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Pain That Exists Before the Test

Pain distribution and symptom burden can support a positive fibromyalgia judgment, but no single score or test establishes cause, truthfulness, or the patient’s whole condition. Eight articles connect criteria, measurement, daily change, clinical boundaries, and the next longitudinal study.

Reading order

From the editors

When fibromyalgia is discussed, the phrase “it does not show up on a test” is often made to do too much. This issue first separates the tools used to observe pain distribution, fatigue, waking unrefreshed, cognitive difficulty, and functional impact. An explicit symptom pattern can support a positive judgment without a definitive biomarker. Yet meeting criteria does not establish a particular pathophysiology, the absence of other illness, whether pain is genuine, or the whole condition of one person.

Measurements therefore cannot substitute for one another. When self-report, quantitative sensory testing, sleep records, and function questionnaires do not move together, the task is not to choose one as the “truth” but to preserve differences in observation window, test conditions, sample, and context. The next study should place symptom events, sleep, activity, seven-day function summaries, infrequent sensory tests, and treatment context on one timeline without collapsing them into one value.

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Pain That Exists Before the Test

Read the 1990, 2010, and 2016 editions of the fibromyalgia criteria in sequence, and a shift becomes visible: diagnosis moved from a single tender-point threshold toward a combination of pain distribution and fatigue, sleep, and cognitive symptoms. Placing quantitative sensory testing and a functional questionnaire alongside those criteria reveals a more important distinction. Symptom pattern, response to an evoked stimulus, and impact on daily life are different layers of measurement. Distinguishing and assessing them makes it possible to identify fibromyalgia positively without a definitive biomarker. That judgment, however, does not establish the biological mechanism of pain, the absence of other conditions, or the whole of a patient's condition.

Abstract

This article compares the 1990, 2010, and 2016 American College of Rheumatology fibromyalgia criteria with studies of quantitative sensory testing and the Revised Fibromyalgia Impact Questionnaire. The 1990 criteria combined widespread pain with tenderness at 11 or more of 18 sites; the 2010 criteria replaced that requirement with a combination of painful-site count and symptom severity; and the 2016 revision added generalized pain in four of five regions. This genealogy shows how a prespecified clinical pattern can support a positive judgment without a definitive biomarker. Meeting the criteria, however, does not establish pathophysiologic mechanism, the absence of other conditions, or the patient's whole condition. Quantitative sensory testing records responses to evoked stimuli, while the FIQR records function, overall impact, and symptoms over the previous seven days; neither tool alone determines cause or establishes an individual's diagnosis.

The Question That Arises Before a Test Can Answer

The difficulty surrounding fibromyalgia often begins with the question, “What shows up on the test?” Yet the diagnostic criteria start by asking something else. How widely is pain distributed across the body? How long has it persisted? How severe are fatigue, unrefreshing sleep, and cognitive difficulties? When different generations of the American College of Rheumatology criteria are placed side by side, the diagnostic center of gravity is seen to lie not in a laboratory value but in the definition of a reproducible clinical pattern.[1, 2, 3]

This does not mean that fibromyalgia is “a label applied without doing any tests.” The 2016 revision explicitly states that possible diagnoses and comorbid conditions should be considered through history taking, physical examination, and testing as indicated before the criteria are applied.[3] Examination and

testing are needed to look for other causes and coexisting conditions. Their results, however, do not serve as a single biomarker specific to fibromyalgia.

The question therefore needs to be divided into four parts: “What clinical pattern meets fibromyalgia criteria?”, “How does the sensory system respond to an evoked stimulus?”, “How does that pattern affect daily functioning?”, and “What mechanism produced the pattern?” These are not the same question. Diagnostic criteria, quantitative sensory testing, and functional questionnaires can address the first three, respectively, but none resolves the last question on its own.[1, 2, 3, 4, 5]

What Was Compared, and How

This article compares three points in the history of the American College of Rheumatology criteria using the same fields. The original abstract of the 1990 multicenter committee article, the full text of the 2010 preliminary clinical diagnostic criteria, and the full text of the 2016 revisions were examined for intended use, definition of pain, required thresholds, duration, wording about coexisting conditions, and the authors' stated reasons for change.[1, 2, 3] A 2025 scoping review of 126 quantitative sensory testing studies and a 2009 validation study of the Revised Fibromyalgia Impact Questionnaire (FIQR) were then added to examine what diagnosis, evoked sensation, and functional impact each measure.[4, 5] The 2011 self-report modification that followed the 2010 criteria is discussed only to the extent that the 2016 paper explains how the two versions were brought together.

For the 1990 source, the original article's PubMed abstract was available, but the full text was outside the material examined here. Accordingly, this article uses only content stated directly in that abstract, including the sample, criterion wording, sensitivity and specificity, and conclusions about concomitant test abnormalities.[1] Full texts were available for the 2010 and 2016 criteria, the quantitative sensory testing review, and the FIQR study.[2, 3, 4, 5] The different study designs were not pooled as though they yielded a single effect size. Two commentaries on specific mechanistic theories were also left uncited and unsummarized because their original passages could not be verified.

1990: Pain Distribution and 18 Tender Points

The 1990 multicenter committee studied 293 patients with fibromyalgia and 265 controls, 558 people in all, and proposed research classification criteria. Trained assessors conducted interviews and examinations without knowing whether a participant belonged to the patient or control group. The criteria combined two elements: widespread pain, defined as axial pain, pain on both the left and right sides, and pain above and below the waist; and tenderness at 11 or more of 18 specified sites.[1]

The original article's key phrase was “tenderness at 11 or more of the 18 specific tender point sites.” The criterion did not simply count the places where a person reported pain. It turned tenderness evoked when an examiner pressed designated sites into a binary threshold. When widespread pain and this tender-point criterion were applied together, sensitivity was 88.4% and specificity was 81.1% in the study sample.[1]

Those values do not represent the accuracy of a biomarker. They describe how well the rule distinguished the fibromyalgia group assembled by the investigators from potentially confusable controls. The article itself called the rule “criteria for classification.” The criteria played a major role in creating relatively homogeneous groups for trials and research, but they did not directly detect a particular pathophysiology.[1, 2]

There was another important boundary. The 1990 article did not exclude a person solely because of concomitant radiographic or laboratory abnormalities, and it no longer separated primary fibromyalgia from fibromyalgia concomitant with another rheumatic disorder at the classification level.[1] From the outset, the criteria were not equivalent to an absolute choice between “fibromyalgia” and “another condition.”

Why the Tender-Point Count Was Removed from the Criteria

The 2010 revision did not arise from a declaration that tenderness was unimportant. The first reason given in the paper was feasibility. It noted that tender-point counts were “rarely performed in primary care” and added that, when they were performed, they were often done incorrectly. Some physicians did not know how to conduct the examination, and others did not perform it at all. Diagnosis in routine practice was already largely symptom based.[2]

The second reason was that the criteria needed to capture a broader phenomenon. Fatigue, cognitive symptoms, unrefreshing sleep, and the extent of multiple somatic symptoms, which the 1990 committee had not included, had come to be recognized as important features of fibromyalgia. Some researchers considered that placing tender points too far in the foreground could mistakenly connect the condition to a peripheral muscle abnormality and obscure the broader symptom burden experienced by patients.[2]

The third reason was the difficulty of representing a condition that changes over time. A patient whose symptoms or tender-point count decreased could fall below the 1990 threshold despite a previous fibromyalgia diagnosis. At the time of the 2010 study, about 25% of patients previously diagnosed with fibromyalgia did not currently meet the 1990 classification criteria. The cutoff of 11 was concise for classification, but blunt as a way to record improvement or worsening on a continuum.[2]

For that reason, the shorthand “abolition of tender points” does not capture the whole change. What disappeared was not physical examination itself, but the requirement that a count of 11 out of 18 sites determine the diagnosis. The 2010 authors wrote that every patient still required a physical examination and that tender areas could be examined when appropriate, even though the new criteria did not include a tender-point item.[2]

2010: Asking About the Extent of Pain and the Severity of Symptoms Together

The 2010 multicenter study developed new clinical diagnostic criteria in 829 patients previously diagnosed with fibromyalgia and controls. It used two axes in place of a tender-point count. The Widespread Pain Index (WPI) records, from 0 to 19, the number of body areas that were painful during the previous week. The Symptom Severity scale (SS) records, from 0 to 12, the combined severity of fatigue, unrefreshing sleep, cognitive symptoms, and somatic symptoms in general.[2]

The core rule was as follows: WPI of 7 or higher with SS of 5 or higher, or WPI of 3–6 with SS of 9 or higher. Symptoms had to persist at a similar level for at least three months, and this edition required that no disorder otherwise explain the pain.[2] The structure allowed a moderate symptom burden when pain involved very many areas, but required a high symptom burden when the number of painful areas was lower.

The rule classified 88.1% of cases classified by the 1990 criteria in the same category and did not require a physical examination or tender-point examination as criterion items.[2] But 88.1% is not agreement with a biological truth. The 2010 article acknowledged that fibromyalgia lacked objective physical or laboratory features and well-characterized pathological findings, and that no independent standard case definition was available for developing the criteria. The new rule was an empirical case definition based on the existing classification criteria and clinicians' judgments.

Even so, the change did not turn diagnosis into a residue left after exclusion. It required observable components, WPI and SS, together with explicit thresholds and duration. Negative findings on tests for other conditions are not enough to satisfy the criteria. The specified distribution of pain and symptom burden must be positively identified.[2]

Whether a diagnosis is present must also be distinguished from measuring its impact after diagnosis. The FIQR records 21 items across three domains—function, overall impact, and symptoms—over the previous seven days. Memory, tenderness, balance, and environmental sensitivity are included in the symptom domain.[5] The questionnaire structures the burden on daily life, but it neither replaces the fibromyalgia criteria nor determines cause.

In the 2009 validation study, 202 participants with fibromyalgia completed the FIQR online, and its three domains correlated with the corresponding domains of the earlier FIQ at coefficients of 0.69–0.88.[5] A focus group of 10 women patients contributed to item development by revising wording and content. This is one instance in which patient perspectives changed the measurement tool itself. The study, however, did not directly assess online test–retest reliability, included only 12 men, and did not estimate sensitivity to change or a minimal clinically important difference.[5] This single study should not be extended into a statement about the priorities of all patients or a fully validated measure of severity in every respect.

