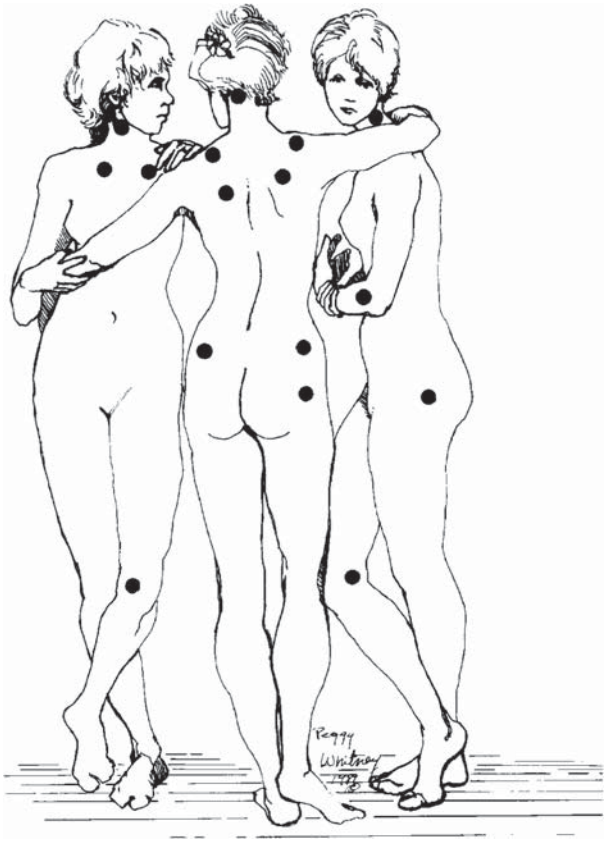

Figure 1. Tender point locations for the American College of Rheumatology 1990 criteria for the classification of fibromyalgia.

Abbreviations

ACR	American College of Rheumatology
CWP	chronic widespread pain
FSS	functional somatic syndromes
ICD	International Classification of Disease
NIH	National Institutes of Health
SS	Symptom Severity scale
WPI	Widespread Pain Index

'Two contributions' was published in the *Bulletin of the Rheumatic Diseases*, a non-peer reviewed four-page bulletin that was mailed to North American general practitioners and rheumatologists by the US Arthritis Foundation. It appears to have been widely read by North American rheumatologists, and this fact may explain why fibromyalgia arose as a 'rheumatic' disorder rather than a pain, orthopedic, or psychiatric disorder.

The 1977 criteria had a number of limitations. Although they required the presence of unrefreshed sleep, fatigue, and widespread aching, no definition or method of ascertainment was proposed for these features. By contrast, the tender point count was explicitly defined, and the number of tender points required noted exactly. As a consequence, the non-tender point features were often, perhaps generally, ignored and fibromyalgia was seen by rheumatologists to be essentially a disorder of decreased pain threshold. The importance of the Smythe–Moldofsky criteria cannot be over-estimated: they provided the first measure of quantification for what had up to then been an amorphous set of symptoms. Theirs was the seminal work in the birth of fibromyalgia.

Tender points rapidly became the central diagnostic feature of the syndrome. Smythe and Moldofsky required tenderness at 12 of 14 anatomic sites (86%) to be positive for tenderness. However, in practice this level of tenderness was rare, and investigators modified the criteria to use fewer tender points. Bennett in 1981 suggested 10 of 25 sites (40%) (14); Goldenberg required 6 tender points (15,16), and Wolfe had criteria that needed 7 of Smythe and Moldofsky's original 14 sites (50%). Other investigators ranged between 29% and 79% of sites examined (17). If each investigator examined patients in the same way, the different criteria would have led to patients with different characteristics being diagnosed with fibromyalgia. Although not formally studied, most patients diagnosed with fibromyalgia had very similar characteristics. This suggested that the examinations that used differing criteria were not being done in a similar way. One possibility for the

apparent agreement seen was that the examiners were getting clues from patient's symptoms and behavioral characteristics and were influenced by these characteristics to alter their examinations. A second possibility was that some examiners used more physical force and some used less physical force in performing the examinations. The reduction in the number of tender points required for diagnosis by the various ad-hoc criteria cited above reflected an appreciation that the number of tender points suggested by Smythe and Moldofsky was too stringent, and persons with ≥ 12 (of 14) tender points were only rarely found in clinical practice (18).

