

# Psychometric properties of the Fibromyalgia Assessment Status (FAS) index: a national web-based study of fibromyalgia

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## ABSTRACT

Fibromyalgia (FM) is a generalised chronic pain condition that is often accompanied by symptoms such as fatigue, sleep disturbances, psychological and cognitive alterations, headache, migraine, variable bowel habits, diffuse abdominal pain, and urinary frequency. Its key assessment domains include pain, fatigue, disturbed sleep, physical and emotional functioning, and patient global satisfaction and health-related quality of life (HRQL). A number of evaluation measures have been adapted from the fields of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, and others such as the Fibromyalgia Assessment Status (FAS) index and the Fibromyalgia Impact Questionnaire (FIQ) have been specifically developed. The aim of this study was to assess the impact of FM on HRQL by comparing the performance of the FAS index, the FIQ and the Health Assessment Questionnaire [HAQ] in 541 female and 31 male FM patients (mean age 50 years; mean disease duration 7.7 years) entered in the database of a web-based survey registry developed by the Italian Fibromyalgia Network (IFINET). Tests of convergent validity showed that the FAS index and FIQ significantly correlated with each other ( $\rho=0.608$ ,  $p<0.0001$ ), but there were also significant correlations between the FAS index and other clinical measures of disability, including the HAQ ( $\rho=0.423$ ,  $p<0.0001$ ), anxiety ( $\rho=0.138$ ,  $p=0.0009$ ), depression ( $\rho=0.174$ ,  $p<0.0001$ ) and, especially, the number of comorbidities ( $\rho=0.147$ ,  $p=0.0004$ ). The FAS index revealed a statistically significant difference between males and females ( $p=0.048$ ), analysed using the Mann-Whitney U-test for all pair wise comparisons.

The FAS index is a valid three-item instrument (pain, fatigue and sleep dis-

turbances) that performs at least as well as the FIQ in FM patients, and is simpler to administer and score. Both questionnaires may be useful when screening FM patients, with the choice of the most appropriate instrument depending on the setting.

## Introduction

Fibromyalgia (FM) is a chronic generalised pain condition characterised by typical tender points upon physical examination, and often by a number of associated symptoms such as fatigue, sleep disturbances, psychological and cognitive alterations, headache, migraine, variable bowel habits, diffuse abdominal pain and urinary frequency (1-3). FM affects at least 2% of the general population in Italy and more than 90% of the patients are female (4). Its pathophysiology is still unclear, although it is characterised by central sensitisation and the amplification of pain perception that seems to be generated by interactions between external stressors, behavioural constructs, neurotransmitters, hormones, and the immune and sympathetic nervous system (5-7).

The 1990 American College of Rheumatology (ACR) Criteria for the classification of fibromyalgia were the product of the first well-designed, multicentre study of FM (8), and recently the ACR has developed preliminary criteria for the diagnosis of FM (9).

The Italian Fibromyalgia Network (IFINET) created the Italian Fibromyalgia Registry, the database of which includes the number of patients, demographics, disease indices, previous and current treatments, efficacy, and adverse outcomes. Pooled data from large numbers of patients can reveal trends that may not be detected when working with smaller groups enrolled in a single rheumatology centre, and our data are collected in a website and

can be very useful in patient follow-up. Having estimates of the impact of individual chronic diseases on patients' health-related quality of life (HRQL) is important for decision-makers as it allows them to plan and allocate research, training and healthcare resources more appropriately (10).

The key assessment domains of FM include pain, fatigue, disturbed sleep, physical and emotional functioning, and patient global satisfaction and HRQL. A number of evaluation measures have been borrowed from the fields of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, and others have been developed specifically for FM. In 1991, Burckhardt *et al.* developed the Fibromyalgia Impact Questionnaire (FIQ) for assessing the current health status of women with the FM syndrome. This is a brief 10-item, self-administered instrument that measures physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue and well-being (11). It has credible construct validity and reliable test/retest characteristics, and is sensitive in identifying therapeutic changes. However, it is rarely used in clinical practice for a number of reasons: its apparent lack of relevance to clinicians and their unfamiliarity with it; the perceived difficulty in administering and scoring it; the possibility of underestimating disease impact and inadequately measuring treatment effect in patients with mild symptoms; and the fact that it has not been validated in men (12).

