# Development and validation of the SImple FIbromyalgia Screening questionnaire for improving the recognition of fibromyalgia in daily practice

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**ABSTRACT**

**Objective.** *To develop and test in a preliminary way a new self-administered and user-friendly screening tool, called SImple FIbromyalgia Screening (SIFIS) questionnaire, to screen Italian speaking patients for the presence of fibromyalgia (FM).*

**Methods.** *The development of the SIFIS questionnaire followed five steps: identification of a specific patient population, item pool development, item reduction, test of the provisional questionnaire, and validation study. The item generation was carried out by a review of the literature on the existing questionnaires. Thirty-three items were identified, and a survey was performed among 139 specialists. The frequency importance product allowed us to select the six most significant items. The validation study allowed the determination of sensitivities, specificities and likelihood ratios (LRs) aiming to calculate the post-test probability of the presence of FM, by applying the Bayesian Analysis Model method.*

**Results.** *The preliminary testing was performed in 284 subjects with multisite pain. In 230 (80.9%) of them, FM was diagnosed according to the modified 2010 American College of Rheumatology (ACR) criteria. For each of the six items, LRs varied between 3.37 and 5.00. The best positive LR was found in item 1, exploring persistent pain. The presence of four out of six items gave a post-test probability ≥80% (range: 81.8–87.1%).*

**Conclusion.** *The SIFIS questionnaire is a useful tool that can be used for potential screening.*

## Introduction

Fibromyalgia (FM) is a condition that affects 2.31% of the European population, and 2.22% of the Italian population (1, 2). Early diagnosis is still difficult to achieve, hampered by a myriad of symptoms that are not always easy to understand (3, 4). Chronic widespread pain (CWP) remains the main feature of the disease, along with fatigue, unrefreshing sleep, digestive, psychological and cognitive dysfunction (5-7). These symptoms are the core of the disease, both in terms of the suffering perceived by patients and in terms of diagnostic value (8).

Since 1990, several sets of classification/diagnostic criteria have been proposed. Some have emphasised certain aspects of the disease more than others. The 1990 American College of Rheumatology (ACR) classification criteria (9), which have been widely used in clinical practice, were primarily focused on pain (requiring the presence of CWP for ≥3 months and of at least 11 out of 18 specified tender points upon digital palpation), and have been criticised for this requirement. On the other hand, the new 2010 ACR criteria defined that FM can be diagnosed by CWP associated with somatic symptoms, recommending the use of a widespread pain index (WPI) and a scale to rate symptom severity (SS) (10). The modified version of the 2010 criteria (11) removed the physician assessment of the extent of somatic symptoms and replaced it by a summary score of three self-reported symptoms, making them easier to use, while maintaining their sensitivity (12, 13). The 2016 diagnostic criteria updated the 2010 provisional criteria, defining that a diagnosis of FM is valid regardless of the presence of other pathological conditions (14).

However, beyond the set of criteria used, the diagnosis of FM remains difficult, especially in primary care (15, 16). General practitioners (GPs) are often the first referral to whom FM patients complain of poor quality of life (QoL) (17). The disease itself, its diagnostic

delay, and sometimes misdiagnosis, may have a major impact on patients' emotional state and QoL, as well as on health care and social costs (18, 19).

For the early detection of FM, several screening questionnaires were developed, including the Fibromyalgia Diagnostic Screen (20), the Fibromyalgia Survey Questionnaire (FSQ) (21,22), the Manchester criteria (23), the FibroDetect (24), the London Fibromyalgia Epidemiology Study Screening Questionnaire (LFESSQ) (25), and the Fibromyalgia Rapid Screening Tool (FiRST) (26). However, none of these tools has been translated or validated in the Italian population, and each of the questionnaires mentioned has some intrinsic limitations.

To respond to the need for a valid, reliable and straightforward screening tool to facilitate the identification of FM patients in daily clinical practice, the aims of the present study were to develop and validate a psychometrically sound, self-reported, with dichotomous response, and user-friendly tool called the SImple FIbromyalgia Screening (SIFIS) questionnaire, to detect FM in patients with chronic and generalised pain.

## Materials and methods

SIFIS was developed according to a standardised methodology, which should ensure its acceptability by the scientific community and suitability for use in clinical practice (27, 28). The validation study resulted in the definition of a scoring method and a threshold enabling the identification of potential FM patients. This paper reports the process for the simultaneous development and validation of SIFIS.