2016: Defining “Widespread Pain” More Precisely Again

As the 2010 and 2011 criteria were used in research and practice, a new problem appeared. The WPI counts painful sites but does not directly restrict how they are distributed across the body. Some localized or regional pain syndromes could therefore be classified as fibromyalgia when combined with a high symptom score. To address this problem, the 2016 revision added a “generalized pain” condition different from the 1990 definition.[3]

The 2016 formula is WPI of 7 or higher with Symptom Severity Scale (SSS) of 5 or higher, or WPI of 4–6 with SSS of 9 or higher. In addition, pain must be present in at least four of five regions: left upper, right upper, left lower, right lower, and axial. Jaw, chest, and abdominal pain count toward the WPI but are excluded when the generalized-pain condition is calculated. Symptoms must generally have been present for at least three months.[3]

Raising the minimum of the lower WPI range from 3 to 4 was not a separate arbitrary adjustment. Requiring pain in four regions makes a WPI of at least 4 necessary. The authors reported that this condition reduced misclassification of regional pain while making only a very small change to the existing 2010/2011 case definition. In the analyzed data, 0.4% of cases were reclassified by the condition.[3]

The 2016 edition also changed the wording of the exclusion condition. The original phrase “valid irrespective of other diagnoses” means that a fibromyalgia diagnosis remains valid regardless of other diagnoses. The paper then explicitly states that a fibromyalgia diagnosis does not exclude the presence of other clinically important illnesses.[3] This does not mean that differential diagnosis is unnecessary. It means that the presence of another condition should not erase a pattern that meets fibromyalgia criteria.

Figure 1. The 1990 criteria combined widespread pain with tenderness at 11 or more of 18 sites. The 2010 criteria replaced the required tender-point count with WPI and SS, and the 2016 revision added pain in four of five regions and clarified comorbidity. None establishes pathophysiologic mechanism.

What the Criteria Establish Positively

The absence of a definitive biomarker does not mean that a positive diagnosis is impossible. Here, “positive” does not mean a positive result on a particular test. It means determining whether a prespecified combination is present: the extent of pain, the severity of core symptoms, duration, and, in the 2016 edition, spatial distribution. Because a defined pattern must be present, this differs from making a diagnosis solely because other tests were negative. A self-scored threshold alone, however, must not be used to establish an individual's diagnosis. The 2016 article distinguishes physician-applied criteria, which are valid for individual diagnosis when used with medical evaluation, from the self-report version, which is intended for research and is not valid for an individual's clinical diagnosis.[2, 3]

The generational changes in the criteria reinforce this point. The 1990 criteria combined widespread pain with examiner-confirmed tenderness; the 2010 criteria combined the number of painful sites with the severity of several symptom domains; and the 2016 criteria again required spatial generalization. No edition defines fibromyalgia through a single symptom or through a “failure to find a cause” alone.[1, 2, 3]

WPI and SS/SSS record, within specified items and score ranges, the number of body areas painful during the previous week and symptoms such as fatigue, unrefreshing sleep, and cognitive difficulties. Applying these items with prespecified thresholds and duration makes it possible to judge whether the reported symptom pattern fits the criteria. This is not evidence that creates the pain; it is the organization of reported experience into the form addressed by the criteria.[2, 3]

Quantitative sensory testing observes another layer. It applies controlled mechanical or thermal stimuli and measures the responses, so its values are not the same as the WPI's count of painful sites during the previous week or the FIQR's account of daily impact.[2, 4, 5] The 2025 scoping review examined 126 studies using static and dynamic tests but reported that no protocol was followed consistently and that testing sites and types of tests varied.[4]

This heterogeneity does not make quantitative sensory testing worthless. It does limit comparisons across studies and application to an individual's diagnosis. The review authors also noted that inconsistency in testing sites and stimulus conditions may reduce its reliability as a biomarker for fibromyalgia.[4] A difference in evoked response is therefore an observation that can be studied, but it is not in itself a test that establishes fibromyalgia or judges whether a patient's reported pain is genuine.

What the Criteria Do Not Establish

First, meeting the criteria does not establish cause. WPI and SSS do not measure why pain arose or determine which of central sensitization, immune change, or autonomic change produced an individual's symptoms. The 1990 tender-point examination was not a test proving a particular peripheral muscle pathology either.[1, 2, 3] Quantitative sensory testing does not simply fill this gap. The 2025 review noted that temporal summation and conditioned pain modulation are often used as measures of central

sensitization, but that the peripheral nervous system also participates, so the parameters used to analyze sensitization need to be defined in each study.[4] The validity of diagnostic criteria, the nature of evoked sensory responses, and the validity of a mechanistic hypothesis are distinct research questions.

Second, meeting the criteria does not establish that no other condition is present. The 2016 wording specifically allows fibromyalgia and another clinically important condition to coexist. For a person being assessed for a new diagnosis, history, examination, and tests suited to the situation remain necessary to evaluate alternative explanations and comorbid conditions. Conversely, finding another condition or an abnormal test result should not automatically cancel a pattern that meets fibromyalgia criteria.[3]

Third, meeting the criteria does not summarize the whole of a patient's condition. The 2016 authors drew a clear boundary: satisfying the criteria cannot define the entirety of a person's medical status.[3] That is why tools such as the FIQR, which separately records function, overall impact, and symptoms, are needed.[5] Yet the FIQR structures self-report over the previous seven days; it is not a complete record of within-day variation, treatment response, comorbid conditions, or life context. Criteria and questionnaires are not the endpoint of care but a shared language with which more specific observation can begin.

The genealogy of the three editions and the two measurement studies leaves a restrained but clear conclusion. Fibromyalgia can be identified through an explicit symptom pattern without a single biomarker. Quantitative sensory testing and functional questionnaires do not replace that judgment as final tests; they observe evoked sensory responses and effects on daily life in greater detail. But this judgment alone does not guarantee a final pathophysiologic explanation or the absence of another condition. The next research question should not be “Is the pain real?” but “How can standardized sensory measures, functional indicators, and observation over time distinguish different trajectories among people who meet the same criteria?”[1, 2, 3, 4, 5]

Declarations

Data availability

This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

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The publishing organization originated at Baekrokdam Korean Medicine Clinic and has clinical and commercial interests. This article is not evidence for a particular diagnosis or treatment effect.

Ethics

Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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What the Absence of a Biomarker Does Not Mean

The absence of a definitive biomarker for fibromyalgia does not mean there is no basis for diagnosis. Nor does meeting symptom criteria mean that every aspect of a person's medical condition has been explained. The evidence assembled for this article calls for holding two principles at once: do not equate pain with a test result, and do not omit an evaluation for other possibilities and coexisting conditions at the time of initial diagnosis. Because a list of specific safety signals and differential diagnoses lies beyond the evidence available here, this article does not create one.

Abstract

This article distinguishes the absence of a definitive biomarker from the absence of a basis for clinical judgment. The 2010 and 2016 fibromyalgia criteria structure patterns of pain distribution, symptom burden, and duration, but they do not establish a sole cause or define the entirety of a patient's condition. An individual's initial diagnosis requires a full medical evaluation that considers other and coexisting diagnoses, and a conclusion may be deferred when symptoms have been brief, are changing, or remain unclear. The current evidence does not provide a list of specific safety signals, a universal differential, a test panel, or a treatment rule. Nor can a particular negative test or QST result establish, beyond the target of the test, that pain is absent, an individual diagnosis is settled, or care is unnecessary.

What Is Absent?

The 2010 American College of Rheumatology preliminary diagnostic criteria paper described a central problem in fibromyalgia criteria as the absence of a gold standard or definitive case definition. The new criteria were not a test validated against an independent biological marker to distinguish true cases from false ones. The criteria proposed in that paper combined the distribution of pain with symptom burden.[2]

What is missing, then, is an external standard that can confirm an individual's diagnosis with a single test value. What is not missing is clinical information that can be assessed systematically: the distribution of pain over the previous week, fatigue, unrefreshing sleep, cognitive symptoms, and the duration of symptoms.[2, 3] This information is not a set of measures that substitutes for a biomarker. It is a different kind of basis for judgment.

Missing this distinction produces errors in opposite directions. One is to say that no judgment is possible because there is no marker. The other is to say that a high symptom score establishes the cause and every coexisting condition. The current evidence supports neither conclusion.

Table 1. The Boundaries Between Biomarker Absence and Clinical Judgment

Observation or judgment	What this evidence supports	What it does not automatically mean	Judgment that remains
No definitive gold standard	Fibromyalgia criteria structure a clinical pattern of pain distribution, symptom burden, and duration.[2, 3]	It does not mean there is no basis for judgment, nor that symptom criteria establish a biological cause.	Interpret the clinical pattern together with the context of evaluation.
Criteria met	The specified clinical pattern fits the criteria.[3]	It does not establish the patient's entire condition, a sole cause, or the only or most important diagnosis.	Consider possible, alternative, and comorbid diagnoses together.
Another diagnosis or abnormal test finding	Another diagnosis or concomitant test abnormality does not automatically cancel the fibromyalgia pattern.[1, 3]	It does not mean that fibromyalgia excludes other clinically important illnesses.	Judge the meaning and importance of each condition in the patient's context.
Self-report criteria	They can be used in research.[3]	They do not independently establish an individual's clinical diagnosis.	Individual diagnosis requires physician-applied criteria and a full initial evaluation.
A particular negative test	Interpret its meaning in relation to what the test actually targeted.[2, 3]	The current evidence provides no general rule for interpreting negative results, and a negative result does not automatically prove that pain is absent or care is unnecessary.	Distinguish the scope of the test result from the scope of the full clinical judgment.
QST result	It records responses to controlled stimuli.[4]	It is not a definitive biomarker for an individual diagnosis or a verdict on whether pain is genuine.	Preserve the protocol, test site, test type, and patient context.

Read the same finding by separating what it says from what it does not automatically mean. The table does not provide specific safety signals, a differential-diagnosis list, a test panel, or treatment or referral rules.

What the Criteria Do and Do Not Do

The 2016 revised criteria ask whether pain is present in at least four of five body regions, whether the combination of the number of painful areas and symptom severity crosses specified thresholds, and whether symptoms have persisted at a generally similar level for at least three months.[3] This is a rule for identifying a recurring clinical pattern in a consistent way.

Meeting the rule means that the pattern a person reports fits the criteria. It does not show which molecule, organ, or neural pathway is the sole cause of that pattern. The criteria structure the person's account of pain and the symptom pattern, but they are not a device that directly measures every mechanism of pain.[2, 3]

The criteria therefore show both the basis for making a positive clinical judgment and the limits of what that judgment establishes. Identifying a clinical pattern is not the same as obtaining an independent biomarker. The first boundary is to recognize the diagnostic pattern without overstating mechanistic certainty.

Other Diagnoses Are Not an Exclusion List

The 2016 revision states that a diagnosis of fibromyalgia can be valid irrespective of other diagnoses and that it does not exclude the presence of other clinically important illnesses.[3] The 1990 classification study likewise did not treat concomitant radiographic or laboratory abnormalities as automatic grounds for exclusion.[1]

This separates two ideas. Finding another illness does not automatically cancel a fibromyalgia pattern. At the same time, meeting fibromyalgia criteria does not end the search for other illnesses. The principle that two diagnoses can coexist means that neither should be used to erase the other.[1, 3]

The revision paper also drew a boundary around what the criteria mean: satisfying them does not define the entirety of a patient's medical condition, nor does it mean that fibromyalgia is the only or most important diagnosis.[3] Deciding which problem matters most now and what else should be assessed belongs to an evaluation of the patient's full situation, not to the criteria sheet itself.