In order to develop a reliable and valid patient-reported outcome (PRO) measure that is easier and less expensive to administer, Salaffi *et al.* (13) have recently developed and analysed the psychometric properties of a new *composite* disease-specific index for evaluating patients with FM. The Fibromyalgia Assessment Status (FAS) index combines in a single measure (score range 0-10) patient assessments of fatigue, sleep disturbances and pain evaluated on the basis of the 16 non-articular sites of the Self-Assessment Pain Scale (SAPS). It has good psychometric properties as a multidimensional PRO instrument for FM that is consistent with the recommendations of the OMERACT Fibro-

myalgia Syndrome Workshop (14) and the IMMPACT group (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) (15).

The aim of this study was to contribute to the ongoing discussion of the choice of methods to assess the impact of FM on patients' HRQL by comparing the performance of the FAS index, the FIQ and the Health Assessment Questionnaire (HAQ) in a large cohort of FM patients entered in the Italian Fibromyalgia Registry (16).

### Patients and methods

*Web-design and structured data entry*  
IFINET (the Italian **F**ibromyalgia **N**ETwork) is a nationwide FM-specific web-based survey registry developed by a task force of experts to help identify the long-term health status, function and health service use of FM patients, thus providing a global perspective and enabling the more effective use of healthcare resources (16). The registry was created by prospectively entering patients with an established diagnosis of FM based on the ACR criteria (8). Four study centres in different parts of Italy (the Rheumatology Unit of L. Sacco University Hospital in Milan, the Department of Rheumatology of the Università Politecnica delle Marche, Ancona, the Division of Rheumatology of the University of Pisa, and the Division of Rheumatology of the Sapienza University of Rome) have so far registered 576 patients: the first patient was entered in October 2008 and the last in May 2010. The screens used in the web-based registry are presented in a logical sequence, and users can download forms such as the FIQ, FAS and HAQ forms, a pain scale form, and an informed consent form (16). The user-friendliness of the design was tested by most users at a joint meeting addressing the practical use of the register. Security experts have ensured that all of the requirements concerning patient data protection are met.

### Patients

The data collected in the IFINET registry include patient age, gender, education, marital status, height, weight, body mass index, disease duration, comorbidities, and previous and current phar-

macological and non-pharmacological treatments (acupuncture, biofeedback, cognitive-behavioural therapy, etc.). The comorbidities include nine specific conditions: hypertension, myocardial infarction, lower extremity arterial disease, major neurological problems, diabetes, gastrointestinal disease, chronic respiratory disease, kidney disease, and poor vision. The exclusion criteria are the presence of concomitant autoimmune diseases, psychiatric disorders, or other causes of chronic pain. Informed consent was obtained from each patient and our local ethics committees approved the study protocol.

### Measurements and instruments

The investigated disease-related characteristics were patient and physician 11-numbered circular visual analogue scale (VAS) for general health (GH), the tender point score (TPS), and the Self-assessment Pain Scale (SAPS). The patient VAS question was "How would you describe your general health over the past week? (0 = very good to 10 = very bad)". The tender point examination was carried out by applying the same manual finger pressure (until blanching of the fingernail bed) to each of nine paired anatomical locations (8); the subjects were told to expect a sensation of pressure but to indicate if this became painful. Regular consensus meetings concerning tender point assessments are part of our routine quality control programme in order to avoid high between-physician variations, but no formal agreement analysis was made for the purpose of this study. The TPS was the total number of tender points.