The development of a self-administered tool for screening generally follows the following steps: 1) population identification, 2) item pool development, 3) item reduction, 4) pre-testing the prototype instrument, and 5) the validation study to define sensitivity, specificity and likelihood ratios (LRs).

The study was approved by the Hospital Clinic ethics committee (Comitato Unico Regionale, ASUR Marche), and all patients gave their informed consent for the anonymous analysis of the data.

*Population identification*

The objective of this tool is to detect the presence of a FM in patients with chronic musculoskeletal pain. The target population was patients with chronic complaints but without a diagnosis of FM yet.

*Item pool development*

Item generation is considered a crucial step in the development of a screening tool. This step must be comprehensive since the final measurement tool can only consist of the specific items identified in this stage. The methodology used for the implementation of this type of questionnaire was one that had already been used (27-31). In particular, item generation was carried out by a review of the literature that was made to identify items that would be appropriate from the description of FM (4, 32). The method employed for item generation was built on the experience of rheumatologists. Predefined areas of screening were culled from specific existing screening questionnaires (such as FSQ, FiRST, Symptom Intensity Scale, FibroDetect, Fibromyalgia Diagnostic Screen, LFESSQ), and from other specific and generic pain-related questionnaires (such as the Wisconsin Brief Pain Questionnaire (BPQ), the Multidisciplinary Pain Inventory (MPI), Multidimensional Assessment of Fatigue (MAF), the Multidimensional Fatigue Index (MFI), the Functional Assessment of Chronic Illness Therapy-Fatigue scale (FACIT-Fatigue), the Italian Revised Fibromyalgia Impact Questionnaire (FIQR), the Medical Outcome Study (MOS)-SF36 (40), the Symptom Checklist (SCL-90), the Sickness Impact Profile (SIP), and the Nottingham Health Profile (NHP)) (33-43).

*Item reduction*

The goal was to create a questionnaire-made up of 5–7 items, those most important to the patient and representative of FM. In order to reduce the number of items, the following exclusion rules were applied: a) gender based items, b) questions requiring special equipment, c) incomprehensible or ambiguous items, d) composite items, e) elimination of alternatives, and f) elimination of duplicates or similarities.

Then, the list of potential items was proposed to a group of 139 physicians (85 rheumatologists, 18 rehabilitation medicine specialists, 11 orthopaedics, 10 neurologists, 5 anesthesiologists/algologists, and 10 internal medicine specialists, respectively), who had not been previously involved in item generation) but who were experienced in the differential diagnosis of chronic multisite pain conditions. The items were assessed using Lynn's process for content validation (44). This was the quantitative phase, which measures the proportion of experts who are in agreement about the relevance of the items. The content validity index (CVI) was used to establish the proportion of agreement among the experts. This approach recommends the use of a relevance rating scale providing ordinal level data through four Likert-like choices – 1: irrelevant, unimportant; 2: somewhat relevant, somewhat important; 3: very relevant, very important; 4: extremely relevant, extremely important. Only items rated 3 or 4 represented the actual CVI, and items rated 1 or 2 were to be eliminated. Moreover, the items were considered to have adequate content validity if they were rated "very relevant" or "extremely relevant" at least by the 88% of the experts. Questionable items ranged from 70 to 88% agreement, and items were found to have unacceptable content validity if they achieved an agreement of 69% or lower.

*Testing the provisional questionnaire*

Pre-testing the SIFIS questionnaire was conducted to ensure that the wording was clear and the patient interpreted the items as they were intended. The questionnaire was administered to a group of patients suffering from FM. To examine participants' level of comprehension of the instruments' content, a proxy question was asked: "Did you have any difficulty understanding the questionnaire items?" (to be answered on a five-point Likert scale).

*Pilot testing of the SIFIS questionnaire in real-life conditions: face validity*

From January 2016 to October 2018, consecutive adult patients with chronic and multi-site pain, referred by GPs

