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Prevalence and characteristics of fibromyalgia according to three fibromyalgia diagnostic criteria: A secondary analysis study

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Abstract

Objective – The purpose of this study was to explore the prevalence of fibromyalgia (FM) according to different diagnostic criteria in a clinical sample and to explore the clinical characteristics in cases and non-cases by the diagnostic criteria used.

Methods – A sample of 182 participants, both positive (n = 120) and negative (n = 62) FM individuals according to a clinical, pragmatic classification was used. Their characteristics were explored according to three different FM diagnostic criteria, i.e., the American College of Rheumatology (ACR) 1990, ACR 2016, and APS Pain Taxonomy (AAPT), respectively. Thus, impact of FM (FIQ), symptoms of anxiety and depression (HADS), tender point (TP) counts, and mechanical pressure sensitivity (in kPa) were compared in cases versus non-cases depending on diagnostic criteria of FM used. Descriptive analyses used chi-square statistic for categorical variables and non-parametric Mann–Whitney U tests for continuous variables.

Results – From the clinical positive FM sample (n = 120), n = 99, 108, and 110 persons were diagnosed positive according to the ACR 1990, ACR 2016, and AAPT FM diagnostic criteria, respectively. All these three diagnostic tools discriminated FM positively from diagnostic FM non-cases when measuring TP-counts, mechanical pressures, and most FIQ-items, but they varied for anxiety and depression.

Conclusion – The prevalence of FM differed somewhat with the use of ACR 1990, ACR 2016, and the AAPT as diagnostic tools. The anxiety and depression symptoms differed significantly between cases and non-cases using some but not all the diagnostic criteria. Regarding other FM symptoms, e.g., TPs and most FIQ items, all diagnostic criteria contrasted case from non-case.

Keywords: fibromyalgia, classification, ACR 1990, 2016 and AAPT diagnostic criteria

1 Introduction

The concept and diagnosis of fibromyalgia (FM) have been controversial for a long time [1]. Following a period of acceptable consensus, the American College of Rheumatology (ACR) 1990 criteria set [2,3] has gradually lost its acceptability, which has resulted in at least four new criteria sets in the last 10 years [4]. Thus, the FM symptoms we describe today are not new but have been conceptualized by different terms throughout history [5]. There has also been a confusion between the diagnostic and classification concepts, especially when ICD-11 followed the ICD-10 in 2022. FM is a heterogeneous condition with various mechanisms and manifestations [6].

The *ACR 1990* criteria were based on the presence of chronic widespread pain (CWP) and mechanical tenderness in 11 out of 18 predefined tender points (TPs) measured by a thumb pressure of minimum 4 kg/m^2 [2]. The ACR 1990 criteria set was designed to be used in research, not clinically. Thus, it never had legitimacy for clinical use but was misused and proved to be difficult due to the identification of TPs. It has also been criticized in both clinical practice and research for bad reliability and construct validity and for being dichotomous [7]. Furthermore, it only encompassed pain, ignoring co-morbid fatigue, sleep disorders, cognitive dysfunction, and other somatic symptoms in the FM phenotype [8].

The later *ACR 2010 FM* diagnostic criteria rejected the mechanical pressure paradigm and introduced the

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Widespread Pain Index (WPI) (range 0–19) based on the reported location of pain plus a Symptom Severity Scale (SSS) score (range 0–12) based on three core FM-symptoms and the physician's assessment of overall symptom load (from 41 number of symptoms) [9].

In 2011, the ACR 2010 criteria were revised so that every item could be obtained and scored completely by patient self-administration and the SSS score was based on six defined common FM symptoms: fatigue, sleep problems, cognitive dysfunction, headache, depressive, and irritable bowel symptoms [10,11]. The 2010 criteria were good for attaining a clinical diagnosis but had inadequate validity for research [9], but the later 2011 criteria solved that. However, based on dialogues and research published in 2010–2016, the FM criteria underwent new modifications in *2016* to achieve both valid diagnostic and classification/research criteria [12]. The sum of the nineteen pain localizations scores in WPI and the six symptom severity scores in SSS was combined for the "Fibromyalgia Severity" (FS) score, also called the *fibromyalgianess* or *polysymptomatic distress* score [12,13]. It includes a scalar (range 0–31) assessment from "mild", through "moderate" and "serious" to "very serious." ACR 2016 is validated in several countries including Norway [14], albeit it does not approach a seamless alignment with the ACR 1990 criteria because the FM definition and its appearance have changed with the paradigm shift. The ACR 2016 criteria also signified a conceptual change in that FM now is valid and sound as a secondary condition, i.e., irrespective if the patient had another disorder, e.g., rheumatoid arthritis. Thus, the previous concept of the 2011 criteria saying that FM was an exclusive diagnosis was removed [12].

