

Measuring Health in Patients With Fibromyalgia: Content Comparison of Questionnaires Based on the International Classification of Functioning, Disability and Health

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Objective. To analyze the content of outcome measures commonly used to assess health in patients with fibromyalgia (FM) by linking the items of the instruments with the International Classification of Functioning, Disability and Health (ICF) in order to evaluate the adequacy of currently used measures.

Methods. Questionnaires used in FM were identified in a structured literature search. All concepts included in the items of the questionnaires were linked to ICF categories, according to previously published linking rules, by 2 independent health professionals. The percentages of linked ICF categories addressing the different ICF components were calculated.

Results. Generic and symptom-specific instruments were included. From the 296 items contained in all 16 instruments, 447 concepts were extracted and then linked to 52 ICF categories of the component body functions, 1 category of the component body structure, 40 categories of the component activities and participation, and 9 categories of the component environmental factors. More than half of the concepts identified were linked to body function, fewer were linked to activities and participation, and only concepts of 4 instruments were linked to the ICF component environmental factors.

Conclusion. Many concepts were linked to the categories in the ICF component body functions. While linking to the broad category, purportedly similar instruments often covered widely varying areas of function at more fine-grained levels of detail. Some categories, such as environmental factors, were barely covered by any of the instruments and might constitute an important aspect of health deserving better coverage and future development.

INTRODUCTION

Fibromyalgia (FM) is a chronic pain condition characterized by widespread pain and tenderness. The American College of Rheumatology established criteria for the classification of FM that require the following: a history of widespread pain for at least 3 months and tenderness in at least 11 of 18 defined tender points (1). Using this definition, 2–4% of the population in industrialized countries satisfy the criteria for having FM (2). In clinical practice, however, patients tend to report a more complex set of

concerns, including fatigue, sleep dysfunction, stiffness, depression, anxiety, poor physical functioning, and cognitive disturbance in addition to pain/tenderness (3,4).

The underlying pathology of FM remains poorly understood, but dysfunction in central neurobiologic structures is suspected (5,6). Actual symptom expression in FM tends to vary on an individual basis, suggesting heterogeneity in the underlying mechanisms of FM and the possibility of subgroups of patients with FM (3,7).

FM is best treated using dually focused interventions: pharmacologic agents to address issues of central pain and

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nonpharmacologic approaches, e.g., aerobic exercise and/or cognitive-behavioral therapy, to address some of the functional consequences of pain, for instance, deconditioning, poor function, and deteriorated mood (8). Significant effort is being applied to the development of new interventions (both pharmacologic and nonpharmacologic) specifically targeting FM. To determine the efficacy of these therapies, a variety of outcome measures have been used to assess improvement in patients with FM, but there has not been uniform agreement as to which domains or which assessment tools should be utilized. Two organizations have provided some guidance in this regard. The first, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), utilized the opinions of an expert consensus panel to determine what should be assessed in any clinical trial designed to assess the efficacy and effectiveness of treatments for chronic pain. This group suggested that the following outcome domains be considered: pain, physical functioning, emotional functioning, patient global ratings of satisfaction, negative health states, adverse events, and patient adherence to the treatment (9). The second group, the Outcome Measures in Rheumatology Clinical Trials (OMERACT) Fibromyalgia Syndrome working group, sought consensus from both patients and clinicians regarding the relevant outcome domains to specifically assess FM. Many of the same domains as defined by IMMPACT were identified for pain, but in addition, problems with sleep, cognition, tenderness, and stiffness were included as concerns more specific to FM (10).

With so many domains and instruments focused on health and functioning, clinicians and researchers can become mired in confusion. Further complicating the picture, assessment instruments claiming to assess the same domain often contain items that assess multiple domains that can differ depending upon the instrument. These differences between supposedly similar assessment tools are in part due to initial vagaries in the domain definition during instrument development.

The International Classification of Functioning, Disability and Health (ICF) (11) classifies health and health-related status and offers a comprehensive understanding of functioning in relation to a disease. In the ICF, functioning is described as the complex interplay of the health components body functions, body structures, activities and participation, and contextual factors, such as environmental and personal factors. Activity is defined in the ICF as the execution of a task or action by an individual, whereas participation is the person's involvement in a daily life situation. Participation may therefore be considered important from the perspective of patients because it refers to whether restrictions are experienced in daily life situations.

To date, no studies have evaluated whether the instruments commonly used to assess outcomes in FM align with the categories of function as defined by the ICF. The outcomes of such a study could both enlighten current instrument selection for assessing function and health in patients with FM and inform the development of new tools (3). Therefore, the goal of this study was to aggregate all items of all questionnaires commonly used to assess FM

and then link the content of those items to specific ICF codes. The intent of this process was to inform clinicians and researchers of the specific areas of health (based on content comparison) that are assessed when each questionnaire is administered and to help identify gaps in our current assessment batteries used to assess the multiple relevant domains of FM.