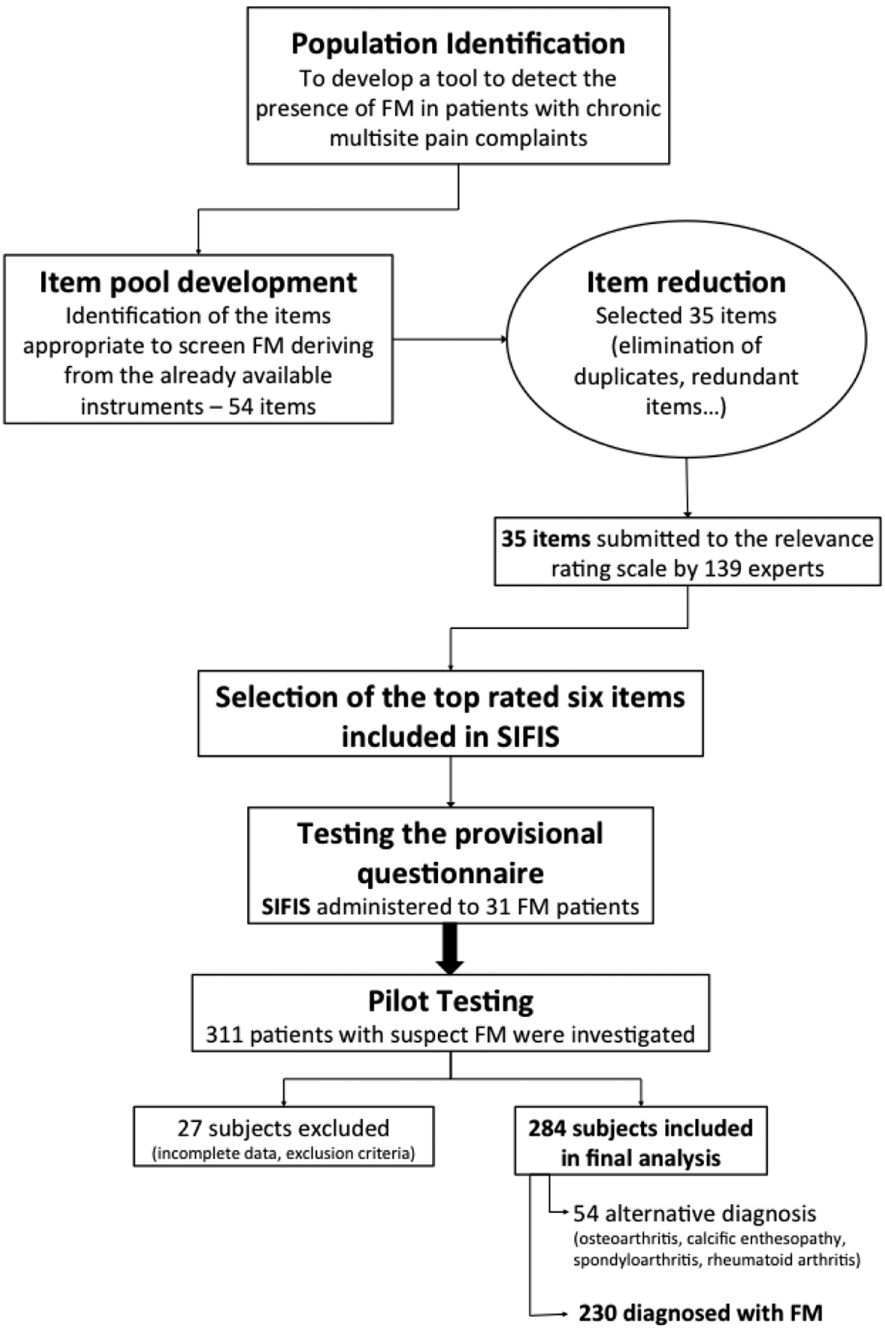


**Fig. 1.** Flow chart summarising the development and validation process of the SIFIS.

to a tertiary level rheumatology centre (Rheumatological Clinic, Università Politecnica delle Marche, Jesi (Ancona), Italy), completed the SIFIS. SIFIS results were managed by a young rheumatologist (MS or GB). Then, the patients were assessed by an experienced rheumatologist (FS or MDC), blinded to the SIFIS results, who was tasked with diagnosing. The ACR 2010 criteria were used as the gold standard for FM diagnosis (10). For the purpose of this study, no data were gathered on treatment, and the tender point count was not recorded. Exclusion criteria were the presence of confounding diseases such as primary neuropathic pain conditions, complex regional pain syndrome, connective tissue diseases or systemic vasculitides; or by medical comorbidities that would render the patient unable to partecipate fully in study procedures (e.g. terminal conditions such as end-stage renal disease, heart failure, or malignancy), major depressive disorder, Parkinson's disease or dementia.