The SAPS considers pain in 16 non-articular sites by asking: "Please indicate below the amount of pain and/or tenderness you have experienced in the last seven days in each of the body areas listed below by putting an X in the boxes. Please be sure to mark both right and left sides separately." Below these instructions, a series of site descriptions are followed by four boxes labelled 0 = none, 1 = mild, 2 = moderate, and 3 = severe. The scale scores range from 0 to 48 but, in order to integrate them into one scale, they were transformed into a scale of 0-10.

We then calculated the FAS index, which is a short and easy to complete self-administered index combining a set of questions relating to non-articular pain (SAPS, range 0–10), fatigue (range 0–10) and the quality of sleep (range 0–10) that provides a single composite measure of disease activity ranging from 0 to 10. The final score is calculated by adding the three subscores and dividing the result by three. All three measures are printed on one side of one page for rapid review, and scored by a health professional without the need for a ruler, calculator, computer or website.

Two other disease-specific questionnaires, the self-administered FIQ (17) and the Health Assessment Questionnaire (HAQ) (18) and two additional instruments for evaluating anxiety and depression (the Zung Self-rating Depression/Anxiety Scales) (19, 20) were also administered.

– *Fibromyalgia Impact Questionnaire (FIQ)*. The Italian version of FIQ (17) is a self-administered, disease-specific, 10-item assessment and outcome instrument developed to measure the components of health status that are believed to be most affected by FM. The first item contains 10 questions related to physical functioning, each of which is rated on a 4-point Likert-type scale. Items 2 and 3 ask the patient to mark the number of days they felt well and the number of days they were unable to work (including housework) because of FM symptoms. Items 4–10 are horizontal linear scales marked in 10 increments on which the patient rates work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety and depression. Each of the 10 items has a maximum possible score of 10, and so the maximum possible total score is 100. Scoring is complicated by the need to reverse the scores of one question and the use of constants to convert the first 13 questions to a standardised 0–10 scale. The average FM patient scores about 50, and severely affected patients usually score 70 or more. The FIQ takes approximately five minutes to complete, and has been extensively used as an outcome measure in FM-related studies.

– *Health Assessment Questionnaire (HAQ)*. In its most widely used form, the HAQ is a self-administered 20-item questionnaire that investigates difficulties in performing eight daily living activities (dressing and grooming, rising, eating, walking, hygiene, reach, grip, and outside activities). For each item, the patients are asked to rate the level of difficulty they have experienced over the preceding week in performing these using a 4-point scale ranging from 0 (no difficulty) to 3 (unable to perform). The final HAQ score is the average score of the eight categories, and therefore also ranges from 0 to 3; the higher the score the greater the level of disability (18).

– *Zung Self-rating Depression/Anxiety Scales*. Both the Zung Self-rating Depression Scale (ZSDS) and the Zung Self-Rating Anxiety Scale (ZSAS) consist of 10 positively worded and 10 negatively worded items asking about related symptoms that are used to quantify the level of depression and anxiety. A number of studies have established that these self-administered tests are reliable and valid for measuring the symptoms of depression/anxiety. Each question is scored on a scale of 1–4 (none or a little of the time, some of the time, a good part of the time, most of the time), and the total scores range from 20 to 80. The scores were used to define four categories of severity for depression (<40: within the normal range or no significant psychopathology; 40–47: minimal to mild depression; 48–55: moderate to marked depression; ≥56: severe to extreme depression) and four categories of anxiety (20–44: normal range; 45–59: mild to moderate anxiety; 60–74 marked to severe anxiety; 75–80: extreme anxiety) (19, 20).