The Evaluation That Still Precedes an Initial Diagnosis

The 2010 study removed the required tender-point count from the diagnostic criteria but retained the position that every patient being diagnosed should have a physical examination.[2] “One test is no longer required” and “no examination is needed” are entirely different statements.

The 2016 revision made this boundary more explicit. When physician-applied criteria are used for an individual's initial diagnosis, they must be accompanied by a full medical evaluation. Essential medical and social information should be gathered; possible, alternative, and comorbid diagnoses should be considered; and the criteria should be applied after an interview, physical examination, and required laboratory studies as the situation calls for.[3]

The scope of that evaluation is not defined by applying the same panel of tests to everyone. The paper notes that the amount of new information to collect varies with the care setting, the patient, and the information already available.[3] The current evidence supports the need for a process of evaluation, but it does not provide a universal test panel or an ordered differential for every patient.

How Far Can We Go in Naming Safety Signals?

The question behind this article includes which safety signals should be checked. The direct evidence available here, however, does not enumerate specific warning symptoms, vital-sign thresholds, test abnormalities, criteria for emergency escalation, or conditions for specialty referral. Filling such a list from common knowledge or memory would create clinical guidance without a source.

The safety principle that can be stated from the evidence is narrower. Necessary information should be gathered before an initial diagnosis; alternative diagnoses and comorbid illnesses should be considered; and the fibromyalgia criteria alone should not be used to explain the patient's entire condition.[3] The criteria also allow diagnosis to be deferred when symptoms have lasted less than three months, are still changing, or remain unclear.[3]

This article therefore does not conclude that there are no safety signals. It says only that this evidence cannot responsibly supply a named list of them. What is urgent in clinical care and which differential diagnoses require attention must be judged in light of current symptoms, examination, existing information, and the purpose of testing. That last sentence is not a rule directing a particular test or referral; it marks the boundary of the judgment this material permits.

What a Negative Test Can Say

The meaning of a negative result must remain tied to what the test actually targeted. The current evidence does not provide an interpretive rule that applies to negative results in general, nor does it show that any one such result directly measures whether a patient is in pain. This limit follows from the structure of fibromyalgia criteria, which operate through pain distribution and symptom burden without an independent gold standard.[2, 3]

Quantitative sensory testing (QST) does not fill this gap at once. A 2025 scoping review included 126 of 2,512 records, but reported no consistent common protocol as well as variation in test sites and test types. The authors cautioned that this heterogeneity could affect the integration of results and the reliability of QST as a biomarker.[4]

A particular negative test therefore cannot be translated into “there is no pain,” and a particular QST result cannot serve as the final verdict on an individual's diagnosis.[2, 3, 4] Conversely, this article does not say that a negative test has no meaning. Its meaning must remain tied to the target of the test and must not be automatically expanded into a verdict on the existence of pain or the patient's entire medical condition.

Why “No Treatment Is Needed” Does Not Follow

The direct evidence available here addresses the composition and application boundaries of diagnostic criteria and the methodological heterogeneity of QST. It does not consist of treatment studies comparing the benefits, harms, or conditions of use of specific treatments.[2, 3, 4] This material alone therefore cannot determine that a particular treatment is needed, nor can a negative test determine that treatment is unnecessary.

Separating the role of test results from decisions about care makes the logic clear. This evidence concerns diagnostic criteria and measurement methods; it does not provide a rule for deriving the need for treatment or support from a test result. It therefore does not predetermine decisions about care.

The statement “this test is negative, so there is no pain and no treatment is needed” contains two leaps: from the test's target to the existence of pain as a whole, and then from the existence of pain to the need for treatment. The explanation permitted by the current evidence is more restrained: “This result provides information about what this test examined. It does not decide in place of the reported pain, the full evaluation, or the care that may be needed.”

An Explanation That Neither Denies Nor Overstates

When explaining the situation to a patient, the first sentence should not set the test result against the patient's experience. Even without a definitive biomarker, clinicians can structure the distribution of pain, accompanying symptoms, and duration to identify a clinical pattern.[2, 3] This is not a provisional phrase used merely to signal belief in pain. It accurately describes the kind of information the current criteria actually use.

The second sentence should state the ceiling of the judgment. Meeting the criteria does not establish a sole cause or every coexisting condition, and another diagnosis does not automatically erase the fibromyalgia pattern.[1, 3] A full evaluation is needed initially, and a conclusion can be deferred if symptoms have been brief, are changing, or remain unclear.[3]

The third sentence should narrow the scope of a negative test: “This result helps us understand what was tested, but it does not prove the absence of pain or that care is unnecessary.” Only then can what has been established, what remains unexplained, and what context is needed for further judgment be separated. This explanation neither rushes to diagnosis nor cancels experience. The conclusion of this article is that the space left by a missing biomarker should be filled by neither denial nor overstatement.

Declarations

Data availability
This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

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The Evidence Landscape of Fibromyalgia

In fibromyalgia research, widespread pain, unrefreshing sleep, fatigue, cognitive difficulties, functional impairment, and heightened responses to stimuli are often placed in the same sentence. But being observed together is not the same as being explained by a single cause. What the current evidence shows most consistently is that multiple symptoms and impacts are repeatedly measured. Agreement among measurements, the direction of change, and mechanisms that can be applied to an individual are far less certain.

Abstract

This article compares the 2010 and 2016 fibromyalgia criteria, a sleep-measurement study in adults with comorbid fibromyalgia and insomnia, an FIQR validation study, and a scoping review of QST. The evidence shows that widespread pain and the burden of sleep, fatigue, and cognitive symptoms are repeatedly assessed together, while function and responses to evoked stimuli form separate measurement layers. Sleep methods can produce different estimates, however; FIQR convergence is a group-level result between questionnaires; and QST protocols are highly heterogeneous. The current evidence therefore does not establish causal order among domains, a single mechanism, or an individual diagnostic biomarker. The next study needs to measure symptoms, sleep, activity and function, and sensory responses repeatedly in the same participants along a connected timeline.

Different Observations Under One Name

The single label “pain syndrome” is not enough to describe fibromyalgia. The 2010 American College of Rheumatology preliminary criteria combined the Widespread Pain Index (WPI), a count of painful areas during the previous week, with a Symptom Severity (SS) scale covering fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden. The 2016 revision retained this structure and added a requirement that pain be present in at least four of five regions.[1, 2]

This structure reflects the judgment that pain alone does not adequately represent the clinical pattern. But the inclusion of these domains in the same criteria does not establish that pain causes disrupted sleep, that fatigue causes cognitive difficulties, or that all of these phenomena arise from a single biological pathway. The criteria define which features and thresholds to assess together; they are not a study that tests a causal model linking those features.[1, 2]

The evidence landscape therefore has at least four layers: the symptom pattern assessed by the criteria; sleep as measured by sleep diaries, actigraphy, and polysomnography; the impact on daily life recorded by questionnaires; and responses to evoked stimuli measured by quantitative sensory testing.[1, 2, 3, 4, 5]

Even when applied to the same person, these layers answer different questions.

How to Read the Map

This article does not combine different forms of research into a single effect size. Two diagnostic-criteria papers show which combination of symptoms is classified as a fibromyalgia pattern.[1, 2] One sleep study compared three measurement methods in 113 adults with both fibromyalgia and insomnia.[3] A validation study examined the FIQR questionnaire structure of function, overall impact, and symptoms,[4] while a scoping review of quantitative sensory testing mapped the methods used in 126 studies.[5]

Here, “consistent” does not mean that every study proved the same mechanism. We need to distinguish whether multiple sources repeatedly measure the same phenomenon, whether corresponding scales converge within one study, and whether different methods produce the same values. Repeated inclusion of a domain in diagnostic criteria, correlation between two measurements, change after treatment, and individual diagnostic accuracy represent different levels of evidence.

The blank spaces are also part of the map. This evidence set contains no study that repeatedly measured all six domains in the same participants at the same intervals. It therefore cannot establish whether the domains improve or worsen together, which change comes first, or which combinations occur in which people.[1, 2, 3, 4, 5]

The Firmest Common Ground: Pain Distribution and Symptom Burden

In the 2010 criteria, the WPI records the number of 19 areas that were painful during the previous week, producing a score from 0 to 19. The SS scale records fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden on a scale from 0 to 12. The criteria required WPI ≥7 and SS ≥5, or WPI 3–6 and SS ≥9, with symptoms present at a similar level for at least three months.[1]

The 2016 revision combined WPI ≥7 and SSS ≥5, or WPI 4–6 and SSS ≥9, and added pain in at least four of five regions.[2] The recurring common ground across the two editions is that widely distributed pain and the burden of multiple symptoms are considered together. A single site of localized pain or one fatigue score alone does not define the fibromyalgia pattern.

The criteria themselves, however, were not tested against an independent biological standard. The 2010 paper noted that no independent gold-standard case definition existed when the fibromyalgia criteria were developed.[1] The 2016 authors also distinguished criteria applied by a physician as part of an overall medical evaluation from a self-report version intended for research. A self-scored result alone should not be used to establish an individual clinical diagnosis.[2]

Sleep, Fatigue, and Cognition: Assess Them Together Without Making Them the Same

Unrefreshing sleep, fatigue, and cognitive difficulties have been explicitly assessed together in the criteria since 2010.[1, 2] That is strong documentary consistency. Their contribution to the same score, however, does not make them interchangeable. Sleep duration, time awake after falling asleep, feeling refreshed in the morning, and daytime fatigue are different observations.

The sleep measurement study makes this difference concrete. The 113 adults with both insomnia and fibromyalgia underwent one night of polysomnography and two weeks of sleep-diary and actigraphy measurement. At baseline, the objective measures estimated shorter sleep-onset latency and greater total sleep time and sleep efficiency than the diaries did. Actigraphy and polysomnography also produced different estimates of sleep-onset latency and time awake during the night.[3]

The repeated-measures analysis included 15 participants from the cognitive behavioral therapy for insomnia group. In this small subset, diaries and actigraphy detected improvement in some sleep measures, while polysomnography did not detect a significant change.[3] This finding supports the conclusion that measurement methods may differ in their time windows and sensitivity to change, not that one method invariably reveals the “true value.” It cannot be generalized to every person with fibromyalgia who does not have insomnia or used to establish an individual's sleep mechanism.

Functional Impairment Asks a Different Question from Symptom Count

The Revised Fibromyalgia Impact Questionnaire (FIQR) records function, overall impact, and symptoms over the previous seven days in 21 items. Its symptom domain includes not only pain and fatigue but also memory, tenderness, balance, and environmental sensitivity.[4] This structure creates a place to record the fact that the same pain score can have different effects on work, mobility, and everyday tasks.

In the 2009 validation study, the three FIQR domains correlated 0.69–0.88 with the corresponding domains of the earlier FIQ.[4] This is group-level evidence that the new questionnaire's domains moved with the related domains of the earlier instrument. It does not mean that FIQR scores agree with sensory-testing results or polysomnography, nor does it identify the cause of functional impairment.