Eventually, in 2019, the American Pain Society (APS) and the Analgesic, Anesthetic, and Addiction Clinical Trial Translations Innovations Opportunities and Networks (ACTTION) Initiative on Methods, Measurement, and Pain Assessments in Clinical Trials introduced further FM diagnostic criteria constructing the ACTTION–APS Pain Taxonomy (AAPT) effort [15].

The prevalence of FM is estimated at 2–4% in the general population [16]. Following this, the prevalence of FM has been studied in various conditions and has differed according to which criteria are used. In co-morbid ankylosing spondylitis, the prevalence of FM ranges between 21 and 35% depending on using the ACR 1990, ACR 2010, ACR 2016, or the AAPT criteria [17]. It is also known that the FM criteria paradigm shift has reduced the female:male ratio from approximately 9:1 to 2–3:1 [16].

There is still a discourse going on about which criteria are "the best," while others say it is time to "stop the FM criteria wars" [18]. The above-mentioned diagnostic criteria may identify different profiles for pain and co-morbidity. Also, each criteria set may hypothetically produce different estimates for the FM prevalence, prognosis, and treatment consequences. Therefore, it is of interest to compare the consequences of applying the different criteria in the same patient population.

The purpose of this study was to explore the prevalence of FM according to different diagnostic criteria in a clinical sample and to explore the clinical characteristics of cases and non-cases by the diagnostic criteria used.

2 Methods

2.1 Design and participants

Clinical FM patients were consecutively recruited from the Norwegian Fibromyalgia Association (NFA) as participants in a Norwegian ACR 2016 validation study [14]. The participants were *eligible* if they had an FM diagnosis beforehand and a positive result on the FM screening question in the HUNT3 survey: "Have you had, or do you have any of the following: Fibromyalgia"? … (among other conditions, e.g. low back pain, etc.) with response alternatives "yes" or "no" (HUNT 3 Q1). In addition, they were asked: … or "are you under consideration for a FM diagnosis?" [19]. Furthermore, a sample without clinical FM, i.e., participants without previous FM diagnoses and negative results on the HUNT survey question, were also recruited. Participants <18 and >70 years of age were excluded.

One hundred and twenty-four persons with clinical FM were eligible and invited to participate in the study. In addition, 64 persons not diagnosed with clinical FM nor suspected of having FM were invited. Of all these eligible participants, four clinical FM patients and two clinical non-FM patients were excluded due to age >70 and missing data, which left 182 participants in total, i.e., 120 versus 62 respectively, aged 18–70 years to be included in the analyses.

The participants signed an informed consent, either electronically or on paper, before inclusion. The first and second authors checked the participants for eligibility, performed the clinical investigation, and diagnosed them according to the three diagnostic criteria, i.e., into ACR 1990, ACR 2016, and AAPT positive or negative diagnostic groups. In this study, we wanted to check if, or to what extent, the clinical FM patients and non-FM participants would receive a diagnosis of FM according to the three valid diagnostic FM criteria or not.

2.2 Assessments

All participants answered questions about their sociodemographic status (age, marital status and habitancy, economy, employment and financial status), pain intensity (VAS 0–10), anxiety and depression with 2 questions from HADS, one addressing anxiety (HADS-A) and one addressing depression (HADS-D) [20], and completed the Norwegian version of the Fibromyalgia Survey Questionnaire, which had items for diagnosing FM according to both the ACR 2016 and the AAPT criteria [14]. Finally, they scored the Fibromyalgia Impact Questionnaire (FIQ) and two investigators (EAF and KAW) thereafter measured their TP numbers and mechanical pressure sensitivity.