#### Statistical analysis

Continuous data are given as mean values and standard deviation (SD) or median values and interquartile range (IQR) depending on their distribution (tested using the Kolmogorov–Smirnov test). Categorical data are given as proportions. The demographic and clinical measures were compared using the Mann-Whitney U-test for continu-

ous variables, and chi-squared analysis for discontinuous variables. *P*-values of <0.05 were considered statistically significant. Relationships were quantified by means of Spearman's *rho* correlation coefficients: correlations of >0.90 were interpreted as very close, 0.70–0.89 as close, 0.50–0.69 as moderate, 0.26–0.49 as poor and ≤0.25 very poor if any (21). All of the data were entered in a Microsoft Access database developed for the management of cross-sectional multicentre studies, and were analysed using MedCalc® version 10.0 (MedCalc Software, Mariakerke, Belgium).

#### Results

The 541 female and 31 male patients were consecutively enrolled. They were all Italian and had a mean age of 50 years (range 16–80 years) at the time of the examination. Average disease duration was 7.7 years (range 1–24 years). Table I shows the mean values ± SD and median values and IQR of their main clinical characteristics. Testing for convergent validity (Table II) showed that the FAS index and FIQ significantly correlated with each other ( $\rho=0.608$ ,  $p<0.0001$ ), but there were generally closer significant correlations between the FAS index and other clinical variables measuring disability (HAQ:  $\rho=0.423$ ,  $p<0.0001$ ; anxiety:  $\rho=0.138$ ,  $p=0.0009$ ; depression:  $\rho=0.174$ ,  $p<0.0001$ ). The correlations between the FAS index and number of comorbidities was particularly interesting ( $\rho=0.147$ ,  $p=0.0004$ ). No correlations were found between disease duration and any score. TP count correlates only with the number of comorbidities ( $\rho=0.143$ ,  $p=0.0006$ ). In addition, the FAS index revealed a statistically significant difference between males and females ( $p=0.048$ ), analysed using the Mann-Whitney U-test for all pair wise comparisons.

#### Discussion

FM is a very frequently encountered widespread pain syndrome that affects approximately 2% of the general population; more than 90% of the patients are female (4, 22, 23).

In order to bring together all Italian FM patients, a national registry was creat-

**Table I.** Mean values and standard deviation (SD), and median values and interquartile ranges.

	Mean	SD	Median	Interquartile ranges (25–75)
Fibromyalgia Impact Questionnaire (FIQ)	61.44	18.91	64.12	49.98–74.91
Fibromyalgia Assessment Status (FAS)	6.86	2.14	7.37	5.57–8.50
Health Assessment Questionnaire (HAQ)	0.90	0.73	0.75	0.25–1.37
No. of tender points (TPS)	13.80	4.98	15.50	12.000–18.00
Physician health status (VAS 0–100)	60.88	19.66	60.00	50.00–80.00
Patient health status (VAS 0–100)	72.743	21.99	80.00	60.00–90.00
Zung Self-Rating Anxiety Scale (ZSAS)	46.84	9.88	46.50	41.00–53.00
Zung Self-rating Depression Scale (ZSDS)	47.02	9.98	47.00	42.00–52.00

ed in 2008 by the Italian Fibromyalgia Network, and currently documents all of the clinical, clinimetric and therapeutic data concerning more than 600 patients. A web-based registry collects data on a long-term continuous basis more accurately and completely than paper case report forms (CRFs) (24) and, as it is seen to be more up-to-date and less time-consuming, the data can be collected quickly at lower long-term costs (24–26). It also creates an opportunity for interim reports. Analysis of this web-based registry has allowed us to characterise the clinical and clinimetric details of Italian FM patients. In 1991, the FIQ was developed by