The validation also had limits. The study did not directly assess test-retest reliability among online participants, included only 12 male participants, and did not estimate responsiveness to change or a minimum clinically important difference.[4] A single total score can summarize the impact of the previous week, but it cannot stand in for variation within a day, worsening after activity, or a long-term trajectory of change.

The Laboratory Language of Sensory Amplification

Quantitative sensory testing (QST) applies controlled mechanical or thermal stimuli and measures the response.[5] This differs from counting self-reported painful areas with the WPI or asking about daily impact with the FIQR. Pain thresholds, responses to repeated stimuli, and inhibitory responses under a conditioning stimulus show how the sensory system responds under experimental conditions.

The 2025 scoping review screened 2,512 records and included 126 studies.[5] The number of studies shows that sensory response is an important research subject. But the review reported that common protocols were not used consistently and that test sites and modalities varied. This heterogeneity limits the synthesis of results across studies and the interpretation of QST as a fibromyalgia biomarker.[5]

Temporal summation and conditioned pain modulation are often linked to central sensitization, but the review noted that the peripheral nervous system also contributes to these measures and that each study must define the parameters used to analyze sensitization.[5] A heightened response observed at the group level is therefore an association worth studying, not a conclusion about an individual's cause of pain, diagnosis, or the validity of their symptoms.

Where the Evidence Overlaps and Where It Diverges

The points of overlap are clear. The clinical pattern of fibromyalgia is described more fully when sleep, fatigue, cognitive symptoms, and functional impact are recorded alongside widespread pain.[1, 2, 4] Sensory testing adds a separate observational layer: responses to evoked stimuli.[5]

The points of divergence are equally clear. In the sleep study, baseline estimates and detection of change differed by method;[3] the FIQR validation correlations represented group-level convergence between questionnaires;[4] and heterogeneity in QST protocols constrained biomarker interpretation.[5] None of these sources permits the conclusion that all six domains are joined by one mechanism within an individual.

Nor does disagreement among measurements invalidate any one experience. A diary records the night as experienced by the participant, actigraphy estimates sleep from movement, and polysomnography records physiological signals during one night.[3] FIQR and QST likewise record daily impact and responses to evoked stimuli, respectively.[4, 5] When values differ, the first question should be whether the methods measured the same target over the same time window.

The Spaces the Map Still Leaves Blank

The current evidence makes three points most reliably. Fibromyalgia criteria consider widespread pain together with the burden of sleep, fatigue, and cognitive symptoms.[1, 2] A functional questionnaire distinguishes symptoms from their impact on daily life.[4] QST measures responses to controlled stimuli,

but substantial methodological heterogeneity prevents a direct move from those results to a single biomarker or an individual's mechanism.[5]

The links among these domains are less certain. Differences among sleep measurement methods and correlations between questionnaire domains are group results from particular samples.[3, 4] This evidence cannot show the sequence in which pain distribution, sleep, fatigue, cognition, function, and sensory response change within the same person, or whether those trajectories distinguish subgroups.

The gap for the next study to fill is not another set of cross-sectional scores but a connected timeline. Symptom diaries, sleep, activity and function, and quantitative sensory testing need to be measured repeatedly in the same participants, with treatment and life context recorded alongside them. Only then can research move from a group-level map of what “occurs together” toward trajectories that show “what changes first, and for whom.” This is not a conclusion established by the current research. It is the next question derived from the gaps in the present evidence.[1, 2, 3, 4, 5]

Declarations

Data availability
This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

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Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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How Is Pain Measured?

Tools for measuring pain are not machines that read a single hidden “true pain value” in different ways. The Widespread Pain Index (WPI) asks where pain has occurred; the Symptom Severity Scale (SSS) asks which symptoms accompany pain and how burdensome they are; pressure pain threshold and quantitative sensory testing (QST) ask how a person responds to controlled stimuli; and functional scales ask how daily life has been affected over the past several days. When the same person is classified differently by different tools, the reason is not necessarily error. The questions, time windows, test sites, and decision rules differ.

Abstract

This article compares what the Widespread Pain Index (WPI), Symptom Severity Scale (SSS), pressure pain threshold (PPT), quantitative sensory testing (QST), and Revised Fibromyalgia Impact Questionnaire (FIQR) measure. WPI and SSS combine pain distribution over the previous week with the burden of accompanying symptoms; PPT and QST record responses under specified stimulus conditions; and FIQR asks about function, overall impact, and symptoms over the previous seven days. Because the constructs, time windows, test sites, protocols, and decision rules differ, the same person can be classified differently across tools. Such disagreement does not make one value false, and no tool by itself establishes the cause of pain, the validity of symptoms, a single mechanism, or an individual's diagnosis. The different measurement layers should be read together without being collapsed, and future studies need to apply them repeatedly to the same people.

Different Questions, Not One Number

The phrase “how severe is the pain?” blends together at least four questions: How many areas of the body are painful? How much burden comes from fatigue and sleep or cognitive symptoms? When does a specified stimulus become painful? How difficult does the condition make everyday tasks? WPI, SSS, QST, and FIQR divide these questions among them.[1, 2, 3, 4, 5, 6]

Their higher and lower values therefore cannot be placed directly on the same axis. A WPI score of 12, an FIQR function score, and a pressure pain threshold measured in kPa are not the same quantity expressed in different units. One counts the distribution of pain during the previous week, another asks about the impact on daily life over the previous seven days, and another records the point at which sensation becomes painful as pressure is applied at a specified rate to a particular site.[1, 5, 6]

Disagreement among tools should not automatically be read as failure. A person can have pain distributed across many areas, a high symptom burden, a low pressure pain threshold, and relatively preserved performance in some areas of function at the same time. These values do not cancel one another out; they preserve different views of what was observed.

Table 1. The Different Questions Asked by Fibromyalgia Measurement Tools

Tool or method	What does it ask?	Time window or test conditions	What does it produce?	What the result alone cannot establish
Widespread Pain Index (WPI)	How many areas of the body were painful?	The previous week; 19 painful areas. In the 2016 criteria, used with the spatial condition of pain in at least four of five regions.	A 0–19 count of painful areas; one component of the criteria when combined with SSS.	Intensity at each site, evoked-stimulus threshold, functional impairment, the cause of pain, or the entirety of a person's medical condition.
Symptom Severity Scale (SSS)	How burdensome are fatigue, unrefreshing sleep, cognitive symptoms, and other specified symptoms?	Assessment of symptoms specified by the criteria; used in combination with WPI.	A 0–12 score of symptom burden; one component of the criteria when combined with WPI.	The cause of each symptom, degree of functional impairment, responses to evoked stimuli, or an individual diagnosis established by self-scoring alone.
Pressure pain threshold (PPT)	When does controlled pressure become painful?	A test moment affected by the specified site, probe, rate of pressure increase, number of repetitions, and participant instructions.	The pressure value at which the participant reports a transition from pressure to pain.	A fibromyalgia-specific lesion, whether the pain experience is genuine, a single central mechanism, or a stand-alone individual diagnosis.
Quantitative sensory testing (QST)	How does the somatosensory system respond to controlled mechanical and thermal stimuli, including repeated and conditioning stimuli?	Depends on modality, site, stimulus and instructions, algorithm, reference values, age, sex, and clinical context.	Protocol-specific measures such as detection and pain thresholds and evoked, repeated, or modulated responses.	A fibromyalgia biomarker, a single central mechanism, a stand-alone diagnosis of neuropathic pain, or a value shared across all protocols.
Revised Fibromyalgia Impact Questionnaire (FIQR)	How much have function, overall impact, and symptoms affected daily life?	The previous seven days; 21 self-report items.	Function, overall-impact, and symptom domains, plus a total score.	The cause of pain, evoked-stimulus threshold, agreement with WPI, SSS, or QST, or the entirety of one person's long-term change.

WPI, SSS, pressure pain threshold, QST, and FIQR do not express the same pain value in different units. Each row places the target of observation beside the limits of interpretation.

WPI: Where Is the Pain Distributed?

In the 2010 criteria, the WPI records the number of 19 areas that were painful during the previous week, producing a score from 0 to 19. A higher score means that more painful areas were reported. It does not show which area hurt more, how pain at one site varied over a day, or the threshold for an evoked

stimulus.[1]

The 2016 revision added a spatial condition to the simple area count. In addition to the combinations of WPI ≥7 and SSS ≥5, or WPI 4–6 and SSS ≥9, pain must be present in at least four of five regions.[2] Two people with the same WPI can therefore differ in whether they meet the criteria, depending on whether their painful areas are clustered on one side or near one another, or are distributed more broadly.

WPI is one component of the symptom pattern required by the criteria, but it is not a test that identifies the cause of pain. The 2010 study acknowledged the lack of an independent standard case definition, and the 2016 criteria likewise stated that they do not define the entirety of a person's medical condition. [1, 2]

SSS: The Symptom Burden Alongside Pain

The 2010 SS scale combined fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden into a score from 0 to 12.[1] The 2016 SSS also works with WPI to form the classification threshold.[2] If WPI maps the geography of pain, SSS compresses the burden of symptoms that accompany it into a score.

Because the two scales are combined, they can compensate for one another within the rule. A person with more painful areas can reach a combination threshold with a comparatively lower SSS, whereas a person with a WPI of 4–6 needs a higher SSS.[2] Two people with the same number of painful areas can therefore be classified differently depending on the burden of fatigue, sleep, and cognitive symptoms.

A high SSS alone, however, does not establish the cause of fatigue or sleep problems. The criteria specify observable items and a combination rule. The self-report version may be used in research, but it does not by itself establish an individual's clinical diagnosis; physician-applied criteria also need to be used as part of an overall medical assessment.[2]

Pressure Pain Threshold: The Point Where Pressure Becomes Painful

Pressure pain threshold (PPT) does not ask about the number of painful areas or daily function. An algometer is applied to the skin and underlying tissue while pressure is increased, and the point at which the participant reports that “pressure” has changed to “pressure and pain” is recorded. In the Tampin study, pressure was increased at 50 kPa per second with a 1 cm² probe, and the mean of three measurements was analyzed.[5]

The result is neither a purely mechanical reading nor simply a questionnaire score. The equipment controls the stimulus intensity and rate, but the participant's perception and response determine the transition point. Comparability can change even among tests called PPT when the test site, probe, rate of pressure increase, number of repetitions, or instructions differ.[3, 4, 5]

A lower PPT means that pain was reported at a lower pressure under those conditions. By itself, it does not establish a fibromyalgia-specific lesion, whether the pain is genuine, or a single central mechanism. PPT is one of several evoked-response measures that QST can produce.[3, 4]

QST: Responses to Controlled Stimuli

QST is a psychophysical method that quantifies somatosensory responses to controlled mechanical and thermal stimuli.[3, 4] Beyond pressure pain threshold, it can include cold and heat pain thresholds, detection thresholds for touch and vibration, responses to repeated stimuli, and pain modulation under a conditioning stimulus.[3, 5]

Which tests are combined, where they are performed, and in what sequence are all part of interpreting the results. A 2025 scoping review screened 2,512 records and included 126 studies, but found that a common protocol was not used consistently and that test sites and test types varied.[3] The NeuPSIG consensus statement likewise called for prespecified standardized stimuli and instructions, validated algorithms, reference values adjusted for site, age, and sex, and interpretation within the clinical context.[4]

QST therefore adds information about the functional state shown by the sensory system under specific test conditions, but it is not an independent final arbiter. The NeuPSIG statement did not recommend QST as a stand-alone diagnostic test for neuropathic pain,[4] and the fibromyalgia scoping review reported that protocol heterogeneity limits evidence synthesis and biomarker interpretation.[3]

Functional Scales: The Impact Pain Leaves on Daily Life

The Revised Fibromyalgia Impact Questionnaire (FIQR) records function, overall impact, and symptoms over the previous seven days in 21 items.[6] Its function domain asks how difficult everyday tasks such as shopping, climbing stairs, and preparing meals have been. It quantifies “what has become difficult to do,” a question that WPI and PPT do not answer.