*Statistical analysis and SIFIS interpretability*

Patient acceptance of the SIFIS was assessed by the proportion of missing or invalid items. The performance of the questionnaire was evaluated through the calculation of the post-test probability which was estimated by applying the Bayesian Analysis Model method (http://araw.mede.uic.edu/cgi-bin/testcalc.pl). This Bayesian calculator can determine diagnostic test characteristics (sensitivity, specificity, likelihood ratios) and/or determine the post-test probability of a disease given the pre-test probability and test characteristics.

Comparisons among combinations of selection items of the SIFIS questionnaire were ranked for their ability to identify disease by positive likelihood ratio (LR+). Interpretation of LR+ can be graphed on Fagan's nomogram, a graphical tool that estimates how much the result on a diagnostic test changes the probability that a patient has a disease: the user is requested to draw a straight line connecting the pre-test probability of disease and the LR+ for the test result. The intercepted point on the right line is the post-test probability of disease. The final version of SIFIS contains the six items and the nomogram.

## Results

*Item pool development, item reduction, and testing the provisional questionnaire*

At the end of the item pool development, 54 items were identified from existing screening tools for FM.

After the application of the exclusion rules, it was possible to draw up a list of 35 items, which was then proposed to the group of experts in order to establish the CVI of each item.

Table I lists the six items that obtained the highest CVI by the group of experts, and which ultimately compose the SIFIS. The items that satisfied the criteria for the inclusion in the final SIFIS questionnaire were six: 1) "I have a persistent deep aching over most of my body"; 2) "I have frequently long periods of fatigue"; 3) "I have frequently problems with memory or ability to concentrate"; 4) "My pain is accompained by other health problems such

**Table I.** The top six ranked items satisfing the inclusion criteria for the SIFIS questionnaire. Content validity index is used to establish proportion/percent agreement among the experts.

| Items | Mean relevance rating scale | Percent agreement | Content validity index |
|---|---|---|---|
| 1. I have a persistent deep aching over most of my body | 2.89 | 99 | 286.11 |
| 2. I have frequently long periods of fatigue | 2.12 | 91 | 192.92 |
| 3. I feel unrefreshed and tired in the morning | 2.09 | 89 | 186.01 |
| 4. I have frequently problems with memory or ability to concentrate on a task | 2.27 | 80 | 181.60 |
| 5. My pain is accompained by other health problems such as headaches, abdominal pain, urinary problems, cramps and feeling of restlessness in my legs at night. | 2.07 | 87 | 180.09 |
| 6. I feel anxious and depressed | 2.11 | 79 | 166.69 |

as headaches, abdominal pain, urinary problems, cramps and feeling of restlessness in my legs at night"; 5) "I feel unrefreshed and tired in the morning"; 6) "I feel anxious and depressed". The Italian version of the SIFIS questionnaire was also translated into English by a native English speaker.

Preliminary testing of SIFIS was conducted on 31 FM patients (20 females and 11 males), aged from 23 to 70 years (mean 45.8±10.8 years). The majority of the patients (93.5%) found the items understandable. Two respondents found 'some difficulty' in understanding and responding to the items. After this provisional testing, no changes were made to the questionnaire.

*Pilot testing: the cohort*

A total of 311 subjects who did not have an a priori clinical diagnosis of FM were included for the purposes of the pilot testing. Twenty-seven patients were excluded for the following reasons: eight received a diagnosis of primary diagnosis of neuropathic pain, seven were diagnosed as suffering from complex regional pain syndrome, three were diagnosed as suffering from giant cell arteritis, two with malignancies with metastatic disease, one with polymyositis. Finally, six subjects were excluded because they did not complete the assessment.

Of the 284 patients included in the analysis, 230 subjects (80.9%, 75 men and 155 women, respectively, with a mean age of 50±16.3 years) met the modified 2010 ACR criteria for FM.

*Alternative diagnoses*

In the 54 patients who were not diagnosed with FM, it was possible to identify as the main alternative diagnosis osteoarthritis or calcific enthesopathy (21 patients), spondyloarthritis (18 patients), and rheumatoid arthritis (15 patients). The flow-chart in Figure 1 summarises the main stages of the study described up to this point.