Burckhardt *et al.* (11) to assess the current health status of women with FM. However, although it is widely used in clinical studies because of its responsiveness to change, has been translated into eight languages and is referenced in over 100 publications, it is rarely used in clinical practice because of its apparent lack of relevance to clinicians and their unfamiliarity with it; it is also perceived to be difficult to administer and score. Recently, the Revised Fibromyalgia Impact Questionnaire (FIQR) was published and it tries to address the limitations of the FIQ preserving the essential properties of the original (27). It has 21 individual questions,

all based on an 11-point numeric rating scale range from 0 to 10, with 10 being “worst”. As in FIQ, all the questions are framed in the context of the previous seven days. The FIQR is subdivided into three linked sets of domains: a) function (9 questions vs. 11 in the FIQ); b) overall impact (2 questions, as in the FIQ), but the questions now relate to the overall impact of FM on functioning and the overall impact of symptom severity; and c) symptoms (10 questions vs. 7 in the FIQ). The symptom domain includes four new questions respectively related to memory, tenderness, balance and environmental sensitivity. The scoring of the FIQR is simpler when compared to the FIQ: the summed score for function (range 0 to 90) is divided by 3, the summed score for overall impact (range 0 to 20) is unchanged, and the summed score for symptoms (range 0 to 100) is divided by 2; the total FIQR score is the sum of the three modified domain scores. The weighting of the three domains is different from the FIQ: about 30% of the total score is attributed to “function” (10% in the FIQ) and 50% to “symptoms” (70% in the FIQ); “overall impact” remains the same as the FIQ at

**Table II.** Convergent validity: relationships were quantified by means of Spearman’s rho correlation coefficients.

	FAS	HAQ	TPS	Physician VAS	Patient VAS	Anxiety (ZSAS)	Depression (ZSDS)	No. of comorbidities	Disease duration
FIQ	0.608 <0.0001	0.544 <0.0001	-0.034 0.4198	-0.024 0.5638	-0.060 0.1527	0.106 0.0109	0.149 0.0003	0.088 0.0345	0.017 0.6895
FAS	----- -----	0.423 <0.0001	-0.020 0.6292	-0.032 0.4458	-0.018 0.6598	0.138 0.0009	0.174 <0.0001	0.147 0.0004	-0.003 0.9381
HAQ		----- -----	-0.052 0.2120	0.033 0.4285	0.026 0.5327	-0.010 0.8170	0.004 0.9316	0.109 0.0090	0.075 0.0733
TPS			----- -----	0.018 0.6672	0.003 0.9478	0.017 0.6797	0.026 0.5407	0.143 0.0006	0.029 0.4931
Physician VAS				----- -----	0.729 <0.0001	0.030 0.4783	-0.018 0.6672	0.049 0.2374	0.061 0.1441
Patient VAS					----- -----	0.022 0.5905	-0.041 0.3294	0.033 0.4225	0.001 0.9878
Anxiety (ZSAS)						----- -----	0.736 <0.0001	0.036 0.3880	-0.051 0.2241
Depression (ZSDS)							----- -----	-0.025 0.5490	-0.053 0.2046
No. of comorbidities								----- -----	0.008 0.8486



20%. The maximum total score of the FIQR is 100, as in the FIQ, but it needs about half the time to be completed.

Therefore, given the high prevalence of FM and the fact that increasing attention is being to it, a new scoring system was developed that can be scanned by a clinician in 10–20 seconds and scored in less than 30 seconds: the FAS index. It provides information concerning the patients' perception of widespread pain, their average level of fatigue and their sleep disturbances on one side of one page.

The main aim of this study was to determine the extent of correlations between the FAS index and the FIQ (it has been previously shown that both scales perform well and are similarly interpreted by patients) (13), and between them and other comparative measures. One interesting finding was that the FAS index correlates with both anxiety and depression scores, something that was not so clear during its development and validation in 226 patients. Most studies of psychological distress in FM patients have reported high somatisation rates (28). Raphael *et al.* found that the risk of lifetime anxiety disorders (particularly obsessive compulsive disorder) seemed to be approximately five times higher in women with FM than in the general population (29). In addition, a number of studies have highlighted the major contribution of local pain and negative pain affect to clinical pain intensity, thus underlining the multidimensional nature of clinical pain intensity in FM (30, 31). Furthermore, negative mood also seems to contribute to the persistence of chronic widespread pain (32).