In the 2009 validation study, the three FIQR domains correlated at 0.69–0.88 with the corresponding domains of the earlier FIQ.[6] This is group-level convergent evidence that the new instrument's domains moved with related domains in the earlier questionnaire. It is not evidence that FIQR agrees with WPI, SSS, or QST, nor that it identifies the cause of functional impairment.

The limits of the validation also matter. The study did not directly assess test-retest reliability among online participants, included only 12 men, and could not calculate responsiveness or the minimal clinically important difference.[6] A functional score summarizes impact within a specified time window, but it does not capture every condition under which an individual is active or all long-term change.

Why the Same Patient Can Be Classified Differently

First, the targets of measurement differ. WPI records the number of painful areas, SSS the burden of accompanying symptoms, PPT and QST responses to evoked stimuli, and FIQR the impact on daily life. Second, time and space differ. A questionnaire recalling the previous week and a response obtained from a specific site during one laboratory visit are not the same observation.[1, 2, 3, 4, 5, 6]

Third, the decision rules differ. The criteria use combination thresholds for WPI and SSS together with pain regions;[2] PPT uses the moment at which pressure becomes painful;[5] QST relies on reference populations and test protocols;[4] and FIQR combines multiple items into domains and a total score.[6] Values near a boundary can be classified differently depending on which rule is applied.

A small comparative study makes this distinction visible in practice. Among 22 participants with fibromyalgia, sensory descriptors on painDETECT did not consistently correspond to the matching QST measures at the area of maximum pain.[5] This does not show that all self-report measures disagree with QST. It is a finding from a specific questionnaire, a specific site, and a small sample, and it establishes neither why the measures differed nor which one represents a “true value.”

Read Them Together Without Collapsing Them

The purpose of using these tools together is not to choose a winner. WPI and SSS add the breadth and burden of the symptom pattern, PPT and other QST measures add evoked responses, and FIQR adds function and impact on daily life. Preserving these different layers is what allows us to distinguish differences hidden within the same score from genuine connections between different scores.

Disagreement is a signal to reassess, not a reason to erase a person's experience. The first questions are whether the tools asked the same thing, covered the same period and sites, and used the same reference values and thresholds. Differences that remain can then become research questions about individual change, measurement variability, and differences among the constructs captured by each tool.[3, 4, 5, 6]

The current evidence did not repeatedly apply these tools to the same people along the same timeline to compare their trajectories. The next step is to track WPI and SSS, function, activity and symptom diaries, and standardized QST together, asking which changes move together and which diverge. This is not an established conclusion. It is the question that remains if we want to determine why different tools produce different answers.

Declarations

Data availability

This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

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The publishing organization originated at Baekrokdam Korean Medicine Clinic and has clinical and commercial interests. This article is not evidence for a particular diagnosis or treatment effect.

Ethics

Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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A Day Before Asking to Be Believed

This article does not reconstruct a day in the life of a person with fibromyalgia from morning to night. The evidence assembled here does not track one person's pain, fatigue, sleep, cognitive difficulties, and changes after activity together over the course of a day. Instead, it asks which fragments of a day different measures preserve and which relationships they miss. Protecting those gaps is not a way of doubting experience. It is a refusal to invent an order the data did not observe.

Abstract

This article examines what fibromyalgia criteria, comparisons of sleep diaries, actigraphy, and polysomnography, FIQR, and QST record under different time windows and conditions. The criteria summarize pain distribution and symptom burden over the previous week; FIQR covers function, overall impact, and symptoms over seven days; the sleep methods observe one night or two weeks; and QST records evoked responses at a test encounter. This evidence does not establish the order in which pain, fatigue, disrupted sleep, cognitive difficulties, and worsening after activity unfold within one person's day. Disagreement among measurements or a single result within a normal range is not evidence that an unobserved relationship is absent. Studying actual temporal paths requires repeated, linked observations of sleep, time-stamped symptoms, activity, function, and recovery in the same people.

Before Telling the Story of a Day

The question “How does a day unfold?” is a question about sequence. To know whether the previous night's sleep came before morning fatigue, whether pain reduced activity or grew after activity, and when cognitive difficulties became most prominent, the same person must be observed repeatedly over time.

The evidence in this article, however, uses different time windows. The American College of Rheumatology criteria ask about painful areas and symptom burden over the previous week, while the Revised Fibromyalgia Impact Questionnaire (FIQR) asks about function, overall impact, and symptoms over the previous seven days. The sleep study compares one polysomnography night with two weeks of diaries and actigraphy, and quantitative sensory testing (QST) measures responses to controlled stimuli at the test encounter.[1, 2, 3, 4]

Joining these data into scenes of morning, afternoon, and night would create a narrative that was never observed. The “day” discussed here is therefore not a representative patient's timetable. It is the gap that remains between the observation windows of different measures.

The Night Before: The Same Sleep, Recorded Differently

A study of 113 adults with comorbid insomnia and fibromyalgia compared one polysomnography night with two weeks of sleep diaries and actigraphy. The three methods recorded sleep through different signals and over different time windows, and the study compared both their estimates and how well they detected change.[2]

At baseline, objective measures estimated shorter sleep-onset latency and higher total sleep time and sleep efficiency than the diaries did. Actigraphy and polysomnography also produced different estimates of sleep-onset latency and time awake after sleep onset.[2] Although all three methods measure “sleep,” they do not repeat the same observation.

Among 15 participants in the cognitive behavioral therapy for insomnia group who were included in the repeated-measures analysis, diaries and actigraphy detected some changes, while polysomnography did not detect significant change.[2] This small subgroup does not establish that one method is always right. It shows only that one standardized night can diverge from nights recalled and recorded over two weeks.

Morning: Symptoms Asked Together Are Not a Timeline

The 2010 criteria recorded the number of 19 areas that had been painful over the previous week as a Widespread Pain Index (WPI) score from 0 to 19. The Symptom Severity (SS) scale combined fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden into a score from 0 to 12.[1]

This structure matters because it does not ask about pain while erasing sleep, fatigue, and cognition. Yet placing these items in the same scale does not establish a sequence or a causal chain in which disrupted sleep the night before produces morning fatigue, which then produces cognitive difficulty.[1]

A score that summarizes a week also does not show how this morning differed from the morning before. The requirement that symptoms have persisted at a similar level for at least three months is a condition for classifying persistence, not a timetable of change within a day.[1]

When Work Begins: Function Is a Different Observation

The FIQR records the impact of the previous seven days through 21 items grouped into function, overall impact, and symptoms. Its symptom domain includes pain and fatigue as well as memory, tenderness, balance, and environmental sensitivity, while its function domain records effects on daily activities separately.[3]

This distinction shows that pain intensity and difficulty with daily life are not the same question. A single seven-day summary score does not separate which task a person performed, what symptoms were present beforehand, or what changed afterward and for how long.[3]

In the validation study, the three FIQR domains correlated with their corresponding domains in the original FIQ at 0.69–0.88.[3] This supports group-level convergence between related questionnaire domains. It does not establish the cause of functional impairment, the sequence of one person's day, or the presence and duration of worsening after activity.

After Activity: The Scene the Evidence Leaves Blank

To describe worsening after activity, a study would need to link at least the type and intensity of activity, the person's pre-activity state, the time until symptoms changed, the magnitude of change, and recovery time within the same individual. The criteria, sleep comparison, FIQR validation, and QST review assembled here contain no such linked data.[1, 2, 3, 4]

This evidence therefore cannot support a representative sequence such as “pain rises first immediately after activity, followed the next day by fatigue and cognitive difficulty.” But failure to establish that sequence also cannot support the conclusion that worsening after activity does not occur. The current studies were not designed to answer that question.

FIQR provides a place to record the impact of activity and function, but a weekly score cannot reconstruct a curve of change before and after activity.[3] This gap is a limitation of measurement design, not a judgment about the credibility of patient experience.

In the Laboratory: An Evoked Response Is Not Daily Life Recreated

QST applies controlled mechanical or thermal stimuli and quantifies sensory responses.[4] It offers control over pressure or temperature, test site, and sequence, but it does not recreate the sustained demands of daily life, such as preparing for work, traveling, concentrating, or doing household tasks.

A 2025 scoping review screened 2,512 records and included 126 studies. It found that no common protocol was used consistently and that both test sites and test types varied.[4] The timing and conditions under which a response is measured are therefore part of its interpretation.

Measures such as temporal summation and conditioned pain modulation are often linked to central sensitization, but the review noted that the peripheral nervous system also contributes and that each study must define the parameters used in its analysis.[4] A single laboratory response cannot establish the cause of a day's pain, whether symptoms are genuine, or the sequence of changes after activity.

What Standardized Measures Leave Outside the Frame

Standardization fixes questions, time windows, and stimulus conditions so that comparisons can be made. The tradeoff is that part of the context falls outside the frame. A count of painful areas over the previous week does not directly show fluctuations within a day; a seven-day impact score does not show

changes before and after a task; one polysomnography night does not directly show perceived changes across many nights; and a laboratory stimulus does not show the sequence of activity in daily life.[1, 2, 3, 4]

When a measurement appears to conflict with experience, the first question should not be which one is true, but what was recorded, when, and under which conditions. The sleep study found differences among methods in both their estimates and detection of change,[2] while FIQR and QST observe different targets from the outset: impact on daily life and responses to evoked stimuli.[3, 4]

The assembled evidence contains no patient interview, repeated within-day survey, or time-stamped record linking activity and symptoms. This article therefore does not present “a typical patient's day.” It says only that temporal relationships remain outside the reach of standardized scores, and limits that statement to this evidence set.

The Record Needed Before Asking for Belief

What can be said with confidence is limited. The criteria consider pain distribution together with unrefreshing sleep, fatigue, and cognitive symptoms;[1] FIQR distinguishes function from symptoms;[3] sleep methods can yield different estimates even in the same sample;[2] and QST records a separate layer of response under controlled stimulation.[4]

What cannot be said is equally clear. This evidence alone cannot establish the order in which pain, fatigue, disrupted sleep, cognitive difficulties, and changes after activity unfold within one person's day, or which change precedes another. A single test result within a normal range, or disagreement among measurements, is not evidence against a relationship that was not observed.