*SIFIS performance*

Exploring the answers to the SIFIS in the 230 FM patients, 230/230 (100%) answered 1/6 yes, 218/230 (94.8%) 2/6 yes, 201 (87.4%) 3/6 yes, 189 (82.2%) 4/6 yes, 141 (61.3%) 5/6 yes, and 101 (43.9%) 6/6 yes. Likelihood ratios (LR) for individual parameters varied between 3.37 and 5.00. The proportion of missing items in the SIFIS ranged from 1.6 to 6%. The item with 6% missing was the mood item ("I feel anxious and depressed").

Of the six items of the SIFIS questionnaire, the better performance was found for the item "I have a persistent deep aching over most of my body" (LR+ 5.00), followed by "I feel anxious and depressed" (LR+ 4.22), and by the item "My pain is accompained by other health problems such as headaches, abdominal pain, urinary problems, cramps and the feeling of restlessness in my legs at night" (LR+ 4.09). Items that explored sleep disorders ("I feel unrefreshed and tired in the morning"), cognitive dysfunction ("I have frequently problems with memory or ability to concentrate on a task"), and fatigue ("I have frequently long periods of fatigue") gave similar results (LR+ 3.89, LR+ 3.59 and LR+ 3.37, respectively). A cut-off of four (4/6 yes) gave the highest rate of correct identification of patients (181/230 patients, 78.9%) with a sensitivity of 89.4% and a specificity of 77.5%. Table II reports the sensitivity, specificity, positive and negative predictive values, LRs, and post-test probabilities for each of the six items of the SIFIS questionnaire.

In the Fagan's nomogram representation, the disease probability in a given patient is the product of the LR+ of each item answered as "yes". A diagnostic test can be considered meaningful if the post-test probability is over 80%. For the SIFIS questionnaire, the presence of at least four affirmative questions results in a post-test probability ≥80% for each possible scenario. It can be affirmed that the occurrence of four out of six items answered as "yes" is the cut-off point for the rheumatological referral (Fig. 2).

*SIFIS App*

We have proposed an electronic version of the SIFIS (SIFIS App), developed to be easy to use, self-scoring, and requiring no calculator (Fig. 3).

## Discussion

FM is a frequent condition seen by GPs, rheumatologists, and pain specialists (45-47). Therefore, a valid, reliable, and straightforward screening tool for GPs that would enable them to translate patients' complaints into clues to potential FM would be highly valuable. A review of the existing questionnaires showed that these either focus on specific aspects, domains or symptoms of FM. No tool has been validated in the Italian population.

The Fibromyalgia Diagnostic Screen was based on patient focus groups and clinician and patient Delphi exercises, which resulted in a ranking of the most common and troublesome FM symptoms (20). However, this tool is, composed of a large number of items requiring minutes to be completed and