MATERIALS AND METHODS

Search strategy. A structured literature search was performed in spring 2007. The following databases were searched using the keywords "instrument," "measure," "assessment," "questionnaire," "functional assessment," "function," and "fibromyalgia": CINAHL (1982–2007), PsychINFO (1988–2007), EMBase (1988–2007), and Medline (1950–2007). Eligibility of the questionnaires was checked in 3 steps. In the first step, descriptive, evaluative, and psychometric studies were selected. Case reports, economic evaluations, primary prevention studies, and reviews were excluded. In the second step, studies and articles that reported the use of functional status questionnaires were selected. In the third step, the following criteria and instruments were applied: questionnaires that 1) assessed functioning and/or health, 2) were specifically developed for FM or were used to assess symptoms associated with FM in studies addressing FM (e.g., depression, fatigue), 3) were published in a peer-reviewed journal, and 4) exist in an English version.

The ICF categorization scheme. In the ICF classification, the letters b, s, d, and e represent functional components (i.e., body functions [b], body structures [s], activities and participation [d], and environmental factors [e]). The components of the ICF are followed by a numeric code starting with the chapter number (e.g., Chapter 6: Domestic Life; 1 digit), followed by the second level (2 digits) and the third and fourth levels (1 digit each). For example, coding "diminished sleep" might use the following coding scheme: the letter (component) would be body functions (b) and would be followed by the digit 1 representing Chapter 1 (Mental Functions) and would thus result in the first-level code b1 mental functions. The second-level code would be b134 sleep functions and the third-level code, b1340 amount of sleep. The fourth level is not available in this case. At the end of each chapter, there are other specified categories (uniquely identified by the final code 8) and unspecified categories (uniquely identified by the final code 9).

Linking to the ICF codes. Linking rules have been developed to link functioning instruments to the ICF in a specific and precise manner (12,13). Based on these linking rules, each item of an instrument should be linked to the ICF category that most precisely represents the item's content. An item of a questionnaire can include more than 1 concept, thus the first step of the analysis was to identify the concepts in each item. A concept was defined as 1 separate meaningful entity, such as a body structure, a

Table 1. Linking of the items of the Fibromyalgia Impact Questionnaire (FIQ) to the ICF*

FIQ item	Concept	ICF category
1. Were you able to do shopping?	To shop	d6200 Shopping
2. Were you able to do laundry with a washer and dryer?	To do laundry	d6403 Using household appliances
3. Were you able to prepare meals?	To prepare meal	d630 Preparing meals
4. Were you able to wash dishes/cooking utensils by hand?	To wash the dishes	d6401 Cleaning cooking area and utensils
5. Were you able to vacuum a rug?	To vacuum a rug	d6403 Using household appliances
6. Were you able to make beds?	To make beds	d640 Doing housework
7. Were you able to walk several blocks?	To walk	d4501 Walking long distances
8. Were you able to visit friends or relatives?	To visit friends/relatives	d9205 Socializing
9. Were you able to do yard work?	To do yard work	d6505 Taking care of plants, indoors and outdoors
10. Were you able to drive a car?	To drive a car	d4751 Driving motorized vehicles
11. Were you able to climb stairs?	To climb stairs	d4551 Climbing
12. Of the 7 days in the past week, how many days did you feel good?	To feel good	pf
13. How many days last week did you miss work, including housework, because of fibromyalgia?	To miss work To do housework Fibromyalgia	d850 Remunerative employment d640 Doing housework hc
14. When you worked, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your work, including housework?	Pain Other symptoms of fibromyalgia To work To do housework	b280 Sensation of pain hc d850 Remunerative employment d640 Doing housework
15. How bad has your pain been?	Pain	b280 Sensation of pain
16. How tired have you been?	To be tired	b1300 Energy level
17. How have you felt when you get up in the morning?	Feeling when getting up in the morning	b1343 Quality of sleep
18. How bad has your stiffness been?	Stiffness	b7800 Sensation of muscle stiffness
19. How nervous or anxious have you felt?	To be nervous To be anxious	b1470 Psychomotor control b1522 Range of emotion
20. How depressed or blue have you felt?	To feel depressed or blue	b152 Emotional functions

* Every item of the instrument was linked to the appropriate ICF category. ICF = International Classification of Functioning, Disability and Health; pf = personal factor; hc = health condition.

body function, an activity, or a contextual factor. Table 1 shows the linking of the items of the Fibromyalgia Impact Questionnaire (FIQ) to the appropriate categories of the ICF, e.g., item 14 of the FIQ: “When you worked, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your work, including housework?” In this item, the following 4 concepts were identified: 1) “pain,” 2) “other symptoms of your fibromyalgia,” 3) “work,” and 4) “housework.” The 4 concepts were linked to the following ICF categories: b280 sensation of pain, d640 doing housework, d850 remunerative employment, and hc (health condition). For the purpose of this study, a meaningful concept that referred to a diagnosis or a health condition, such as “symptoms of your fibromyalgia,” was assigned to hc.

