

The prevalence of fibromyalgia in the general population – a comparison of the American College of Rheumatology 1990, 2010 and modified 2010 classification criteria

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ABSTRACT

Background The ACR 1990 fibromyalgia classification criteria are based on widespread pain and tenderness. In 2010 new criteria were proposed, focusing more on multiple symptoms and these, latterly, were modified to require only self-report. The current study aimed to determine the population prevalence of fibromyalgia, and to compare differences in prevalence, using the alternative criteria.

Methods A cross-sectional survey was conducted. Questionnaires, including items on pain, symptoms, and rheumatological diagnoses, were mailed to 4600 adults in northeast Scotland. Participants with chronic widespread pain, or who met the modified 2010 criteria, plus a sub-sample of other participants were invited to a research clinic. Attendees completed an additional questionnaire, and a rheumatological examination, and were classified according to the ACR 1990, 2010 and modified 2010 criteria. The prevalence of each was calculated, weighting back to the target population by age, sex and area of residence.

Results Of 1604 questionnaire participants, 269 were invited and 104 (39%) attended the research clinic, of whom 32 (31%) met ≥ 1 of the fibromyalgia criteria. The prevalence of fibromyalgia using the 1990, 2010 and modified 2010 criteria was 1.7% (95%CI: 0.7-2.8%); 1.2% (0.3-2.1%); and 5.4% (4.7-6.1%), respectively. The female/male ratio was 13.7 to 4.8 and 2.3, respectively.

Conclusion Fibromyalgia prevalence varies with the different classification criteria – specifically, prevalence is higher, and a greater proportion of men are identified, with the modified 2010 criteria, compared to those requiring clinician input. This has important implications for the use of the new criteria both in research and in clinical practice.

INTRODUCTION

Fibromyalgia is one of the most common reasons for referral to a rheumatologist (1) and, while there are a number of estimates of the occurrence of fibromyalgia in rheumatology clinic populations, there are few studies of prevalence in the general population. Data from a national health interview survey in Denmark estimated the prevalence to be <1% (2). Others have reported a prevalence of 2.4% in Spain (3); and in North America estimates vary from 2.0% to 3.3% (4;5). Prevalence increases with age, reaching a peak around the seventh decade, and at every age is more common in women than in men (4).

The above studies all employed the American College of Rheumatology (ACR) 1990 criteria for the classification of fibromyalgia (6) comprising (a) a history of chronic widespread pain (pain, present for at least three months, in the left and right sides of the body; above and below the waist; and in the axial skeleton); plus (b) pain on digital palpation in ≥ 11 of 18 specific sites (see Figure 1). In 2010, new classification criteria for fibromyalgia were proposed (the 'ACR preliminary diagnostic criteria' (7)) and differed from the 1990 criteria in two main respects: firstly, they operationalized the measurement of chronic widespread pain; and secondly – more fundamentally – they did away with the requirement for a tender-point examination in favour of an assessment of fatigue, waking un-refreshed, cognitive symptoms and somatic symptoms in general. Under these new criteria a patient would be classified as having fibromyalgia if a clinician determined that they had (a) high pain plus moderate symptoms, or moderate pain plus high symptoms; (b) symptoms present at a similar level for ≥ 3 months; and (c) no disorder that would otherwise explain the pain (see Figure 2). These criteria have not been formally adopted and are only 'approved by the ACR Board of Directors as Provisional' (7). Then, in 2011, a modified version of the 2010 criteria were proposed for clinical and epidemiological studies that relied on self-reported pain and a simplified self-reported version

of somatic symptoms (8). These preliminary research criteria are hereafter referred to as the modified 2010 criteria (see Figure 3).

The prevalence of fibromyalgia as per the ACR modified 2010 criteria were assessed in a large population survey in Germany (9). Fifty-two of 2445 participants were found to have fibromyalgia, giving a prevalence of 2.1%. Given the reliance on self-report and absence of clinical judgement, one might expect an elevated estimate of prevalence. However, these authors concluded that the modified 2010 criteria do not result in high levels of fibromyalgia. However, it is not known what the prevalence of fibromyalgia would have been in this population using the previous classification criteria and, therefore, to what extent this is a valid conclusion.