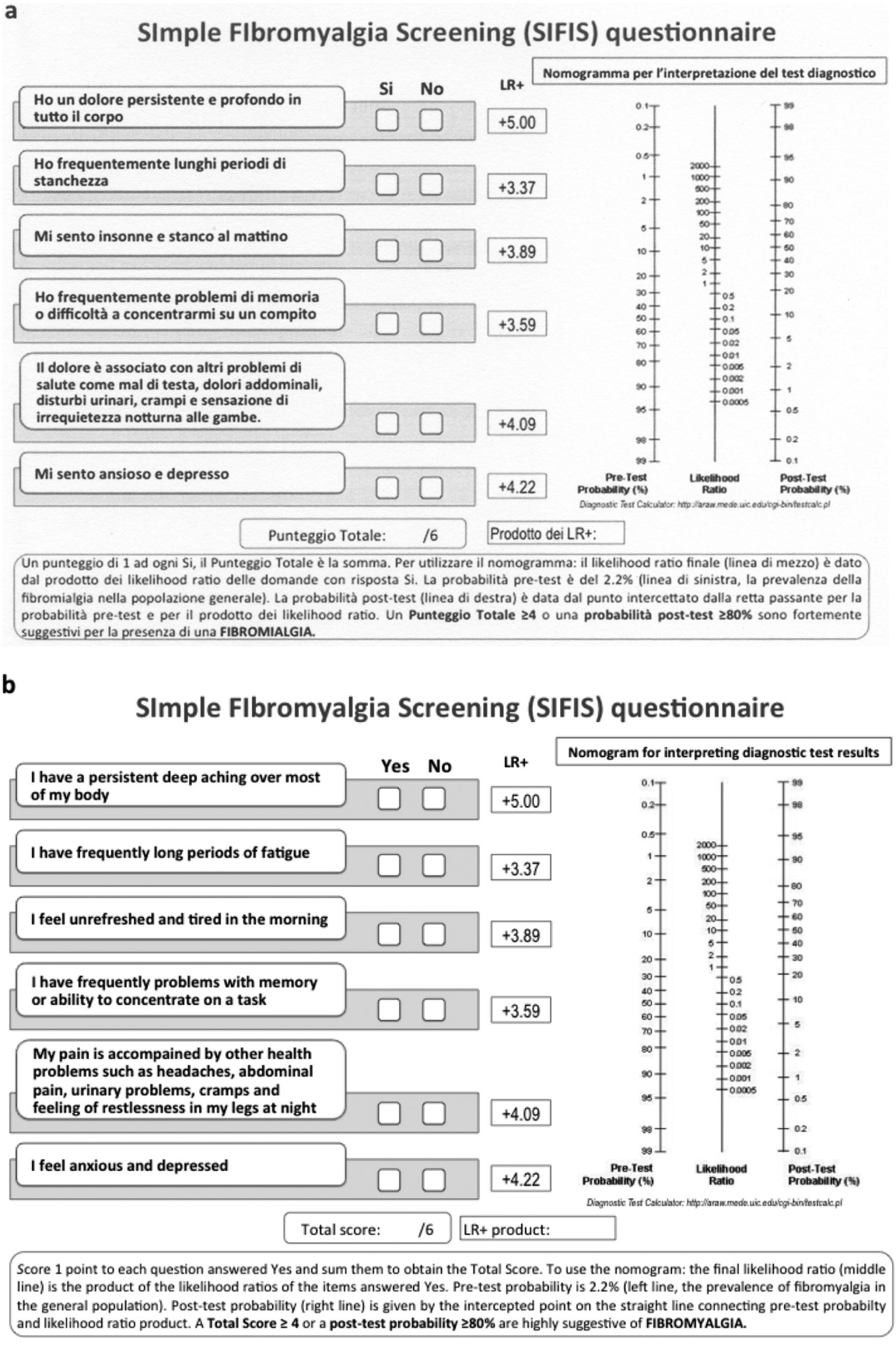


**Fig. 2.** Italian (**a**) and English (**b**) versions of the Simple Fibromyalgia Screening (SIFIS) questionnaire. For each item, a score of 1 is given when the response is "Yes" and a score of 0 is given if the response is "No". The total score is obtained by adding the score for each of the six items. The presence of four out of six items gave a post-test probability ≥80% (range: 81.8–87.1%).

**Table II.** Sensitivity, specificity, positive and negative predictive values, likelihood ratios and post-test probabilities of the six items of the SIFIS questionnaire.

| Items | Sensitivity | Specificity | LR+ | 95% CI LR+ | LR- | 95% CI LR- |
|---|---|---|---|---|---|---|
| 1. I have a persistent deep aching over most of my body | 0.909 | 0.818 | 5.00 | 2.06– 12.01 | 0.11 | 0.07-0.18 |
| 2. I have frequently long periods of fatigue | 0.880 | 0.739 | 3.37 | 1.69-6.72 | 0.16 | 0.10-0.25 |
| 3. I feel unrefreshed and tired in the morning | 0.865 | 0.778 | 3.89 | 2.25-6.74 | 0.17 | 0.12-0.25 |
| 4. I have frequently problems with memory or ability to concentrate on a task | 0.864 | 0.759 | 3.59 | 1.88-6.85 | 0.18 | 0.12-0.27 |
| 5. My pain is accompained by other health problems such as headaches, abdominal pain, urinary problems, cramps and feeling of restlessness in my legs at night. | 0.885 | 0.784 | 4.09 | 2.21-7.57 | 0.15 | 0.10-0.22 |
| 6. I feel anxious and depressed | 0.904 | 0.786 | 4.22 | 2.36-7.54 | 0.12 | 0.08-0.19 |

computed. In a similar way, also the FSQ is not easy to be fully self-administered (21). Moreover, FibroDetect is probably to long, being composed of 14 questions in a four-page leaflet (24). The Manchester criteria use a pain diagram to establish the diagnosis, in which the patient indicates the areas of pain on a simple drawing. These criteria are purely focused on widespread pain, excluding other symptoms (23). FiRST is short, clear and simple, but also focused exclusively on pain (26).

Taking into account the major symptoms and dimensions of FM, we developed and validated a short and user-friendly (single-page questionnaire), psychometrically sound, self-administered screening tool for detecting FM in Italian patients with chronic diffuse musculoskeletal pain.