FIQ is a questionnaire often used to examine the impact of FM on function and level of symptoms during the previous week [21,22]. It has 10 items (20 questions) and measures function, overall/work impact, symptom score, and FIQ total score. The FIQ is scored in such a way that a higher score indicates a greater impact of the syndrome on the person. The first item consists of 11 questions that make up the physical functioning (FIQ function) scale, i.e., physical impairment. The 11 questions are related to the ability to perform day-to-day activities and scored on a 4-point Likert scale from "always" (0) to "never" (3). The scores are summed and divided by the number of questions to get a raw score between 0 and 3. Then, the scores are recoded by multiplying the raw score by 3.33 to give an FIQ function 0–10 score. The *FIQ "overall/work impact"* scores have two items/questions ranging from 0 to 7, which are recoded by multiplying the two raw scores by 1.43 to give 0–20 scores. The *FIQ symptom score* is the sum of 7 items/questions measuring the severity of 7 symptoms rated from "no symptoms" (0) to "substantial symptoms" (10) (range 0–70). The FIQ *total* is the sum score of all 10 items (range 0–100). The average FM patient will have an FIQ total score of about 50; severely afflicted patients usually score 70 or higher [22].

The *ACR 1990 criteria* case versus non-case classification depended on their amount of TP counts (>10/18) and that they had CWP. A diagnosis of FM according to the *ACR 2016 criteria* was made if the following three conditions were met: (1) the WPI ≥7 and the SSS score ≥5, or WPI 4–6 with SSS score ≥9; (2) generalized pain, defined as pain present in at least four of five regions (left/right upper quadrants, left/right lower quadrants, axial skeleton); and (3) the symptoms had been present and stable for at least 3 months. *The AAPT FM criteria* require pain to be present in at least 6 from a total of 9 sites (head, left/right arm and leg, chest, abdomen, upper back and spine, lower back and spine), moderate-to-severe sleep problems *or* fatigue, and that the pain plus sleep problems or fatigue have lasted for at least 3 months, as in the ACR 2016 criteria [15].

All questionnaires were returned by mail, or by an electric survey platform hosted by NFA. The data were sent directly to NFA, so they were blind for the investigators.

2.3 Statistics

The data management and the analysis were conducted with the SPSS version 25 (IBMSPSS, Chicago, IL, USA). Descriptive analyses of demographic and clinical characteristics of the groups with FM according to the clinical classification and the three different diagnostic criteria sets (ACR 1990, ACR 2016, and AAPT) were performed with the *chi-square statistic* for categorical variables and with *nonparametric Mann–Whitney U test* for continuous variables since the distribution was not normal. Due to multiple outcome measures of importance (16 in total), the *P*-value considered significant is set lower than 0.05 to keep the risk of Type-I error small. According to the Bonferroni correction, the 0.05 value is derived with the number of outcomes of interest; thus, the *P*-value considered significant in the present study is ≤0.0031 (α = 0.05/16) [23].

Ethics: The study was approved by the Regional Committee for Medical and Health Research Ethics (project REK Nord # 2014/938), including fulfillment of the General Data Protection Regulation and in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

3 Results

One hundred and eighty-two participants in total, i.e., 120 clinical FM-patients and 62 clinical non-FM patients respectively, age mean (SD) = 51.5 (11.9) and range 18–70 years, were included in the analyses.

Table 1 shows the frequencies and characteristics of the clinical FM cases, the different diagnostic FM criteria according to ACR 1990, ACR 2016, and AAPT and their sociodemographic and clinical characteristics.

Table 1 shows that all the diagnostic FM criteria cases identified fewer positive FM individuals than in the clinical sample. The prevalence of diagnoses according to the three FM diagnostic criteria sets, i.e., the ACR 1990, ACR 2016, and the AAPT varied from n = 99, n = 108 to n = 110, which were

Table 1: Prevalence and characteristics of fibromyalgia according to different fibromyalgia diagnostic criteria (i.e., ACR 1990, ACR 2016, and the AAPT) in a clinical fibromyalgia sample

			Total	Clinically *classified* fibromyalgia	ACR 1990 *diagnosed* fibromyalgia	ACR 2016 *diagnosed* fibromyalgia	AAPT *diagnosed* fibromyalgia
Subjects total	*n*		182	182	182	182	182
Pos FM	*n* (% of ref.[1])			120 (ref.)	99 (82.5)	108 (90)	110 (91.7)
Missing	*n*			ref.	3	1	2
Age	Mean (SD)	Years	51.5 (11.9)	53.1 (10.9)	53.0 (10.7)	52.3 (10.9)	52.2 (10.9)
Gender	*n* (%)	Female	178 (97.8)	119 (99.2)	99 (100)	106 (98.1)	107 (97.3)
Co-habiting	*n* (%)	Yes	136 (75.6)	88 (73.3)	74 (76.3)	80 (74.1)	84 (76.4)
Education level	*n* (%)	High	88 (48.4)	40 (33.3)	36 (36.4)	36 (33.3)	41 (37.3)
Economy	*n* (%)	good	66 (37.7)	32 (28.3)	29 (31.2)	23 (22.5)	30 (28.8)
		Moderate	85 (48.6)	62 (54.9)	44 (47.3)	57 (55.9)	52 (50.0)
		Poor	24 (13.7)	19 (16.8)	20 (21.5)	22 (21.6)	22 (21.2)
Employed in 100% position	*n* (%)	Yes	61 (34.3)	19 (15.8)	19 (19.6)	17 (16.2)	21 (19.8)