To the best of our knowledge, there have been no published studies of fibromyalgia comparing the ACR 1990, 2010 (preliminary diagnostic) and modified 2010 (preliminary research) classification criteria for fibromyalgia in the general population. Thus, the aim of the current study was, firstly, to determine the prevalence of fibromyalgia in the general population; secondly, to compare the prevalence estimates obtained using the established (ACR 1990) and the two proposed (ACR 2010 and ACR modified 2010) classification criteria; and thirdly, to determine the main influences of any differences in identified cases, when using the alternative criteria.

MATERIALS AND METHODS

A two-stage population-based prevalence study was conducted, in the last quarter of 2012 and the first quarter of 2013. This consisted of, firstly, a cross-sectional postal questionnaire survey followed, secondly, by clinical examination of a subset of survey participants.

Population survey

In the UK, the majority of healthcare is provided by the National Health Service (NHS); in 2009 it is estimated that only 3% of all general practice consultations were undertaken by private primary care practitioners (10). Thus, NHS general practice lists provide a convenient population-based sampling frame for epidemiological research. A sample of 4600 individuals, aged ≥ 25 yrs, was randomly selected from the NHS register in Grampian, northeast Scotland. Grampian comprises a single city and a mixture of sub-urban and rural areas, with a 2010 mid-year population estimate of approximately 340,000 persons aged ≥ 25 yrs.

Selected individuals were sent an advance letter, indicating that they had been selected for the study, followed by the survey pack one week later. The pack consisted of an invitation letter, an information sheet, the questionnaire, and a pre-paid reply envelope. Two weeks later, a duplicate pack was sent to non-respondents. Participants were asked: 'thinking back over the past four weeks, have you had any aches or pains that have lasted for one day or longer?' Those answering positively were directed to shade the location of these pains on four-view blank body manikins, and asked whether they had experienced these pains for ≥ 3 months. They were also asked whether they had experienced pain or tenderness over the past seven days in each of the areas listed in the Widespread Pain Index of the ACR modified 2010 fibromyalgia criteria, plus the questions that comprise the Symptom Severity Scale of the same criteria (see Figure 3). Further, they were asked

to report whether they had ever been told by a healthcare provider that they had one, or more, of: osteoarthritis (confirmed by x-ray), rheumatoid arthritis, osteoporosis, lupus, scleroderma, ankylosing spondylitis, gout, or fibromyalgia.

Clinical examination

Participants who screened positive on the questionnaire were those who reported:

- (a) Chronic widespread pain; and / or
- (b) Fibromyalgia as per the ACR modified 2010 criteria.

In order to determine what proportion met the various criteria for fibromyalgia, these individuals were invited to attend the University of Aberdeen Clinical Research Facility for further examination.

However, it was also important to establish whether any participants who screened negative were deemed to have fibromyalgia on subsequent examination. Therefore, a sub-sample of participants was also invited to attend who reported:

- (c) Pain, but not meeting the above definition; or
- (d) No pain.

In the clinic, participants completed a second questionnaire and underwent a clinical examination by a single examiner (author: FA, a consultant rheumatologist). This included a full clinical history and tender-point examination, as per the ACR 1990 criteria for fibromyalgia.

Prevalence of fibromyalgia

The number of cases of fibromyalgia were determined as follows:

- ACR 1990 Data from the clinic questionnaire and tender-point examination;
 - ACR 2010 Data from the clinic questionnaire and clinical history / examination;
- and

- ACR modified 2010 Data from the postal questionnaire.

The prevalence of fibromyalgia was then calculated, weighting the results to the target population by the inverse of the sampling fraction, based on age, sex and area of residence (urban or rural).

Ethical approval

The study was approved by the North of Scotland Research Ethics Committee (REC reference: 12/NS/0079).

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RESULTS

Out of 4600 distributed questionnaires, 183 were considered not to have been received by the invited participant (for example, due to being returned marked as deceased, or being no longer resident at the given address) and 1604 (36.3%) of the remaining 4417 eligible invitees returned a completed questionnaire. The median age of respondents was 55yrs (inter-quartile range: 44-65yrs), 55% were female, and the median time from sending the questionnaire to response was six days (inter-quartile range: 3-16 days).