If the content of a concept was more general than the corresponding ICF category, the code of the higher level was linked. An example is the concept “I have to limit my social activity” from the Functional Assessment of

Chronic Illness Therapy–Fatigue Scale (FACIT-FS), which was linked to Chapter 9: Community, Social and Civic Life because “my social activity” is more general than the available second-level categories in this chapter. A concept that was considered as not being contained in the ICF classification was assigned as not covered, for instance, the concept “attempts at suicides” of the Hamilton Rating Scale for Depression (HRSD). Furthermore, if the information about a concept was not sufficient to make a decision about the most appropriate ICF category, the concept was linked to not definable, such as “I am forced to spend time in bed,” a concept of the fatigue-assessment questionnaire FACIT-F.

The linking process was carried out by 2 health professionals according to the description or definition of the item of the instrument in the literature. The number of concepts identified in each questionnaire and the ICF categories linked were reported both in total and separated by component.

Table 2. Questionnaires included in the analysis

Instrument (reference)
Fibromyalgia specific
Fibromyalgia Impact Questionnaire (FIQ) (18)
Pain
McGill Pain Questionnaire (MPQ) (19)
Short Form McGill Pain Questionnaire (SF-MPQ) (20)
Brief Pain Inventory (BPI) (21)
Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale (LANSS) (22)
Fatigue
Functional Assessment of Chronic Illness Therapy (FACIT-FS) (30)
Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) (30)
Fatigue Severity Scale (FSS) (31)
Multidimensional Fatigue Inventory (MFI) (32)
Multidimensional Assessment of Fatigue (MAF) (33,40)
Sleep
Sleep scale from Medical Outcomes Study (MOS) (26)
General health
Short Form 36 Health Survey (SF-36) (36,37)
Sexuality
Arizona Sexual Experiences Scale (ASEX) (34)
Depression
Beck Depression Inventory (BDI) (38)
Hospital Anxiety and Depression Scale (HADS) (10)
Hamilton Rating Scale for Depression (HRSD) (38)

Rater interreliability. Consensus between 2 health professionals (Edda Amann and Barbara Kollerits) was used to determine which concepts were identified in all items of the questionnaires and which ICF category should be linked to each concept. In the case of disagreement between the 2 health professionals, a third person trained in the linking rules was consulted. In a discussion led by the third person (AC), the 2 health professionals that linked the concept stated pros and cons for the identification of a concept and for linking this concept to a specific ICF category. Based on these statements, the third person made an informed decision.

The degree of agreement between the 2 health professionals regarding the identified and linked concepts was calculated by means of the kappa statistic (14). Kappa values generally range from 0 to 1, where 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance alone. A kappa coefficient >0.61 was regarded as good or acceptable for this study (15). The statistical analysis was performed with SPSS 12.0.1 (SPSS, Chicago, IL).

RESULTS

Literature search. In step 1, the literature search produced 284 hits in CINAHL, 52 in PsychINFO, 547 in EMBase, and 661 in Medline. In the second step, the selection criteria for the articles were applied and 24 articles and 5 abstracts were reviewed in detail. In the third step, 16 questionnaires were identified according to the selection criteria and included in the analysis and are

Table 3. Frequencies of items, concepts, and International Classification of Functioning, Disability and Health (ICF) categories in relation to each other*

	FIQ	MPQ	SF-MPQ	BPI	LANSS	FACIT-FS	FACIT-F	FSS	MFI-20	MAF	MOS	SF-36	ASEX	BDI	HADS	HRSD
No. of items	20	4	17	23	7	13	40	9	20	16	12	10	5	21	14	19
No. of concepts	26	8	18	47	8	20	57	16	21	28	15	57	5	22	14	85
Concepts linked to ICF component																
Body function	8 (31)	7 (87)	18 (100)	21 (45)	6 (76)	12 (60)	22 (39)	10 (62)	14 (67)	13 (47)	15 (100)	16 (28)	5 (100)	14 (64)	13 (93)	60 (71)
Body structure	0 (0)	0 (0)	0 (0)	0 (0)	1 (12)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Activities and participation	15 (58)	0 (0)	0 (0)	7 (15)	0 (0)	6 (30)	17 (30)	4 (25)	4 (19)	14 (50)	0 (0)	28 (49)	0 (0)	3 (14)	1 (7)	7 (8)
Environmental factors	0 (0)	0 (0)	0 (0)	10 (21)	1 (12)	1 (5)	4 (7)	0 (0)	0 (0)	3 (13)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Concepts linked to personal factors	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (5)	0 (0)	1 (5)	0 (0)	0 (0)	3 (5)	0 (0)	4 (18)	0 (0)	1 (1)
Concepts linked to health condition	2 (8)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (8)
Concepts not definable	0 (0)	1 (13)	0 (0)	8 (17)	0 (0)	1 (5)	11 (19)	2 (13)	2 (10)	0 (0)	0 (0)	10 (18)	0 (0)	1 (5)	0 (0)	8 (9)
Concepts not covered	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
No. of different ICF categories	18	3	1	15	5	8	21	7	7	17	9	26	4	14	7	35