To study the course of an actual day, researchers would need repeated, linked observations in the same person: sleep and the state on waking, time-stamped symptoms, the type and intensity of activity, function, changes before and after activity, and recovery time. Laboratory measures could be placed on the same timeline when relevant. This is not an answer established by the current data. It is the next study design derived from the gap left by measures that were not built to answer a question about the sequence of a day.[2, 3, 4]

Declarations

Data availability
This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

Funding
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Ethics

Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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Pain, Sensitization, Fatigue, and Functional Impairment

Pain, sensitization, fatigue, and functional impairment refer to different observations. Post-activity worsening remains a separate evidence gap because the material reviewed here does not show the temporal relation. Distinguishing what was recorded, over what period, and by what method prevents different observations from being merged into a causal chain or a single measure of severity.[1-3]

Abstract

This article distinguishes the observations denoted by pain, fatigue, sensitization, functional impairment, and post-activity worsening in discussions of fibromyalgia. The 2016 criteria structure painful sites, spatial distribution, and fatigue over the previous week, while the FIQR distinguishes difficulty with activities and overall impact over the past seven days from its symptom items. QST observes protocol-dependent psychophysical responses to controlled stimuli; it is not a sole mechanism, an individual diagnosis, or a test of whether pain is genuine. Because the current evidence does not align activity and symptoms on one time axis, it does not establish the onset, magnitude, duration, recovery, causal direction, or universality of post-activity worsening. Observations recorded together may be related, but they are neither identical nor causally ordered by that fact.

1. Before Placing Five Terms on One Line

Criteria and questionnaires used in fibromyalgia bring together several symptoms and effects. Recording them together shows that their co-occurrence matters clinically, but it does not mean that each item is a different name for the same phenomenon.[1, 2]

Pain can be recorded as the sites that hurt over the previous week and their spatial distribution, while fatigue is recorded as the severity of a symptom experienced over the same period. Function is assessed by asking how difficult particular activities were and how much fibromyalgia affected the week as a whole. Sensitization research observes responses to controlled stimuli.[1, 2, 3]

The first question for distinguishing these terms is therefore, “What was observed?” The observation window and the instrument come next. Combining different observations into one score or one explanation adds an order and a cause that the data do not establish.[1, 2, 3]

Table 1. The Observations Denoted by Five Terms and the Boundaries of Interpretation

Term	Observation denoted in this article	Instrument or evidence status	Time window or test context	What may overlap but is not identical	What this observation alone cannot establish
Pain	The number of areas that were painful during the previous week and the spatial-distribution condition asking whether pain was present in at least four of five body regions	The 0–19 Widespread Pain Index (WPI) in the 2016 criteria and a separate generalized-pain condition [1]	The previous week. Jaw, chest, and abdominal pain are excluded from the generalized-pain distribution calculation	It may be recorded alongside fatigue in the criteria but is a different observation from fatigue, sensitization, and functional impairment	Pain intensity, pain mechanism, fatigue, sensitization, or functional impairment
Fatigue	The severity of fatigue separately rated by the patient over the previous week	The 0–3 fatigue item in the Symptom Severity Scale (SSS). Waking unrefreshed and cognitive symptoms are separate items [1]	Self-report over the previous week	It is recorded alongside pain in the criteria but is not the same as waking unrefreshed, sleep state, or functional impairment. Nor is it interchangeable with energy, the label of an FIQR item [1, 2]	Sleep state, functional impairment, or a biological cause
Sensitization	Psychophysical responses evoked by mechanical or thermal stimuli at controlled intensities, and the bounded inference drawn from those responses	Quantitative sensory testing (QST). Test sites and types, stimulus parameters, equipment, and interpretive definitions are heterogeneous and not fully standardized [3]	The context of the test occasion and specified protocol. The peripheral nervous system also contributes to interpreting temporal summation and conditioned pain modulation, and each study must define its parameters	A laboratory-evoked response distinct from spontaneously reported pain and fatigue and from functional impairment over the past seven days	A sole mechanism, an individual diagnosis, a verdict on whether pain is genuine, or a universal sensitization pattern
Functional impairment	Self-reported difficulty performing specified activities over the past seven days and the impact on the week as a whole	The function and overall-impact domains of the Revised Fibromyalgia Impact Questionnaire (FIQR). Its 21 items are rated from 0 to 10 [2]	A summary of the past seven days. It does not track within-day change or change immediately after activity	The same FIQR includes symptom items for pain, energy, and sleep, but these are separate from difficulty with activities and overall impact	Overall disease severity, etiology, or temporal order within a day

Term	Observation denoted in this article	Instrument or evidence status	Time window or test context	What may overlap but is not identical	What this observation alone cannot establish
Post-activity worsening	An explicit evidence gap in a temporal relation that was not directly observed in the material reviewed here	No data align activity and symptoms over time within individuals [1, 2, 3]	Not established: activity dose, pre-activity state, onset, magnitude of change, duration, recovery, or universality	It cannot be said to have been recorded alongside the other four terms. The absence of temporal evidence is not evidence that no relation exists	Time of onset, magnitude of change, duration, recovery pattern, causal direction, or whether the pattern is the same for everyone

This table supplements rather than replaces the article's linear explanation. The five rows should not be compared as one quantitative scale or an ordered ranking of severity.

2. Pain: Reported Sites and Spatial Distribution

In the 2016 criteria, the Widespread Pain Index (WPI) records the number of areas that were painful during the previous week on a scale from 0 to 19. It is a self-reported count of painful sites, not a direct measure of pain intensity or cause.[1]

Separate from the number of sites, the same criteria ask whether pain is present in at least four of five body regions. This “generalized pain” condition is intended to distinguish how pain is distributed spatially. Pain in the jaw, chest, and abdomen is not included in this regional distribution calculation.[1]

Even within the word “pain,” the number of sites and spatial distribution are distinct. Both structure a patient's report of pain, but neither substitutes for measuring a sensitization mechanism, the severity of fatigue, or difficulty performing activities.[1, 2, 3]

3. Fatigue: A Symptom Report Distinct Even from Waking Unrefreshed

The 2016 Symptom Severity Scale (SSS) rates fatigue, waking unrefreshed, and cognitive symptoms separately according to their severity over the previous week. Each of the three items is scored from 0 to 3 before the scores are summed.[1]

The inclusion of fatigue and waking unrefreshed in the same scale means that both experiences matter. Their structure as separate items, however, shows that the terms are not interchangeable. A fatigue score alone cannot establish the state of a person's sleep.[1]

The FIQR likewise uses separate symptom items for pain, energy, and sleep quality. Here, energy is the label of an FIQR item, while fatigue is the symptom separately rated in the 2016 criteria. The two expressions should not be substituted as though they were the same item, and neither is the same

observation as pain distribution, responses to stimuli, or difficulty with activities.[1, 2]

4. Sensitization: Reading Responses to Controlled Stimuli

Quantitative sensory testing (QST) applies mechanical or thermal stimuli at controlled intensities and measures the responses. What is observed is a psychophysical stimulus-response evoked under specific test conditions. The setting of observation already differs from a report of pain that arises spontaneously in daily life.[3]

A 2025 scoping review screened 2,512 records and included 126 studies, but found inconsistency in test sites and types, stimulus intensity and duration, rest intervals, equipment, and interpretive definitions. This is why results from different protocols are difficult to read as one universal sensitization value.[3]

Temporal summation and conditioned pain modulation are frequently used to study central sensitization, but the review noted that the peripheral nervous system is also involved and that each study must define the parameters used to analyze sensitization. In this article, sensitization is a bounded observation and inference based on evoked responses—not a sole mechanism, an individual diagnosis, or a test of whether pain is genuine.[3]

5. Functional Impairment: Difficulty with Activities and Overall Impact over the Past Seven Days

The FIQR rates all 21 items from 0 to 10 and groups them into three domains: function, overall impact, and symptoms. Every item refers to the past seven days. This structure differs from a test of ability at the present moment or a direct record of change within a day.[2]

The function domain asks how difficult fibromyalgia made specified activities during the past seven days. The overall-impact domain separately asks about accomplishing goals for the week and the degree to which symptoms were overwhelming. In this article, functional impairment refers to these self-reports of difficulty with activities and overall impact.[2]

Even within the FIQR, pain, energy, and sleep are symptom items, while difficulty with activities and overall impact belong to other domains. The fact that they can be combined into a total score does not make functional impairment equivalent to overall disease severity or another name for pain or fatigue.[2]

6. Where Is Overlap Observed?

The first overlap appears when several items are recorded within the same criteria or questionnaire. The WPI and SSS address pain sites and fatigue together, while the FIQR records function and overall impact alongside distinct items for pain, energy, and sleep.[1, 2]

The second overlap is that different measurements are used to describe the same person or group. Reported pain and fatigue, difficulty with activities over the past seven days, and laboratory-evoked responses can illuminate different aspects of one person's state.[1, 2, 3]

Co-recording, however, is neither identity nor causality. It does not follow that pain proves sensitization or that fatigue is functional impairment. Given the protocol heterogeneity in QST, group-level evoked responses should also not be transferred to an individual as a fixed explanation.[1, 2, 3]

7. Post-Activity Worsening: The Missing Time Axis

The criteria, FIQR, and QST review examined here do not align activity level and pre-activity state on a time axis and then trace symptom onset, magnitude of change, duration, and recovery within individuals.[1, 2, 3]

This evidence scope therefore cannot determine when post-activity worsening begins, how long it lasts, how recovery unfolds, or whether everyone experiences the same pattern. Difficulty with activities over the previous seven days on the FIQR cannot be reinterpreted as a record of change immediately after activity.[2]

This gap is not evidence that no relation exists. It means only that there is no basis here for filling in a universal sequence or duration. Post-activity worsening must remain an explicit evidence gap in this terminology map.[1, 2, 3]

8. Reading Together Without Merging

Pain can be read as reported sites and distribution; fatigue as reported symptom severity; sensitization as a bounded inference from responses to controlled stimuli; and functional impairment as difficulty with activities and overall impact over the past seven days. For post-activity worsening, the material reviewed here leaves the time axis unfilled.[1, 2, 3]

This distinction is not meant to fragment experience. Naming different observations precisely helps prevent one measurement from erasing another experience. A test result within the expected range, or one that differs from expectations, should not be used to invalidate reports of pain, fatigue, or function.[1, 2, 3]

The conclusion is that these observations may be related, but they are not the same. If future research asks how they are related, it should repeatedly measure activity, pain, fatigue, sleep, and function on the same time axis and specify the QST conditions. This is not a finding of the current evidence; it is a research question derived from the observational differences and temporal gap identified here.[1, 2, 3]

Declarations

Data availability

This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

Funding

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Is Central Sensitization an Explanation or a Conclusion?