Of the questionnaire responders, 269 were invited to attend the clinical examination, of whom 104 (39%) attended and 32 (31%) were found to meet at least one of the criteria for fibromyalgia: eleven participants met the ACR 1990 criteria; seven met the ACR 2010 criteria; and 27 met the ACR modified 2010 criteria. The overlap between different classification criteria was modest (see Figure 4). In total, only four participants (12.5%) met all of the three criteria, and only nine (28%) met more than one.

The prevalence of fibromyalgia, as ascertained by the ACR 1990, 2010 and modified 2010 criteria, weighted back to the characteristics of the target population, was 1.7% (95%CI: 0.7-2.8%), 1.2% (0.3-2.1%) and 5.4% (4.7-6.1%), respectively. Compared to the ACR 1990 criteria as gold standard, the ACR 2010 criteria had a sensitivity of 55% and a specificity of 99%; in contrast, values for the modified 2010 criteria were 64% and 78%, respectively.

Patients meeting the ACR 1990 criteria were predominantly female, with a female to male ratio of 13.7:1. The ratio was lower in those meeting the ACR 2010 criteria (4.8:1), and lower still among those meeting the ACR modified 2010 criteria (2.3:1) (see Table 1). There were also differences in the proportion of participants who, in the questionnaires, reported prior rheumatological diagnoses

(see Table 1). This varied from over half of those meeting the ACR 1990 criteria, to just over one-quarter of those who met the ACR 2010 criteria. It should be noted, however, that these figures represent patient-reported diagnoses which are completely independent of whether the examiner felt that the patient had 'a disorder that would otherwise explain the pain'.

This element of the ACR 2010 criteria – i.e. the exclusion of patients that are considered to have an underlying disorder, responsible for pain – may explain both the low prevalence (1.2%), and the comparatively low proportion of cases reporting prior diagnoses. However, even without this exclusion, the prevalence was still considerably lower (2.6%) than that ascertained using the ACR modified 2010 criteria. All participants who fulfilled both the ACR 2010 and modified 2010 criteria met the latter by reporting a high score on the Widespread Pain Index, rather than the Symptom Severity Scale (see Table 2). In contrast, among the group who met only self-reported criteria, around one-third satisfied the case definition as a result of high symptoms, plus only moderate pain (see Table 2).

DISCUSSION

We have demonstrated that the prevalence of fibromyalgia varies more than four-fold with the application of different ACR fibromyalgia classification criteria, the lowest estimate being with the 2010 criteria, and highest with the modified 2010 criteria. Further, we have shown that there are fundamental differences in the populations identified, in terms of gender ratio, and pre-existing comorbid rheumatological conditions.

There are a number of methodological issues to consider in the interpretation of these findings. Firstly, the response rate in the initial survey was modest (36%). Questionnaire survey response rates are falling over time (11) and a response of 30-40% is not uncommon. Compared to non-responders, questionnaire respondents in the current study were significantly more likely to be female, and were older. Also, only 39% of the 269 participants invited to attend the research clinic actually did so. Attenders were more likely to be male, older, and more likely to live in urban areas, than those who were invited but did not attend. However, because the initial sampling frame was from the NHS register, information on age and sex was available not only from the questionnaire respondents, but on all persons invited to participate in the initial survey. Thus, to counteract the effects of potential selection (non-participation) bias, the prevalence estimates were weighted back to the age and sex distribution of the target population, and on the proportion living in urban / rural areas. However, one limitation of the current study is that generalisations are made about the prevalence of fibromyalgia based, in some groups, on very small samples. For example, for men aged ≤ 50 yrs, there were no cases of fibromyalgia identified using either the ACR 1990 or ACR 2010 criteria. Accordingly, the weighting process will assume that there are no cases at all in this particular population stratum. While this is probably unlikely, it is known that this is a group that has a particularly low risk of fibromyalgia (4) and so this finding is not unexpected.

Another limitation in the current study was the use of a single clinician for the clinical examination and case history (author: FA, a consultant rheumatologist). The clinical consultation is inherently a subjective experience and it is possible that a different examiner might have come to a different conclusion regarding (a) tender-points (ACR 1990 criteria); and / or (b) diagnosis that might otherwise explain the pain symptoms (ACR 2010 criteria). However, the use of a single clinician not only more closely resembles routine clinical practice, but in the context of a research study has the desirable effect of reducing any between-participant variation. Further, the prevalence of fibromyalgia in the current study (1.7%, as ascertained using the ACR 1990 criteria) is exactly in the range one might expect based on other earlier studies in Europe and North America (2-5). Our sample size precludes a robust examination of differences in prevalence by various demographic characteristics, but it is worthy of note that cases were more likely to be older females, rather than younger males – as would be expected.