If the Smyth–Moldofsky criteria and the ad-hoc criteria that followed were measures of decreased pain threshold, criteria introduced by Yunus et al. tapped into a different vein: symptoms (19). In 1981 Yunus et al. introduced a formal set of criteria (19) as opposed to the ad-hoc criteria used by the above authors. They required aching and pain or stiffness in three anatomical areas for at least 3 months AND the presence of at least five tender points. In addition, patients had to have three of the following symptoms: modulation of symptoms by physical activity, modulation of symptoms by weather factors, aggravation of symptoms by anxiety or stress, poor sleep, general fatigue or tiredness, anxiety, chronic headache, irritable bowel syndrome, subjective swelling, or numbness. If there were only three to four tender points positive, then five of the symptoms from the symptom list were required. With these criteria, there was a relative de-emphasis on reduced pain threshold and a greater emphasis on the importance of symptoms, a set of symptoms that were often considered to be associated with psychiatric illness.

By the late 1980s there were many different formal and ad-hoc criteria sets. There was no clear agreement on which tender point sites should be examined or how they should be examined, nor how many sites had to be tender for a positive examination. Similarly, the format and content of symptom questions was unknown. Both in the clinic and in research settings, the reliability and validity of the available criteria was not known.

The number of tender points necessary for diagnosis was investigated in the signal 1990 American College of Rheumatology (ACR) fibromyalgia criteria study (1). In that study, $\geq 11/18$ tender points were required for diagnosis. To manage examiner heterogeneity, training sessions were undertaken so that each of the 22 study physicians would examine patients in the same way. In addition, a rule was proposed: that 4 kg of force be the amount of force exerted by the palpating finger or thumb (1). In unpublished data from the criteria study, we noted that prior to the training session different examiners used substantially different amounts of force, but that even though examiner variance decreased during the study it was still quite noticeable. That is, even among trained experts there was considerable variability in the performance of the tender point examination.

With that as background, a consortium of investigators undertook a criteria study that would ultimately lead to the promulgation of the 1990 American College of Rheumatology (ACR) classification criteria for fibromyalgia (1). A team of 22 rheumatologists served as volunteer investigators. Each contributed from their practice 10 patients with fibromyalgia, 10 with fibromyalgia and rheumatoid arthritis, 10 patients who did not have fibromyalgia but who had other rheumatic conditions involving pain (e.g. osteoarthritis, low back pain), and the last 10 were rheumatoid arthritis patients without fibromyalgia. Each patient underwent a tender point examination that included many tender point sites, including those known not to be sensitive to pressure (20–22). In addition, patients were evaluated for different symptoms of fibromyalgia, including those of the Yunus criteria (19). Investigators underwent a training session so that the tender point examination was performed the same way by each investigator.

There were a number of goals to the study. How many tender points should be examined? What number of tender points was required? What other variables could or should contribute to diagnosis? Did the criteria work in secondary or concomitant fibromyalgia, secondary or primary fibromyalgia being fibromyalgia in the presence of other rheumatic disorders? Was there any difference between primary and secondary fibromyalgia with respect to criteria? Based on comparing patients with similar but non-fibromyalgia pain complaints, the ACR committee proposed that the presence of widespread pain combined with at least 11 of 18 tender points (61%) best separated patients with fibromyalgia and controls, and should be the classification criteria for fibromyalgia (Table I). The selection of tender point sites was based on data generated in the 1990 criteria study, but also on the need to have tender points in all areas of the body. In fact, it was virtually impossible to achieve the required 11 tender points without involvement of the lower section of the body. Initially intended for research purposes, the criteria were widely used in clinical diagnosis, particularly among specialists. The endorsement by the American College of Rheumatology aided in establishing fibromyalgia as a respectable clinical diagnosis.

The 1990 criteria were very important in establishing that decreased pain threshold was the predominant identifier of fibromyalgia. The criteria also established the concept of 'chronic widespread pain' (CWP). The ACR criteria defined CWP as

Table I. The 1990 American College of Rheumatology criteria for the classification fibromyalgia (3).