[1]Reference.

82.5, 90, and 91.7% respectively, of the clinical FM sample consisting of n = 120 clinical classified FM patients.

3.1 Diagnosed FM cases versus diagnosed non-cases:

Those who had FM according to the ACR 1990, ACR 2016, and the AAPT diagnostic criteria reported higher scores for TP counts, mechanical pressure sensitivity, FIQ total, and all FIQ items except anxiety and depression ($p < 0.001$) than those not fulfilling the respective criteria. Patients with FM according to all criteria but the ACR 2016 criteria scored similarly to controls for FIQ anxiety. For FIQ depression, all criteria except the AAPT cases and non-cases had similar scores.

The prevalence of anxiety defined by HADS was higher in cases compared to non-cases only when applying the ACR 2016 diagnostic criteria, but not for the other criteria. For depression defined by HADS, the prevalence was higher in the FM groups for all criteria except of the ACR 1990. In our sample, when applying the ACR 1990 criteria there was no difference between cases and non-cases in neither anxiety nor depression by FIQ score or prevalence based on HADS. See Table 2. Significant differences are shown in bold.

4 Discussion

We found a discrepancy in the number of cases diagnosed with FM based on three different diagnostic criteria. For all these criteria the number of cases was lower than what was identified with clinical inclusion. The number was lowest for the ACR 1990, higher for the ACR 2016 and highest for the AAPT. For all the three FM diagnostic criteria, cases reported higher scores for most FM-relevant symptoms than their respective negative cases. However, for anxiety and depression, we found that their link to FM varied with the applied diagnostic criteria.

Many regard FM as a condition presenting a continuous severity score from mild-to-severe fibromyalgianess, but it could also be viewed as a heterogenous disorder with sub-groups or phenotypes, as suggested in other chronic pain studies [24]. Important questions are whether the different diagnostic FM criteria identify the same patient population or not. Pain is the key symptom in FM, and the focus is on distribution and duration. Consequently, we cannot say whether the observed differences in prevalences are related to pain intensity or loss of function. Possible differences might also relate to different phenotypes caused by other symptoms than pain and various pathophysiological mechanisms. Since both the ACR 2016 and the AAPT criteria include other symptoms than pain, it is possible that these are the main factors explaining differences in prevalence. These differences may potentially have relevant implications for treatment, management, and clinical outcome.

The 1990 criteria have been regarded as stricter than the later self-reported criteria [9]. This view supports our findings that the ACR 1990 criteria have a lower prevalence than the ACR 2016 and AAPT criteria. Some authors have suggested that the focus shift from pain toward the later

Table 2: Features of the participants by yes or no to clinical FM and the ACR 1990, ACR 2016, and AAPT diagnostic FM criteria groups