The specificity of the ACR 2010 criteria, when compared to the ACR 1990 criteria as a gold standard, was near perfect. Of the 93 participants identified as not having fibromyalgia according to the ACR 1990 criteria, 92 were correctly identified by the 2010 criteria. However, the sensitivity of the new criteria was modest, just over half of the 1990 fibromyalgia cases were correctly identified by the new criteria. The modified 2010 criteria, while exhibiting an improved sensitivity (more ACR 1990 positive participants were correctly identified), suffered from a decrease in specificity (fewer ACR 1990 negatives were correctly identified). Others have examined the sensitivity and specificity of the modified 2010 criteria in clinical populations. Bennett et al found a specificity of 67% in non-fibromyalgia chronic pain patients – i.e. 33% of people with other chronic pain conditions were incorrectly classified as having fibromyalgia with the new criteria (12). Similar to the current study (specificity = 78%), this is perhaps not surprising and is probably a function of the willingness of participants to self-report symptoms that, on physical examination by a clinician, were not considered eligible of inclusion. This is reflected in the fact that none of the participants who met

both the ACR 2010 and modified 2010 criteria (clinician determined, and self-report, respectively) did so as a result of high symptoms score: all had a Widespread Pain Index ≥ 7 and Symptom Severity Scale ≥ 5 , whereas nearly one-third of the participants who met the self-report criteria alone, had Widespread Pain Index 3-6, plus Symptom Severity Scale ≥ 9 . However, the numbers in the former group were very small, and further validation of these findings in another study is warranted.

The other clear difference between the ACR 2010 and the modified 2010 criteria, other than being physician versus patient completion, is the fourth part of the Symptom Severity Scale. In the former, the physician is asked to rate somatic symptoms in general from 0 (no symptoms) to 3 (a great deal of symptoms), and more than forty symptoms are listed that might be considered. Whereas, in the modified 2010 criteria the same score, 0-3, is based on the patient's report of three symptoms in the past six months: headaches; pain or cramps in the lower abdomen; and depression; each scored yes or no. Agreement between the two questions was very poor (Kappa = 0.09). Participants were much more likely to report symptoms (27% reported none; 18% reported all three) than was reflected in the physician's assessment of somatic symptoms generally (66% scored zero; 5% scored three). This suggests that the former is not a good proxy for the latter, and explains (at least in part) the increase prevalence observed with the modified 2010 criteria.

Although the modified 2010 criteria have been used in several studies (9;13-16), this has been almost exclusively in clinical populations and we believe that the current study is the first to attempt to implement the new criteria by a group completely independent of the original authors. We found considerable difficulty operationalizing ACR 2010 criteria for fibromyalgia. To satisfy these criteria, a patient must meet several conditions: firstly, a certain pattern of pain and somatic symptoms must be present; and, secondly, it is a requirement that 'symptoms have been present at a similar level for ≥ 3 months'. However, it is not clear from the proposed criteria (Figure 2) whether this relates solely to the symptoms encompassed by the Symptom Severity Scale, or whether it also includes pain. In

addition, it is a requirement that the 'patient does not have a disorder that would otherwise explain the pain' but, similarly, it is not clear whether this relates solely to the Widespread Pain Index or whether it also includes some of the (painful) somatic symptoms. These are subtle but crucial points and it is likely that different observers might come to different conclusions about these criteria, even in the same patient. In the current study, we adopted an inclusive approach and interpreted 'symptoms' to mean 'symptoms including pain'; and 'pain' to mean 'pain and / or other symptoms'. Therefore, if any bias has been introduced, it will have served to overestimate the number of participants with symptoms (or pain) present at a similar level for ≥ 3 months; to overestimate the number of participants with a disorder that would otherwise explain the pain (or symptoms); and thus to underestimate the prevalence of ACR 2010 fibromyalgia.