1. History of widespread pain
   Definition. Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. 'Low back' pain is considered lower segment pain.
2. Pain in 11 of 18 tender point sites on digital palpation
   Definition. Pain, on digital palpation, must be present in at least 11 of the following 18 sites:
   Occiput: Bilateral, at the suboccipital muscle insertions.
   Low cervical: bilateral, at the anterior aspects of the intertransverse spaces at C5–C7.
   Trapezius: bilateral, at the mid-point of the upper border.
   Supraspinatus: bilateral, at origins, above the scapula spine near the medial border.
   Second rib: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces.
   Lateral epicondyle: bilateral, 2 cm distal to the epicondyles.
   Gluteal: bilateral, in upper outer quadrants of buttocks in anterior fold of muscle.
   Greater trochanter: bilateral, posterior to the trochanteric prominence.
   Knee: bilateral, at the medial fat pad proximal to the joint line.
   Digital palpation should be performed with an approximate force of 4 kg.

For a tender point to be considered 'positive' the subject must state that the palpation was painful. 'Tender' is not to be considered 'painful'.
For classification purposes, patients will be said to have fibromyalgia if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second clinical disorder does not exclude the diagnosis of fibromyalgia.

pain above the waist, pain below the waist, pain on both sides of the body, and pain involving the axial skeleton. To be 'chronic', pain had to be present for at least 3 months.

The ACR 1990 criteria and the growth of fibromyalgia

The criteria study investigators did not foresee the consequences of their work. The subsequent endorsement of the criteria by the American College of Rheumatology (ACR) brought official recognition to fibromyalgia (1). Prior to this imprimatur, the condition was generally disparaged and ignored by organized medicine, the National Institutes of Health (NIH), and physicians generally. In the years that followed the certification of the criteria by the ACR, fibromyalgia received an International Classification of Disease (ICD) code, international recognition as a source of disability, funding resources from the NIH, and academic recognition. The ACR criteria acceptance went far to legitimize the syndrome. Patient groups sprang up and multiplied. Political pressure on behalf of fibromyalgia and those who had it became widespread. Scientific studies into the mechanism of fibromyalgia expanded. With the approval of drugs for the treatment of fibromyalgia, there was a vast, if self-serving, dissemination of information to the general public by the pharmaceutical industry, as well as support for pro-fibromyalgia educational and political activities. In a 25-year period, fibromyalgia had expanded from the clinical observations of a few investigators to become one of the most commonly recognized pain and rheumatic disorders.

Criticism of the concept of fibromyalgia

The 1990 criteria also attracted vigorous criticism. Although the central tenet of the criticism was that fibromyalgia was not a valid medical disorder, a criticism that would be repeated over and again in the next two decades (23–26), the initial attack was formulated in terms of criteria criticism. Critics argued that the criteria were circular (27,28). That is, since the investigators knew of and believed the Smythe–Moldofsky criteria (13), and the investigators provided the fibromyalgia patients, how could they fail to find that the components of the Smythe–Moldofsky definition were not the most important criteria items?

Another attack on the fibromyalgia concept developed from studies that followed the ACR 1990 criteria publication. These studies indicated that the central features of fibromyalgia were also found in illnesses such as chronic fatigue syndrome, irritable bowel syndrome, headache syndromes, and multiple chemical sensitivities, among many others (29). The symptom contents of the syndromes were very similar, as were the treatments and the demographic characteristics of patients who have the disorders. Taken together, the syndromes have been called functional somatic syndromes (FSS) (3), and it has been suggested by many that a single diagnostic term, rather than individual syndrome names, should be used for diagnosis (30–32). Other encompassing terms that have been suggested include functional somatic syndromes and bodily pain disorder (32). In addition, many physicians doubted the existence of fibromyalgia as a separate entity, considering instead that it was primarily a psychological illness—not a

'real disease' (5,33–35). Patients with fibromyalgia symptoms are labeled with the diagnoses somatoform pain disorder (29) or affective disorder (15) by psychiatrists. Epidemiological and clinical studies gave no support to the idea that fibromyalgia is a distinct entity (36–38). However, within the general population a cluster of persons with high levels of biopsychosocial distress could be identified which met the survey criteria of fibromyalgia (39).