Clinical features	Clinical FM			ACR 1990			ACR 2016			AAPT		
	Yes	No	*p*-value	Yes	No	*p*-value	Yes	No	*p*-value	Yes	No	*p*-value
Tender-point counts	**14(5)**	**3(5)**	<0.001	**14(3)**	**5(5)**	<0.001	**14(5)**	**5(6)**	<0.001	**14(5)**	**5(8)**	<0.001
Algometer (kPa)[1]	**324(154)**	**529(107)**	<0.001	**291(86)**	**501(151)**	<0.001	**322(106)**	**499(162)**	<0.001	**325(112)**	**493(193)**	<0.001
FIQ total[1]	**53(19)**	**19(31)**	<0.001	**53(16)**	**24(35)**	<0.001	**54(17.8)**	**21.8(32)**	<0.001	**54(18)**	**23(34)**	<0.001
FIQ symptoms total[1]	**39(16)**	**15(22)**	<0.001	**40(14.5)**	**20.5(27.9)**	<0.001	**41(13)**	**17(21)**	<0.001	**41(15.5)**	**17(25.5)**	<0.001
FIQ function total[1]	**2.7(2.6)**	**0(1.6)**	<0.001	**2.8(2.6)**	**0(2.4)**	<0.001	**2.9(2.7)**	**0(1.9)**	<0.001	**3(2.7)**	**0(1.9)**	<0.001
FIQ wellbeing[1]	**7.2(5.7)**	**1.4(5.7)**	<0.001	**7.2(5.7)**	**2.9(5.2)**	<0.001	**7.2(5.7)**	**2.9(5.7)**	<0.001	**7.2(5.7)**	**2.9(6.4)**	<0.001
FIQ no works[1]	**2.9(4.3)**	**0(1.4)**	<0.001	**2.9(4.7)**	**0(1.4)**	<0.001	**2.9(4.3)**	**0(1.4)**	<0.001	**2.9(4.7)**	**0(1.4)**	<0.001
FIQ impact on work[1]	**6(3)**	**1(4)**	<0.001	**6(3.25)**	**2(5)**	<0.001	**6.5(2.5)**	**1(4.6)**	<0.001	**6(3.3)**	**1(5)**	<0.001
FIQ pain (VAS 0–10)[1]	**7(3)**	**3(4)**	<0.001	**7(3)**	**3.5(5)**	<0.001	**7(3)**	**3(4)**	<0.001	**7(2.75)**	**3(4)**	<0.001
FIQ fatigue[1]	**8(2)**	**4(3)**	<0.001	**8(2)**	**4.3(5)**	<0.001	**8(2)**	**4(4)**	<0.001	**8(2)**	**4(4.3)**	<0.001
FIQ sleep[1]	**8(4)**	**3(4)**	<0.001	**8(3)**	**4(5)**	<0.001	**8(3)**	**3(4.4)**	<0.001	**8(2.5)**	**3(4)**	<0.001
FIQ stiffness[1]	**8(3)**	**2.25(4)**	<0.001	**8(2.3)**	**3.8(6)**	<0.001	**8(3)**	**3(5.3)**	<0.001	**8(3)**	**3(6)**	<0.001
FIQ anxietya	*1.5(5)*	*0.5(2)*	0.029	*2(5)*	*1(2)*	0.042	**2(4.5)**	**0(1.9)**	<0.001	2(5)	0(2)	0.06
FIQ depression[1]	1(4)	0(1.75)	0.013	1(5)	1(2)	0.034	1(5)	0(2)	0.021	**1.5(5)**	**0(2)**	<0.0031
HADS-A[2]	55(82.1)	12(17.9)	0.009	45(69.2)	20(30.8)	0.028	**52(77.6)**	**15(22.4)**	<0.0031	51(76.1)	16(23.9)	0.005
HADS-D[3]	**70(84.3)**	**13(15.7)**	<0.001	*55(67.9)*	26(32.1)	0.013	**64(77.1)**	**19(22.9)**	<0.001	**65(78.3)**	**18(21.7)**	<0.001

Bonferroni adjusted significance levels (alfa): 0.05/16 = 0.0031. Significant differences are shown in bold.

[1]Median (IQR).

2HADS anxiety for each FM group is calculated [*n* (%)] from those with HADS anxiety in the total sample (*n* = 182).

[3]HADS depression for each FM group is calculated [*n* (%)] from those with HADS depression in the total sample (*n* = 182).

multiple FM symptom perspective has led to an inclusion of more maladapted patient profiles, i.e., other features like depression, stress, catastrophizing, etc., in addition to pain [25,26].

Another aspect is that a diagnosis according to the 1990 criteria set is based on a clinical evaluation, while the ACR 2016 and AAPT criteria are self-administered and therefore could possibly capture more subjective distress and thus increase the perceived severity of the self-reported symptoms [26,27].

Several studies have found FM to be related to anxiety and depression [28,29]. We found that the link between FM and both anxiety and depression varied based on the FM criteria used. A vital question is whether one or both conditions should be considered part of the FM phenotype or as co-morbid conditions associated with FM. Our findings question whether anxiety and depression are integrated parts of the FM phenotype or should be regarded as co-morbid conditions, which should be considered and diagnosed independently. This is not just a theoretical exercise. It has important implications for clinical practice. Patients will often be sensitive to whether a condition is regarded as somatic or psychological and an important task for clinicians is to bridge this dichotomy, especially in multifactorial conditions like FM. If the diagnosis itself implies preset conclusions that the patient reacts negatively toward, this might seriously affect management and the doctor–patient relationship.