There was also difficulty operationalizing the modified 2010 criteria (Figure 3). Firstly, they suffer from the same interpretational problems as the ACR 2010 criteria, above. But more importantly, most patients are insufficiently qualified to determine whether they have a disorder that would otherwise explain the pain (and / or symptoms). In the current study, although we asked participants to report whether they had ever received one or more of a number of rheumatological diagnoses, we excluded this condition when determining the prevalence using these criteria. This will have served to overestimate the prevalence of fibromyalgia using this definition. This is a concern, because these criteria gave the highest prevalence estimates. However, were we to apply this condition (i.e. were we to exclude patients who have, in the past, received a rheumatological diagnosis), the prevalence drops by 44%, from 5.4% to 3.0%. We should stress, however, that in the questionnaire participants were simply asked whether or not they have ever received such a diagnosis, and not whether they thought it explained their pain. Separately, and blind to the questionnaire data, the rheumatologist who examined the participants came to her own decision about the presence / absence of a condition, rheumatological or otherwise, that might explain the

pain and symptoms. It was this latter assessment that was used in the application of the ACR 2010 criteria.

The ACR 2010 and modified 2010 criteria reflect a conceptual change in the thinking about fibromyalgia – or at least in the classification of fibromyalgia – from predominantly a pain syndrome, to a multi-symptom syndrome. This paradigm shift may or may not be appropriate – there is a certain circularity in classification criteria being developed by clinicians, then validated against ‘clinically diagnosed’ patients (typically the patients of the same clinicians). However, using the 2010 criteria, we have shown that 45% of patients previously classified as having fibromyalgia would now not be classified as such. This may have important implications for treatment, invalidity benefit, and health insurance.

The modified 2010 criteria also reflect a change from physician-derived classification criteria recommended for use in the clinic, to those based on self-report and able to be captured in large-scale epidemiological surveys. However, the performance of these criteria when compared to the ACR 2010 criteria is not satisfactory, with a sensitivity of 57% and a specificity of 76%.

The current study is the first to compare all three classification criteria in a general population sample, and we cannot support previous claims that the modified 2010 criteria do not result in inflated prevalence estimates (9). Furthermore, we have demonstrated that the new criteria define a demonstrably different patient group, compared to the 1990 criteria (which they may replace). For example, the modified 2010 criteria not only identifies a greater proportion of men, but also appear to be more influenced by somatic symptoms, rather than pain. Most importantly, operationalization of any new criteria must be clear and unambiguous, and immediately able to be implemented. This is not currently the case. Both the ACR 2010 and modified 2010 criteria are currently considered preliminary and we strongly recommend that the ACR consider these important

issues in deciding whether to confirm these proposed criteria for use in future clinical practice and /
or research.

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Authors' contributions

GTJ, FA, PSP and GJM conceived the idea for the study. The population survey was undertaken by EF. The clinic visits were coordinated by MB; and FA conducted the clinical examination on study participants. MB conducted the analysis. GTJ and GJM provided day-to-day supervision of the project. GTJ produced the first draft of the manuscript and all authors provided critical input to revision of the manuscript, and approved the final submitted version.

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FIGURES

Figure 1 ACR 1990 criteria for the classification of fibromyalgia (6)

1.	History of widespread pain	
	Definition	Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered for each involved side. "Low back" pain is considered lower segment pain.
2.	Pain in 11 of 18 tender point sites on digital palpation	
	Definition	Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites.
	<i>Occiput</i>	bilateral, at the sub-occipital muscle insertions.
	<i>Lower cervical</i>	bilateral, at the anterior aspects of the intertransverse spaces at C5-C7.
	<i>Trapezius</i>	bilateral, at the midpoint of the upper border.
	<i>Supraspinatus</i>	bilateral, at origins, above the scapula spine near the medial border.
	<i>Second rib</i>	bilateral, at the second costochondral junctions, just lateral to the junctions on the upper surfaces.
	<i>Gluteal</i>	bilateral, in upper outer quadrants of buttocks in anterior fold of muscle.
	<i>Greater trochanter</i>	bilateral, posterior to the trochanteric prominence.
	<i>Knee</i>	bilateral, at the medial fat pad proximal to the joint line.

Figure 3 A modification of the ACR 2010 preliminary diagnostic criteria for fibromyalgia (8)

A patient satisfies modified ACR 2010 fibromyalgia diagnostic criteria if the following 3 conditions are met:

- 1 Widespread pain index (WPI) ≥ 7 and symptom severity (SS) scale score ≥ 5 , or WPI between 3-6 and SS scale score ≥ 9 .
- 2 Symptoms have been present at a similar level for at least 3 months.
- 3 The patient does not have a disorder that would otherwise explain the pain.