Others criticized the idea of fibromyalgia as a separate disorder by pointing out that fibromyalgia lies at the extreme end of the spectrum of polysymptomatic distress (25,35), where fibromyalgia diagnosis depends on splitting the distress continuum, placing on one side of the divide those with fibromyalgia and on the other side all other persons. In the 1990 ACR criteria, the dividing point is represented by a combination of tender points and widespread pain. But all patients with polysymptomatic distress who have less than 11 tender points are not considered, including those, for example, with 10 tender points who also have very high levels of distress. This criticism asserts that it is more sensible to consider polysymptomatic distress as a continuous variable than artificially to divide the spectrum into fibromyalgia-positive and fibromyalgia-negative patients.

Fibromyalgia was also criticized for being a socially constructed (40,41), medicalized disorder (42) in which medicalization is driven primarily by three components. The first is the primary need for patients with fibromyalgia and other functional somatic syndromes for legitimization: others need to understand that the problem is real and serious, and not primarily a psychosomatic illness (25). The diagnosis of a 'valid' fibromyalgia provides entry to medical insurance and treatment and is grounds for work disability and pension. Extensive networks of patient organizations throughout the world work toward this purpose (25). The second pillar of medicalization in fibromyalgia is the pharmaceutical industry (43). Direct-to-patient advertising is ubiquitous and seeks to expand the definition of fibromyalgia, entice persons with pain and fatigue into the diagnosis, and strongly promote its treatments as effective (43). The industry financially supports patient and professional organizations, medical education and symposia (25,44), and advertising in professional and lay journals. Almost all major authors of fibromyalgia drug studies have received pharmaceutical company support. The influence of drug companies has increased dramatically in the last two decades to the extent that '… companies are having an increasing impact on the boundaries of the normal and the pathological, becoming active agents of social control' (41). Although 'medicalization is now more driven by commercial and market interests than by professional claims-makers' (41), physicians and professional organizations remain the important sources of scientific support; and National Institutes of Health (NIH) grants for fibromyalgia research have become common.

Criticism of the 1990 criteria items

A number of practical concerns arose about the tender point examination. First, in the 20 years of use after the publication of the 1990 criteria, it became clear that the tender point examination was often not performed by generalists or was performed incorrectly. In particular, the cervical spine tender points were extremely difficult to examine properly without extensive training. Second, not only was 4 kg of force not widely observed during the ACR criteria study, but measurement of force exerted was virtually impossible in clinical practice. Overall, the examination of tender points was unreliable. Efforts to better standardization of tender points were made, but were only suitable for research environments (45).

The 1990 criteria did not deal adequately with patients who once met 1990 criteria but for reasons of improvement or measurement error now failed to satisfy the criteria, a condition found in about 30% of patients previously diagnosed with fibromyalgia (2). Did these patients have fibromyalgia? This problem arose because positive fibromyalgia diagnosis was based on symptom severity.

Finally, by concentrating on tender points, the 1990 criteria ignored other key symptoms of the disorder.

Revised ACR criteria: American College of Rheumatology 2010 preliminary diagnostic criteria

The 2010 criteria (Table II) addressed a number of problems with the 1990 criteria. They eliminated the tender point count, a physical examination item, substituting the widespread pain index, a 0–19 count of the number of body regions reported as painful by the patient. In addition, the 2010 criteria assessed on a 0–3 severity scale a series of symptoms that were characteristic of fibromyalgia: fatigue, non-refreshed sleep, cognitive problems, and the extent of somatic symptom reporting. The items were combined into a 0–12 Symptom Severity (SS) scale. Finally, as suggested later (46), the Widespread Pain Index (WPI) and SS scales could be combined into a 0–31 fibromyalgianess scale, a second measure of polysymptomatic distress. Thus, it was possible to diagnose

Table II. The American College of Rheumatology 2010 preliminary diagnostic criteria for fibromyalgia (2).