We also investigated the relationships between the FAS index and the main sociodemographic characteristics and comorbidities. A number of studies have concentrated exclusively on the health of female patients with FM (33–36), but there are conflicting views as to whether FM is characterised by gender differences as some studies have found that women experience poorer health than men (37), and others have not (38). We found slightly significant between-gender differences in the FAS scores ( $p=0.048$ ), with women reporting worse health than men.

The FIQ was originally developed on the basis of experience with predominantly female patients attending an FM clinic, and may therefore be affected by a gender bias. This is particularly true of item 1 as four of the 10 sub-items are often considered to be more likely to be performed by women (12). However, as pointed out by Bennet in 2005 (12), it is not uncommon for men to make meals, use a dishwasher, make beds and do the laundry in 21<sup>st</sup> century Western societies. The FAS index has no gender-related questions, and its use in a larger population of men with FM would probably help to clarify this aspect. On the other hand, our findings confirmed the lack of any significant age-related differences among FM patients.

Finally, there was no correlation between TP counts and the FAS, FIQ, HAQ, anxiety or depression scores; the counts only correlated with the number of comorbidities. This highlights the much debated question as to how important and reliable TP counts are in classifying and diagnosing FM patients. Although currently the accepted clinical evaluation of FM severity, TP counts have been criticised because of their lack of objectivity, the absence of validation for clinical diagnoses, and their inconsistent use by rheumatologists and non-rheumatologists; furthermore, their relationship with the underlying pathophysiology is uncertain. Objective measures of physical function would be of value in the clinical assessment of FM severity, and could provide useful guidance. The Association of Medical Scientific Societies in Germany (AWMF) criteria were in fact developed to overcome the problems associated with the 1990 ACR's TP criterion; they do not include a TP examination and can be used by non-rheumatologists to make a clinical diagnosis of FM (39). Moreover, the recent preliminary diagnostic criteria of the ACR replace TP counts with a widespread pain index (WPI) (9). Finally, it is possible to infer that the number of peripheral pain areas and the peripheral pain intensity described by the FAS index are better predictors of overall FM pain than TP counts, and this seems to indicate their pathogenetic relevance.

One strength of this study is that it was based on a national sample drawn from a web-based registry, but it also has a number of limitations. First of all, because of the nature of the sample, the results cannot be generalised beyond FM patients treated in rheumatology practices. Secondly, the cross-sectional study design does not allow an evaluation of test-retest reliability or provide any information concerning sensitivity to change after treatment: these aspects need to be addressed by larger multi-centre studies over longer periods of time or after therapeutic interventions. Finally, the patients were assessed by different teams of clinicians, although this should not be a major concern because the analyses and results were based on PRO measures.

## Conclusions

The FAS index is a valid, simple three-item instrument (pain, fatigue, sleep disturbances) that performs at least as well as the FIQ in FM patients, and is simpler to administer and score. Both questionnaires may be useful when screening FM patients and the choice of the most appropriate instrument depends on the setting. We expect that the use of the IFINET web-based registry will greatly expand over coming years and that especially collaborative study groups will find it an efficient means of collecting data concerning FM patients.

## References

1. MEASE P: Fibromyalgia syndrome: review of clinical presentation, pathogenesis, outcome measures, and treatment. *J Rheumatol* 2005; 32 (Suppl. 75): 6–21.
2. MEASE P, ARNOLD LM, BENNETT R *et al.*: Fibromyalgia syndrome. *J Rheumatol* 2007; 34: 1415–25.
3. BENNETT RM, JONES J, TURK DC, RUSSELL J, MATA LLANA L: An internet survey of 2,596 people with fibromyalgia. *BMC Musculoskeletal Disorders* 2007; 8: 27.
4. SALAFFI F, DE ANGELIS R, GRASSI W; MARCHE PAIN PREVALENCE; INVESTIGATION GROUP (MAPPING) STUDY: Prevalence of musculoskeletal conditions in an Italian population sample: results of a regional community-based study. I. The MAPPING study. *Clin Exp Rheumatol* 2005; 23: 819–28.
5. DI FRANCO M, IANNUCELLI C, VALESINI G: Neuroendocrine immunology of fibromyalgia. *Ann N Y Acad Sci* 2010; 1193: 84–90.
6. DI FRANCO M, IANNUCELLI C, ALESSANDRI C *et al.*: Autonomic dysfunction and neuropeptide Y in fibromyalgia. *Clin Exp*