Ascertainment

WPI Note the number areas in which the patient has had pain over the last week. In how many areas has the patient had pain? Score will be between 0 and 19ⁱ.

Shoulder girdle (left and right)	Jaw (left and right)
Upper arm (left and right)	Chest
Lower arm (left and right)	Abdomen
Hip (buttock, trochanter) (left and right)	Upper back
Upper leg (left and right)	Lower back
Lower leg (left and right)	Neck

SS For the each of fatigue, waking unrefreshed, and cognitive symptoms, indicate the level of severity over the past week using the following scale:

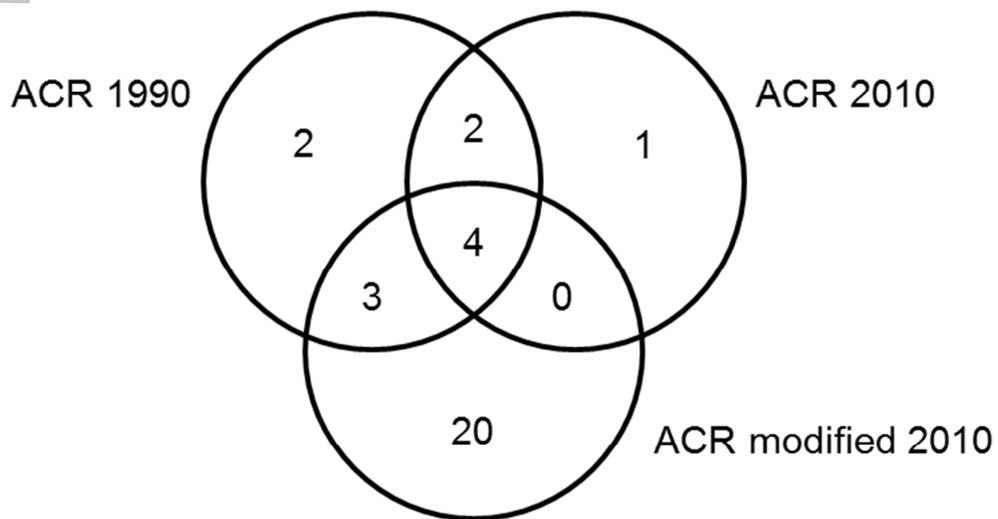
- 0 = no problem
- 1 = slight or mild problems, generally mild or intermittent
- 2 = moderate, considerable problems, often present and/or at a moderate level
- 3 = severe: pervasive, continuous, life-disturbing problems

The Symptom Severity Score is the sum of the severity of the 3 symptoms above, plus the sum of the number of the following symptoms occurring during the previous 6 months: headaches, pain or cramps in lower abdomen, and depression (0-3). The final score is between 0 and 12.

ⁱ For areas indicated left and right, these should be scored separately.

Figure 4

Overlap between three different case definitions for fibromyalgia



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Table 1 *Prevalence of fibromyalgia*

Criteria	Prevalence (95%CI)	Female / Male	Rheumatological diagnoses ¹
ACR 1990	1.7% (0.7-2.8%)	13.7	55%
ACR 2010	1.2% (0.3-2.1%)	4.8	28%
ACR modified 2010	5.4% (4.7-6.0%)	2.3	45%

¹ Proportion of respondents who answered positively the question: Have you ever been told by a healthcare provider that you have any of the following diseases (osteoarthritis, rheumatoid arthritis, osteoporosis, lupus, scleroderma, ankylosing spondylitis, gout, or fibromyalgia)?

Table 2 *Proportion of participants who met each case definition in the ACR modified 2010 criteria, stratified by the ACR (non-modified) 2010 criteria*

ACR modified 2010 case definition	ACR 2010 positive participants (n=4)	ACR 2010 negative participants (n=23)
Widespread Pain Index ≥ 7 ; + Symptom Severity Scale ≥ 5	n=4 (100%)	n=16 (70%)
Widespread Pain Index 3-6 + Symptom Severity Scale ≥ 9	Nil	n=7 (30%)