The American College of Rheumatology 2010 preliminary diagnostic criteria for fibromyalgia

Criteria:

A patient satisfies diagnostic criteria for fibromyalgia if the following three conditions are met:

1) Widespread Pain Index ≥ 7 and Symptom Severity Score ≥ 5 or Widespread Pain Index between 3 and 6 and Symptom Severity Score ≥ 9
2) Symptoms have been present at a similar level for at least 3 months
3) The patient does not have a disorder that would otherwise explain the pain

Ascertainment:

1) Widespread Pain Index (WPI): Note the number areas in which the patient has had pain over the last week. In how many areas has the patient had pain? Score will be between 0 and 19:

Shoulder girdle, Lt	Hip (buttock, trochanter), Lt	Jaw, Lt	Upper back
Shoulder girdle, Rt	Hip (buttock, trochanter), Rt	Jaw, Rt	Lower back
Upper arm, Lt	Upper leg, Lt	Chest Neck	
Upper arm, Rt	Upper leg, Rt	Abdomen	
Lower arm, Lt	Lower leg, Lt		
Lower arm, Rt	Lower leg, Rt		

2) Symptom Severity Score:
   Fatigue
   Waking unrefreshed
   Cognitive symptoms

For the each of the three symptoms above, indicate the level of severity over the past week using the following scale:

0 = No problem
1 = Slight or mild problems: generally mild or intermittent
2 = Moderate: considerable problems, often present and/or at a moderate level
3 = Severe: pervasive, continuous, life-disturbing problems

Considering somatic symptoms[a] in general, indicate whether the patient has:

0 = No symptoms
1 = Few symptoms
2 = A moderate number
3 = A great deal of symptoms

The Symptom Severity Score is the sum of the severity of the three symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the extent (severity) of somatic symptoms in general. The final score is between 0 and 12.

[a]For reference purposes, here is a list of somatic symptoms that might be considered: muscle pain, irritable bowel syndrome, fatigue/tiredness, problems thinking or remembering, muscle weakness, headache, pain/cramps in abdomen, numbness/tingling, dizziness, insomnia, depression, constipation, pain in upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, diarrhea, dry mouth, itching, wheezing, Raynaud's, hives/welts, ringing in ears, vomiting, heartburn, oral ulcers, loss/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, hearing difficulties, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms.

fibromyalgia or simply to measure polysymptomatic distress—for those who did not wish to treat a continuous spectrum disorder as a dichotomous condition. Finally, the polysymptomatic distress scales allowed assessment of the degree of distress in criteria-positive and criteria-negative patients. The polysymptomatic distress scales could be used on patients with any medical condition, and measurement for diagnosis of fibromyalgia was not a requirement.

But the 2010 criteria imposed some burdens on the examiner. The SS scale items requires a detailed and thoughtful interview of the patient, and the WPI scale also requires a detailed assessment. The criteria committee considered that the diagnosis of a symptom severity disorder should require more than an 'augenblick' diagnosis. Instructions, a Criteria Worksheet, and a Patient Pain Location Report are available on-line as an aid to ACR 2010 assessments (www.arthritis-research.org/research/fibromyalgia-criteria).

Limitations of the ACR 2010 criteria

Symptom assessment by physicians is inherently subjective. While the committee realized that validated questionnaires were available to assess these symptoms, it was also clear that such questionnaires would almost never be used in the primary care setting. Given the reliability problems of a tender point count, a detailed physician interview seems like a good alternative.

Assessment by self-report

A diagnosis of fibromyalgia can provide entrée to the medical care and disability setting. The committee was wary of allowing self-diagnosis. The

2010 criteria always require an examiner's assessment and should never be defaulted to patient self-report. Self-report questionnaires can be used to gather information about fatigue, non-refreshed sleep, cognitive problems, and the extent of somatic symptom reporting, but the interpretation and assessment of questionnaire validity belongs to the physician.

Despite the admonition against self-diagnosis, it would be desirable to be able to assess diagnosis and severity by self-report in clinical and survey research. A modification of the 2010 criteria has been published that allows assessment by self-report (47). These modified criteria are invalid for diagnosis in the individual patient. They should never be used for individual diagnosis.

In summary, criteria for fibromyalgia developed from the hypotheses of Smythe and Moldofsky (13) and gradually evolved to a set of classification criteria (1) that emphasized tender points and widespread pain, measures of decreased pain threshold. In 2010, fibromyalgia diagnostic criteria were published that abandoned the tender point count and placed increased emphasis on patient symptoms. The 2010 criteria also offered the opportunity to assess polysymptomatic distress on a continuous scale. This enabled physicians who were opposed to the idea of fibromyalgia to assess and diagnose patients using a different nomenclature.

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