- Rheumatol* 2009; 27: S75-8.
7. GEENEN R, BIJLSMA JW: Deviations in the endocrine system and brain of patients with fibromyalgia: cause or consequence of pain and associated features? *Ann N Y Acad Sci* 2010; 1193: 98-110.
  8. WOLFE F, SMYTHE HA, YUNUS MB *et al.*: The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia: Report of the Multicenter Criteria Committee. *Arthritis Rheum* 1990; 33: 160-72.
  9. WOLFE F, CLAUW DJ, FITZCHARLES MA *et al.*: The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. *Arthritis Care Res* 2010; 62: 600-10.
  10. SPRANGERS MA, DE REGT EB, ANDRIES F *et al.*: Which chronic conditions are associated with better or poorer quality of life? *J Clin Epidemiol* 2000; 53: 895-907.
  11. BURCKHARDT CS, CLARK SR, BENNETT RM: The fibromyalgia impact questionnaire: development and validation. *J Rheumatol* 1991; 18: 728-33.
  12. BENNETT R: The Fibromyalgia Impact Questionnaire (FIQ): a review of its development, current version, operating characteristics and uses. *Clin Exp Rheumatol* 2005; 23: S154-S162.
  13. SALAFFI F, SARZI-PUTTINI P, GIROLIMETTI R, GASPARINI S, ATZENI F, GRASSI W: Development and validation of the self-administered Fibromyalgia Assessment Status: a disease-specific composite measure for evaluating treatment effect. *Arthritis Res Ther* 2009; 11: R125.
  14. MEASE PJ, ARNOLD LM, CROFFORD LJ *et al.*: Identifying the clinical domains of fibromyalgia: contributions from clinician and patient Delphi exercises. *Arthritis Rheum* 2008; 15: 952-60.
  15. TURK DC, DWORKIN RH, ALLEN RR *et al.*: Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2003; 106: 337-45.
  16. SARZI-PUTTINI P, ATZENI F, SALAFFI F, CAZZOLA M, STISI S; on behalf of THE ITALIAN FIBROMYALGIA NETWORK (IFINET): Registro Nazionale AISF. [www.registroaisf.it](http://www.registroaisf.it).
  17. SARZI-PUTTINI P, ATZENI F, FIORINI T *et al.*: Validation of an Italian version of the Fibromyalgia Impact Questionnaire (FIQ-I). *Clin Exp Rheumatol* 2003; 21: 459-64.
  18. FRIES JF, SPITZ P, KRAINES RG, HOLMAN HR: Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
  19. ZUNG WW: The Depression Status Inventory: an adjunct to the Self-Rating Depression Scale. *J Clin Psychol* 1972; 28: 539-43.
  20. ZUNG WW: A rating instrument for anxiety disorders. *Psychosomatics* 1971; 12: 371-9.
  21. NUNALLY JC: Psychometric Theory. 2nd ed. New York: McGraw Hill. 1978.
  22. WOLFE F, ROSS K, ANDERSON J, RUSSELL U, HEBERT L: The prevalence and characteristics of fibromyalgia in the general population. *Arthritis Rheum* 1995; 38: 19-28.
  23. SALAFFI F, DE ANGELIS R, STANCATI A, GRASSI W, MARCHE PAIN; PREVALENCE INVESTIGATION GROUP (MAPPING) STUDY: Health-related quality of life in multiple musculoskeletal conditions: a cross sectional population based epidemiological study. II. The MAPPING study. *Clin Exp Rheumatol* 2005; 23: 829-39.