Although chronic pain is the cornerstone of FM diagnosis, symptoms (such as unrefreshing sleep, fatigue, restless legs syndrome, cramping and muscle spasms, interstitial cystitis, cognitive dysfunction, anxiety, depression, headache, back and/or neck pain), have been included among the domains recognised by the Outcomes Measures in Rheumatology Clinical Trials (OMERACT) as important for assessment in FM (48).

In line with the methodology adopted by OMERACT, we conducted a Delphi exercise involving a panel of 139 experts to develop consensus on a prioritised list of key domains of the FM syndrome (49). The highest scored items were those related to pain, fatigue/energy, sleep quality, cognitive dysfunction, and mood disorders (depression and anxiety).

The item related to pain obtained the best performance in terms of maximum percentage of agreement, mean relevance rating, as well as higher sensitivity, specificity, and LR+.

Fatigue was rated as the second most important domain to measure. Patients often describe fatigue as "disruptive or extremely disruptive" to their QoL (50).

Sleep disturbance was noted as one of a core set of domains considered essential for assessment in FM clinical trials, and in study has been rated as the third domain to measure. The high prevalence of sleep disturbances in FM patients is recognised and it is suggested that playing a critical role in exacerbating symptoms (51).

In the plethora of somatic symptoms of FM, headaches and migraines, gastrointestinal problems, urinary problems, and restless legs syndrome and cramping and muscle spasms are certainly the most frequent and relevant (4, 6, 10, 22). In this research we have tried to condense these features in a single item, which appeared important in the opinion of experts.

The subjective experience of cognitive dysfunction ("fibrofog") is also com-

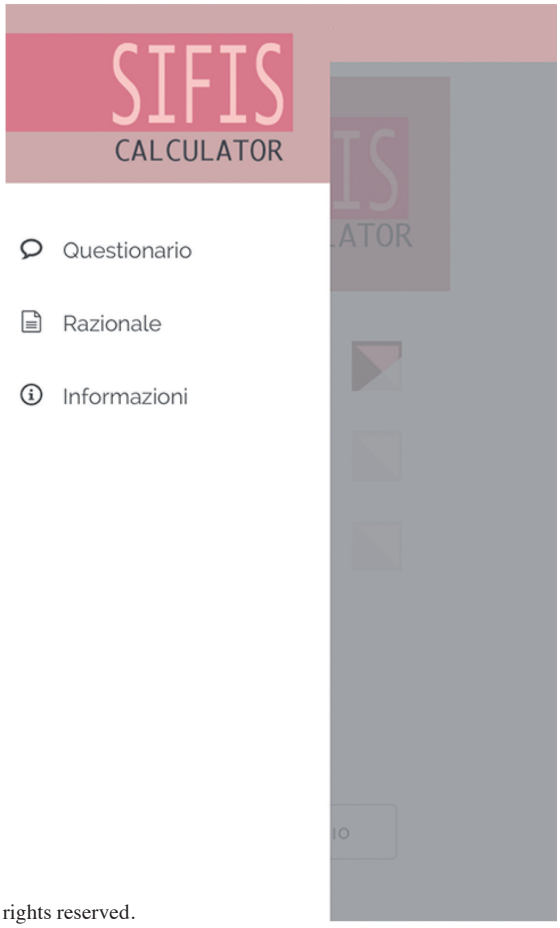


**Fig. 3.** Screenshot of SIFIS calculator App for iOS/Android mobile platforms.

mon in FM (52). For this reason an item exploring this domain was considered appropriate.

Extensive evidence suggests that negative affects like depression and anxiety are frequently observed in patients with FM. In a study by Yunus and coworkers, 70% of the patients considered themselves anxious, and in 68% the symptoms were worsened due to anxiety and mental stress (53). Consequently, a statement aimed at investigating the emotional state was considered relevant.

Overall, SIFIS demonstrated good screening performance. The six dichotomously answered questions, represented on a single page or via app certainly makes it easy to use.

The main limitations of the study are the recruitment to a single centre and the testing against rheumatological conditions only. In addition, in the context of a cross-sectional study, it was not possible to assess test-retest reliability. The properties of SIFIS should be confirmed in multi-centre studies, the generalisability of the questionnaire must be also studied in non-Italian patients, taking into account chronic pain conditions that are not only rheumatological.

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