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The Next Study That Tracks Symptoms and Function Together

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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.

Keywords: longitudinal fibromyalgia study · fibromyalgia symptom diary · fibromyalgia activity · fibromyalgia sleep · fibromyalgia function · FIQR · quantitative sensory testing · QST · within-person change · feasibility study · prespecification · stopping rules

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]
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]

Note. 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

Author contributions (CRediT)	Baekrokdam Research Commons (BRC): Investigation, Data curation, Evidence verification, Writing – original draft, Writing – review & editing
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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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