Central sensitization is a key concept used to understand the sensory amplification observed in fibromyalgia. Yet there is a wide gap between observing responses to controlled stimuli and concluding that those responses identify the sole cause of pain or establish an individual's diagnosis. The current evidence supports using several evoked-pain measures to examine the involvement of sensory processing. The direction of causation, differences among patients, and thresholds for individual classification remain open questions.[1,2]

Abstract

This article distinguishes observation, explanation, and conclusion in research on sensory amplification in fibromyalgia. Multiple evoked-pain measures can be used to study the involvement of sensory facilitation and modulation, but they are not a single interchangeable test. The quality assessment in a 34-study review, protocol and site heterogeneity in a scoping review that included 126 of 2,512 records, and discordance between self-report and QST in a 22-participant comparison all limit mechanistic and individual-level conclusions. The current evidence does not establish central sensitization as a sole or exclusively central cause, an individual diagnostic criterion, a pain-validity test, or a stable temporal marker. Longitudinal designs that repeatedly measure standardized sensory responses alongside symptoms and function in the same people are needed to distinguish causal direction and subgroups.

Observation, Explanation, and Conclusion

Quantitative sensory testing (QST) is a psychophysical method that applies mechanical or thermal stimuli of specified intensity and quantifies the resulting somatosensory responses.[2, 3] It records how a person perceived and responded to a stimulus under particular conditions. It does not directly image or sample tissue damage or a single lesion in the nervous system.

When those responses show patterns such as temporal summation, reduced inhibition, or a lower threshold, researchers can ask whether pain-facilitation and pain-modulation processes are involved. This is the first step from observation toward explanation. No single measure, however, establishes by itself the sole cause of fibromyalgia, the condition in its entirety, or whether reported pain is genuine.[1, 2, 3]

“Central sensitization may be involved” is therefore not the same statement as “central sensitization is the cause.” The former is a research explanation based on functional responses observed under test conditions. The latter is a conclusion that also establishes the mechanism's location, causal direction, and sufficiency. The current evidence allows the first statement to be examined but does not warrant the second.[1, 2]

Involvement Indicated by Multiple Measures

A 2022 systematic review of algometry examined several measures across 34 studies, including temporal summation, after-sensations, spatial summation, nociceptive flexion reflex threshold, conditioned pain modulation, the cutaneous silent period, and slowly repeated evoked pain.[1] This list shows that sensitization has been studied not as a single number but through distinct observations of facilitation, inhibition, persistence, and reflex activity.

The review concluded that these measures could be used to investigate the involvement of central sensitization in fibromyalgia.[1] “Involvement” is the important word. It means that a response evoked in the laboratory may reveal one aspect of sensory processing, not that the same process operates to the same degree in every patient.

The quality of the evidence must be read alongside these findings. Of the 34 studies assessed in the same review, 28 were classified as low quality, three as moderate quality, and three as high quality.[1] The repeated study of multiple measures demonstrates the breadth of the research program, but their number alone does not yield strong mechanistic certainty or predictive power for an individual.

Different Processes Under One Umbrella

Temporal summation, conditioned pain modulation, pressure pain threshold, after-sensations, and reflex thresholds are different evoked-pain measures.[1] Even when they are placed under the single heading of “central sensitization,” they are not identical tests that can be used interchangeably.

The boundary is not anatomically simple either. A 2025 scoping review noted that temporal summation and conditioned pain modulation are commonly used as measures of central sensitization, but the peripheral nervous system is involved as well.[2] Translating a difference in one measure directly into a change arising only in the central nervous system therefore exceeds what the measurement permits.

Central sensitization can serve as an umbrella for organizing different findings and designing the next experiment. The umbrella is not itself a conclusion. Whether different measures occur together in the same person, reflect the same biological process, or change alongside symptoms must each be tested separately.[1, 2]

When the Protocol Changes, Meaning Becomes Unstable

The 2025 scoping review screened 2,512 records and included 126 studies.[2] Those numbers reveal a broad research landscape, but common protocols were not applied consistently, and test sites and test types varied. A large body of research does not mean that its findings can be compared on a single scale.

When stimulus type and intensity, duration, rest intervals, equipment, test site, and reference values differ, tests with the same name record different conditions.[2, 3] The NeuPSIG consensus called for predefined stimuli and instructions, validated testing algorithms, reference values adjusted for anatomical site, age, and sex, and interpretation in clinical context.[3]

This heterogeneity is not merely a matter of formatting. Values obtained under different conditions limit synthesis across studies and reliability as a biomarker.[2] Interpretation should therefore begin not with the shorthand label “sensitization positive,” but with what was measured, where, by which procedure, and against which reference population.

From Group Research to Individual Classification

QST can provide supplementary information about somatosensory function, but it is not a stand-alone device for establishing an individual's diagnosis. Even within its own context of neuropathic pain, the NeuPSIG consensus did not recommend QST as a stand-alone diagnostic test.[3] That statement should not be transferred into a fibromyalgia-specific guideline, but it clearly marks the boundary between measuring function and establishing a diagnosis.

In fibromyalgia research, that boundary calls for more specific thresholds. We would need to know how accurately a given combination of tests, sites, and reference values distinguishes individuals, whether the same responses occur in other pain conditions, and whether classifications persist on repeat testing. The current scoping review mapped the methods; it did not validate that kind of individual diagnostic accuracy.[2]

There is also no basis for using a test value to judge whether pain is genuine. QST records responses to evoked stimuli and does not capture spontaneous pain in its entirety.[2, 3] If an expected change is absent, the conclusion should remain that the change was not observed with that protocol at that site.

Discordance as Counterevidence and a Question

The Tampin study asked 22 participants with fibromyalgia about the sensory descriptors in painDETECT and measured several QST parameters at the area of maximal pain.[4] In this small sample, the self-reported sensory descriptors did not consistently align with the corresponding QST patterns. The same person could therefore be classified differently by verbal descriptions of sensation and by laboratory responses to evoked stimuli.

That discordance is not a verdict that one side is false. The researchers stated that the reason for the difference was unclear and that the small sample limited generalizability.[4] Findings from this particular questionnaire, test battery, and maximal-pain site cannot be expanded into a universal account of the relationship between all self-reports and all QST measures.

Instead, the result adds counterevidence to the assumption that a single sensitization measure represents the whole of an individual's experience. When symptom descriptions and evoked responses diverge, it remains to be determined whether the difference reflects measurement error, timing or test site, distinct sensory constructs, or patient subgroups.[2, 4]

The Arrow Between Cause and Effect

A cross-sectional test cannot distinguish whether sensory amplification helps pain persist, whether persistent pain together with sleep, activity, emotion, and treatment context changes evoked responses, or whether both directions operate together. The 2022 review likewise concluded that further research was needed to clarify the mechanisms of some measures and to standardize and optimize protocols.[1]

There is also a large gap in the time dimension. The 2025 scoping review reported that few studies measured QST before and after an intervention, leaving the stability of QST in fibromyalgia poorly understood.[2] Without knowing stability and sequence of change, it is difficult to determine whether a test difference is a preceding cause, a consequence of a state, or a marker that changes alongside it.

The current evidence contains no direct longitudinal study that repeatedly measures multiple standardized QST measures together with symptoms and function in the same people to determine temporal order. Causal direction is therefore neither disproved nor established. It remains an open question because the designs needed to distinguish the direction are still lacking.[1, 2]

Use It as an Explanation Without Closing It as a Conclusion

The safest current summary is this: several evoked-pain measures provide a window for studying the involvement of sensory facilitation and modulation in fibromyalgia. At the same time, evidence quality, differences among measures, heterogeneity of protocols and test sites, peripheral involvement, and the discordance between self-report and QST found in a small study all set an upper limit on interpretation.[1, 2, 4]

Future studies should use the same protocols and reference values, describe patient characteristics and coexisting symptoms, and apply multiple measures repeatedly in the same people. Changes in symptoms and function should be placed on the same timeline to test whether sensory responses come before or after them and in which subgroups they move together.[1, 2, 3] These are design principles for narrowing the gaps, not pathways established by the current evidence.

Central sensitization may be a useful hypothesis for organizing an explanation. A good explanation does not close every question; it helps distinguish which observations hold, which inferences are premature, and what needs to be tested next. An individual's pain does not require permission from a test result to exist, and no single result establishes that person's diagnosis and cause on its own.[2, 3]

Declarations

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The Next Study That Tracks Symptoms and Function Together

The aim of the next study is not to define fibromyalgia more forcefully with a single number. It is to align symptom diaries, sleep, activity, function, quantitative sensory testing, and treatment context on each person's time axis, then determine what changes together and what diverges. The schedule and analyses proposed here are a study design, not findings whose effects have already been demonstrated.[1-5]

Abstract

This article proposes a longitudinal fibromyalgia study that aligns symptom diaries, sleep, activity, FIQR function, quantitative sensory testing (QST), and treatment context on a shared person-level clock while preserving them as distinct measures. After a brief feasibility phase, frequency, windows, valid-day rules, retest intervals, and primary outcomes would be prespecified; within-person change would be separated from between-person differences; and rival explanations, including reverse direction, burden, and missingness, would be compared. Clinical safety signals, participant burden, and measurement- and study-level stopping rules remain separate. This is neither a validated optimal protocol nor a finding of causality or treatment effect: activity is not function, actigraphy is not sleep experience, and QST is not a sole mechanism, individual diagnosis, or pain-validity test.

1. Research Question: From Average Differences to Change Paths

Current tools observe different time windows. The 2016 criteria structure painful sites and symptoms such as fatigue and waking unrefreshed, while the FIQR asks about function, overall impact, and symptoms over the past seven days. Quantitative sensory testing (QST) records responses to controlled stimuli at the time of testing.[1, 2, 4]

Each measure is necessary, but comparing only total scores and group averages while leaving these different clocks unaligned makes it difficult to know when symptoms change after activity within one person and when that change reaches function. The evidence reviewed here contains no time-linked activity and symptom data, so it cannot establish the sequence of pre-activity state, onset, magnitude, duration, and recovery.[1, 2, 4]

The central question is therefore not, “Which test best proves fibromyalgia?” It is, “Within individuals, in what sequence do activity, sleep, pain, fatigue or energy, function, and QST responses change together or separately, and how much do those paths differ across people and treatment contexts?” Temporal

precedence can narrow a hypothesis, but it does not by itself establish a cause.[1, 2, 3, 4, 5]

2. Whom and Where Should the Study Observe?

The population should be defined as adults who meet the 2016 criteria after clinical evaluation, with recruitment routes and care settings recorded. The self-report version of the criteria should not substitute for individual diagnosis, and the requirement that pain and symptoms have persisted at a similar level for at least three months should be read only as an entry condition, not as evidence that no later change occurs.[1]

Comorbid conditions should be treated as interpretive context rather than grounds for blanket exclusion. The 2016 criteria also state that a fibromyalgia diagnosis does not exclude the presence of other clinically important illnesses. Situations requiring clinical assessment should nevertheless be routed separately from research measurement so that new or changing clinical findings are not handled only as study variables.[1]

To distinguish heterogeneity, the study should include participants with varied baseline pain distribution, fatigue or energy, sleep problems, functional levels, treatment status, and comorbid conditions, and report the numbers in each recruitment stratum. If enrollment is concentrated by sex, age, or care site, or retains only people able to use the devices, that scope should be stated when interpreting results. Sample size should not be fitted to a desired number of subgroups; it should be calculated from valid primary effects and the repeated-measures structure, using pilot estimates of variability, missingness, and attrition.