4.1 Strengths and limitations

Patients were recruited by the NFA based on a previous FM diagnosis from a clinical setting and validated with a positive answer on the HUNT survey FM question. This means that our sample reflects a broad FM population representing a variety of patients as they present to the health care services. The classification and diagnostics were made by two of the authors (EAF and KAW, both specialists in general practice), who did subsequent testing of interrater and intrarater reliability measures [14], but not by the last author (ASH). The outcomes were based on validated questionnaires commonly used in research.

There were limitations to our study. We present a secondary analysis not part of the initial project. Most importantly, the sample size is rather small, and we lack power

to analyze in more detail which items in the criteria sets that might explain the observed differences. Therefore, our findings must be interpreted with care. However, the findings raise important questions that should be explored further in a larger sample of patients recruited from primary care or the general population to reduce bias introduced when recruiting from the patient organizations.

4.2 Implications

Differences in FM prevalence and characteristics of the patient population based on the criteria used have implications both for research and for clinical management. FM is a clinical diagnosis given to patients, and like any other diagnosis, there must be criteria making it possible to differentiate cases from non-cases. How categorical this should be depends on the purpose of the diagnosis. When the diagnosis will guide potentially harmful treatment or form the basis for social benefits, the diagnosis must be rigid. In other situations, the diagnosis might improve understanding of the overall condition and aid self-management and coping, and then it might be useful to consider FM to be symptoms on a spectrum with no specific cut-off. There are no purely clinical FM criteria, and the approach used in this study is the best we have in the clinical setting. Further, the criteria used in research cannot be substantially different from criteria in the clinic as this will seriously reduce the external validity of the research. This has been acknowledged for ACR 2016 which is validated for both research and clinic.

In the recent years, many researchers have identified varieties of FM patients who share some common subgroup characteristics, but they are not aligned to different diagnostic criteria, as in our study. Some studies have classified psychophysiological responses [30] and pain acceptance [31], while other studies have considered the variability of childhood maltreatment and biomarkers [32]. Chronic pain per se may reveal different symptom profiles [24]. In this study, we found that the FM patients may be differentiated on anxiety and depressive symptoms according to which diagnostic instruments they had used.

The diagnosis could have implications for the person, her family, and the social welfare and insurance compensations, and clinicians must try to explain their diagnosis to patients and family by stating that there are many different ways to define the group, both according to severity using the fibromyalgianess score, but also in line with the heterogenous symptom profiles [33,34]. Thus, it may be useful to fetch the symptom profiles in the different FM diagnostic criteria and explore possibly different FM outcomes over time, e.g., anxiety and depression to provide a tailored treatment. However, our study had a cross-sectional design, but this can be done in later prospective and longitudinal studies.

It is difficult to conclude which criteria are “the best” in suggesting “real” FM since there is no consensus of a gold standard; as a matter of fact, some have urged to “stop the criteria wars” [18]. Nevertheless, of the new FM diagnostic criteria, the ACR 2016 appears slightly better than AAPT in our study, a finding in line with, e.g., Salaffi et al. [35], if we focus on their ability to discriminate between cases and non-cases. The ACR 2016 criteria are also valid for use in both research and treatment.

5 Conclusion

The ACR 1990, ACR 2016, and AAPT criteria revealed a slightly lower prevalence of FM compared to the corresponding clinical FM sample in our study. Of these, the number was lowest for the ACR 1990, higher for the ACR 2016, and highest for the AAPT. Anxiety and depression contrasted cases and non-cases using some, but not all the three diagnostic criteria. Concerning the other FM symptoms, e.g., TPs mechanical pressure sensitivity and most FIQ items, all the diagnostic criteria contrasted cases from non-cases.

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Research ethics: Approved by the Regional Committee for Medical and Health Research Ethics (project REK Nord # 2014/938), including fulfillment of the General Data Protection Regulation and in accordance with the Declaration of Helsinki.

Informed consent: All participants signed an informed consent, either electronically or on paper, before inclusion.

Author contributions: All authors have contributed to the study design, data analyses, drafting of the article, and the manuscript review. EAF and KAW contributed to the data collection and patient recruitment. All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

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Data availability: The raw data can be obtained from the corresponding author on request.

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