  24. SCHMITT-EGENOLF M: PsoReg – the Swedish registry for systemic psoriasis treatment. The registry's design and objectives. *Dermatology* 2007; 214: 112-7.
  25. SANTORO E, ROSSI V, PANDOLFINI C, BONATI M: DEC-net: the development of the European register of clinical trials on medicines for children. *Clin Trials* 2006; 3: 366-75.
  26. SCHMITT-EGENOLF M: Psoriasis therapy in real life: the need for registries. *Dermatology* 2006; 213: 327-30.
  27. BENNETT RM, FRIEND R, JONES KD, WARD R, HAN BK, ROSS RL: The Revised Fibromyalgia Impact Questionnaire (FIQR): validation and psychometric properties. *Arthritis Res Ther* 2009; 11: 4.
  28. BIRTANE M, KAN UNZUNCA K, TASTEKIN N, TUNA H: The evaluation of quality of life in fibromyalgia syndrome: a comparison with rheumatoid arthritis by using SF-36 Health Survey. *Clin Rheumatol* 2007; 26: 679-84.
  29. RAPHAEL KG, JANAL MN, NAYAK S, SCHWARTZ JE, GALLAGHER RM: Psychiatric comorbidities in a community sample of women with fibromyalgia. *Pain* 2006; 124: 117-25.
  30. OFFENBACHER M, GLATZEDER K, ACKENHEIL M: Psychological distress and depression in male and female patients with fibromyalgia. *Arthritis Rheum* 1998; 41: S255.
  31. GEISSER ME, ROTH RS, THEISEN ME, ROB-INSON ME, RILEY JL III: Negative affect, self-report of depressive symptoms, and clinical depression: relation to the experience of chronic pain. *Clin J Pain* 2000; 16: 110-20.
  32. NICASSIO PM, MOXHAM EG, SCHUMAN CE, GEVIRTZ RN: The contribution of pain, reported sleep quality, and depressive symptoms to fatigue in fibromyalgia. *Pain* 2002; 100: 271-9.
  33. REISINE S, FIFIELD J, WALSH S *et al.*: Employment and quality of life outcomes among women with fibromyalgia compared to healthy controls. *Women Health* 2004; 39: 1-19.
  34. RUTLEDGE DN, JONES K, JONES CJ: Predicting high physical function in people with fibromyalgia. *J Nurs Scholarship* 2007; 39: 319-24.
  35. ZAUTRA AJ, FASMAN R, PARISH BP, DAVIS MC: Daily fatigue in women with osteoarthritis, rheumatoid arthritis, and fibromyalgia. *Pain* 2007; 128: 128-35.
  36. PÖYHÄ R, DA COSTA D, FITZCHARLES MA: Previous pain experience in women with fibromyalgia and inflammatory arthritis and nonpainful controls. *J Rheumatol* 2001; 28: 1888-91.
  37. UBAGO LINARES MC, RUIZ-PÉREZ I, BERMEJO PÉREZ MJ, DE LABRY-LIMA AO, HERNÁNDEZ-TORRES E, PLAZAOLA-CASTAÑO J: Analysis of the impact of fibromyalgia on quality of life: associated factors. *Clin Rheumatol* 2008; 27: 613-9.
  38. BUSKILA D, NEUMANN L, ALHOASHLE A *et al.*: Fibromyalgia syndrome in men. *Semin Arthritis Rheum* 2000; 30: 47-51.
  39. HÄUSER W, HAYO S, BIEWER W *et al.*: Diagnosis of fibromyalgia syndrome – a comparison of the Association of the Medical Scientific Societies in Germany survey and American College of Rheumatology criteria. *Clin J Pain* 2010; 26: 505-11.