3. Placing Several Time Windows on One Clock

The key is not to repeat every measure at the same frequency, but to record the timing of distinct measurements accurately on a shared clock. Pain, fatigue, waking refreshed, and states before and after activity should be captured in brief, event-near diaries; activity and sleep-wake patterns should be recorded as continuously as feasible; and the FIQR should preserve the instrument's past-seven-day window.[2, 3]

The evidence reviewed here cannot determine the optimal number of daily diary entries or duration of observation. A short feasibility phase should first examine response burden, missed entries, weekday and weekend coverage, wear time, and symptom variability. Frequency, allowed response windows, minimum valid days, and observation length should then be fixed before the main analysis. Participants with extensive missing data should not be silently excluded; the timing and reasons for missingness should also be retained as time data.

QST is not a measure to be administered daily like a diary. It should use the same stimuli, instructions, sites, equipment, rest periods, and interpretive rules at baseline and at prespecified follow-up points, while recording sleep, activity, symptoms, and treatment exposure before the test. The exact retest

interval should be fixed after the feasibility phase assesses burden and repeat-testing effects, and the result should not be used for individual diagnosis or as a verdict on whether pain is genuine.[4, 5]

Table 1. Six Measurement Layers on One Clock Without Collapsing Them into One Value

Measurement layer	What is recorded separately	Time window or temporal relation to preserve	Unresolved decision to prespecify after feasibility testing	What this layer alone cannot establish
Symptom and event diary	Pain intensity and distribution, fatigue or energy, waking unrefreshed, cognitive difficulty, pre-activity state, and post-activity change are recorded as separate items [1, 2]	Event-near reports are linked to a common clock without being collapsed into the same value as activity, sleep, seven-day function summaries, or quantitative sensory testing (QST)	Daily response frequency, allowed response window, minimum valid days, observation period, and rules for recording the onset, magnitude, duration, and recovery of post-activity change	Universality of post-activity change, causality from temporal order, or using one symptom to stand in for another experience or for function
Activity record	Raw device data are recorded separately from derived values such as steps, acceleration, and active and inactive intervals	Continuous recording where feasible is linked to symptom events while device, wear location, wear time, and non-wear status are retained	Device and wear location, non-wear detection, derived values and activity criteria, minimum valid days, observation period, and missing-data rules	Interpreting movement quantity as functional impairment, symptom severity, post-activity worsening, a cause, or a verdict on whether pain is genuine [2]
Sleep record	Diary reports of sleep experience and actigraphic sleep-wake estimates are retained as separate variables, including their discordance	Diaries and actigraphy are repeated in their own observation windows; polysomnography overlaps only when a separate question justifies the burden	Diary frequency, actigraphy period, valid-day and missing-data rules, and whether and when to overlap polysomnography	A judgment that one method is the sole truth about sleep, or a treatment effect. The supporting study included 113 people with comorbid insomnia, and its treatment-change analysis was limited to a 15-person cognitive behavioral therapy for insomnia (CBT-I) subgroup [3]
Revised Fibromyalgia Impact Questionnaire (FIQR) summary	Twenty-one items in the function, overall-impact, and symptom domains are each rated from 0 to 10 [2]	The instrument's past-seven-day summary window is preserved and distinguished from shorter event diaries and device records	Timing of repeated administration, number of valid observations, missing-data handling, and domains and outcomes for confirmatory analysis	Objective activity, within-day sequence, overall disease severity, etiology, or a substitute for event-near symptoms
Quantitative sensory testing (QST)	Psychophysical responses evoked under specified stimulus, instruction, site, equipment, rest, context, and interpretive rules are recorded [4, 5]	Testing occurs at baseline and prespecified infrequent follow-up points, with pretest sleep, activity, symptoms, and treatment exposure recorded	Retest interval, repeat-testing effects, sites and stimuli, equipment, rest, quality criteria, cross-site standardization, and missing-data rules	A sole mechanism, individual diagnosis, already established mediation, prediction, or validation of treatment response, or a verdict on whether pain is genuine [4, 5]

Measurement layer	What is recorded separately	Time window or temporal relation to preserve	Unresolved decision to prespecify after feasibility testing	What this layer alone cannot establish
Treatment context	Medication changes; rehabilitation, exercise, psychological, and sleep interventions; acute illness; and major life changes are timestamped as precisely as feasible	It is placed on the same person-level clock as symptom, activity, sleep, function, and QST records but retained as time-varying context and stratification information	Precision of exposure timing, coding of concurrent interventions, adherence, and planned changes, inclusion criteria for analysis, and whether to conduct a separate effect comparison	Treatment effect, mediation, prediction, exclusion of reverse causation, or causal direction in an observational study [3, 4]

Row order follows the article's exposition; it does not indicate priority, measurement frequency, temporal order, or causality. This table is neither a completed protocol nor a study result, and it supplements rather than replaces the article.

4. What Should Be Measured Together but Not Read as Substitutes?

The symptom diary should ask separately about pain intensity and distribution, fatigue, waking unrefreshed, cognitive difficulty, pre-activity state, and change after activity. No item should stand in for another. For post-activity change, activity type, duration, perceived intensity, start time, and the onset, magnitude, duration, and recovery of symptom change should be linked to the same event whenever possible. These questions do not presume a universal worsening path; they are records intended to test whether such paths exist.[1, 2]

Activity measurement should separate raw device data from derived values such as steps, acceleration, and active and inactive intervals, while retaining device type, wear location, wear time, and rules for detecting non-wear. Reported difficulty with activities should remain a separate FIQR function measure. Less movement is not identical to functional impairment, and more movement does not mean that symptoms are mild.[2]

Sleep should not be collapsed into one value either. In a study of 113 adults with comorbid insomnia and fibromyalgia, sleep diaries, actigraphy, and polysomnography did not give the same baseline estimates or detect post-treatment change in the same way. The treatment-change analysis was limited in particular to a 15-person cognitive behavioral therapy for insomnia (CBT-I) subgroup, so the next study should keep diary-reported sleep experience and actigraphic sleep-wake estimates as separate variables and analyze discordance rather than treating it as a defect.[3]

5. Treatment Context Is a Timeline, Not an Effect Estimate

Medication starts, stops, and dose changes; rehabilitation, exercise, and psychological-therapy sessions; sleep interventions; acute illness; and major life changes should be dated and timed as precisely as feasible. Recording exposure timing, whether a change was planned, concurrent interventions, and

adherence, rather than treatment name alone, makes it possible at least to order measurement changes before or after treatment.[3, 4]

Differences before and after treatment in this observational study must not be called effects. Treatment may not be randomized, and rival explanations remain, including reverse causation when worsening symptoms lead to treatment changes, regression to the mean, expectations, seasonality, and diary reactivity. Treatment context should initially be used as a time-varying covariate and stratification variable; an effect comparison should be prespecified only when supported by a separate design and sample-size rationale.[3, 4]

The QST review proposed that before-and-after intervention QST is scarce and should be distinguished by treatment type, but that is not a finding that QST change mediates or predicts treatment response. Symptoms or function may improve while QST remains unchanged, and the reverse is also possible. These rival models should be retained together. Change in one measure does not determine the validity of another.[4, 5]

6. Analysis Plan: Sequence Within People and Differences Between People

The first unit of analysis should be repeated observations within individuals rather than the group average. All data should be aligned to a common clock while preserving their original windows, and several candidate lags should be used to explore relations among activity and sleep intervals, symptom change, and function on the next day or during the next week. Lags and primary outcomes used for confirmatory analysis should be fixed after the feasibility phase and before viewing those results.

The model should allow person-specific baselines and slopes and separate within-person effects from between-person differences. Subgroups should not be assumed to be fixed types from the outset; discovery clustering and a replication sample should be separated. QST protocol, recruitment site, treatment exposure, comorbid conditions, device wear, and missingness should be recorded together to test whether observed paths are tied to a particular method or sample.[1, 3, 4, 5]

At least three rival explanations should be compared: a model in which sleep change precedes next-day symptoms, a model in which the relation between activity and symptoms varies with baseline function or treatment context, and a model in which measurement burden and missingness create apparent worsening. Reverse-direction and simultaneous-change models should also remain in consideration. A better-fitting path alone must not be used to declare a biological cause or a universal patient type.

7. Safety, Burden, and Stopping Rules

Observation does not replace clinical care. When a participant reports new neurological signs, a rapid change in condition, or a clinical safety signal specified in advance by the research team, measurement should be paused and the participant directed to a separate clinical assessment pathway rather than

automatic analysis continuing. Specific safety signals and responsibility for the response should be established through clinical and ethics review before the study starts, and study data alone should not be used to attribute them to fibromyalgia.[1]

Participants should be able to stop some or all diary, device, or QST procedures without giving a reason. A measure should be stopped or adjusted immediately if QST causes pain or discomfort beyond permitted limits, a device causes skin problems or disrupts sleep, or repeated questions create excessive burden. Stopping is an outcome of acceptability and safety, not a failure; its reason and timing should be retained where analytically possible rather than deleted at discretion.[4, 5]

The study also needs rules for stopping or redesigning its procedures. If valid wear time and diary response fall below prespecified criteria, QST standardization cannot be maintained across sites, or burden and attrition concentrate in a particular group, investigators should pause and revise the procedure rather than conceal the problem by expanding recruitment. Data collected before and after a revision should be distinguished, and hypotheses formed after the change should not be written as though they had been specified from the start.

8. What Would Count as Success?

Success should not be defined as finding one biomarker or a single patient type. The first questions are whether distinct measures were placed on the same time axis with sufficient accuracy and acceptability, whether enough repeated observations remain to estimate individual paths, and whether discordance and missingness can be explained without being hidden.[2, 3, 4, 5]

Results should then be reported in three layers: average tendencies that recur overall, different paths among individuals or reproducible subgroups, and relations that the current design cannot distinguish. Raw data and derivation rules, protocol deviations, analysis code, and prespecified decisions should be retained together so that discovery can be separated from confirmation and tested in another sample.

The question this design addresses is not whether pain is real. A patient's report exists before the test; the test is a tool for recording more precisely how that experience changes in relation to function. When symptoms, sleep, activity, function, QST, and treatment context are placed on one clock without being collapsed into the same phenomenon, heterogeneity becomes a testable change path rather than a label.[1, 2, 3, 4, 5]

Declarations

Data availability
This article used only the public literature listed in its references. No individual patient data or separate clinical dataset was used.

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Competing interests

The publishing organization originated at Baekrokdam Korean Medicine Clinic and has clinical and commercial interests. This article is not evidence for a particular diagnosis or treatment effect.

Ethics

Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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