* Values are the number (percentage) unless otherwise indicated. The total 1,454 ICF categories comprise 310 categories in the component body structures, 493 categories in the component body functions, 393 categories in the component activities and participation, and 258 categories in the component environmental factors. See Table 2 for definitions.

Table 4. International Classification of Functioning, Disability and Health (ICF) categories covered by each instrument*

ICF category	FIQ	MPQ	SF- MPQ	BPI	LANSS	FACIT- FS	FACIT- F	FSS	MFI- 20	MAF	MOS	SF- 36	ASEX	BDI	HADS	HRSD
Body functions																
b1100 State of consciousness																1
b1261 Agreeableness																1
b1263 Psychic stability														1		1
b1265 Optimism														1		3
b1266 Confidence														3		
b130 Energy and drive function										6		1				
b1300 Energy level	1					11	11	8	6		2	3		1	1	2
b1301 Motivation								1	1							
b1302 Appetite														1		1
b134 Sleep functions				1								1				
b1340 Amount of sleep												2				
b1341 Onset of sleep												3				2
b1342 Maintenance of sleep												2				3
b1343 Quality of sleep	1						1					2		1		
b140 Attention functions									3							
b1400 Sustaining attention									1							
b1470 Psychomotor control	1											1			1	5
b152 Emotional functions	1			1		1	8		1	1		8		2	7	5
b1522 Range of emotion	1			1								1			2	4
b1600 Pace of thought																1
b1602 Content of thought														1	1	10
b1603 Control of thought																1
b1644 Insight																1
b1800 Experience of self																2
b1801 Body image														1	1	
b2702 Sensitivity to pressure					1											
b280 Sensation of pain	2	4	18	14	3		1					2				
b2801 Pain in body part				2												
b28010 Pain in head and neck		2		2								1				1
Body functions																
b28012 Pain in stomach or abdomen		1														
b28013 Pain in back																1
b3302 Speed of speech																1
b410 Heart functions																1
b440 Respiration functions																1
b450 Additional respiratory functions												1				
b4550 General physical endurance									2							
b4552 Fatiguability								1		6						1
b460 Sensations associated with cardiovascular and respiratory functions												1				1
b515 Digestive functions																3
b5252 Frequency of defecation																1
b5254 Flatulence																1
b530 Weight maintenance functions														1		1
b535 Sensations associated with the digestive system																1
b5350 Sensations of nausea							1									
b620 Urination functions																1
b640 Sexual functions													2			1
b6400 Functions of sexual arousal phase													1	1		
b6402 Functions of orgasmic phase													1			
b6403 Functions of sexual resolution phase													1			
b780 Sensations related to muscles and movement functions																1
b7800 Sensation of muscle stiffness	1															
b840 Sensation related to skin					2											
Body structure																
s810 Structure of areas of skin					1											
Activities and participation																
d177 Making decisions														1		2
d2200 Carrying out multiple tasks						1	1									

(continued)

Table 4. International Classification of Functioning, Disability and Health (ICF) categories covered by each instrument* (Continued)

ICF category	FIQ	MPQ	SF- MPQ	BPI	LANSS	FACIT- FS	FACIT- F	FSS	MFI- 20	MAF	MOS	SF- 36	ASEX	BDI	HADS	HRSD
d2201 Completing multiple tasks						1	1									
d230 Carrying out daily routine						2	2	1	3			2				
d4102 Kneeling												1				
d4105 Bending												2				
d4154 Maintaining a standing position				1												
d430 Lifting and carrying objects												1				
d4300 Lifting				1								1				
d4450 Pulling												1				
d450 Walking				2						1						
d4500 Walking short distances												1				
d4501 Walking long distances	1											2				
d4551 Climbing	1											2				
d4552 Running												1				
d4751 Driving motorized vehicles	1															
d510 Washing oneself										1						
d5101 Washing whole body												1				
d540 Dressing										1		1				
d550 Eating						1	1									
d620 Acquisition of goods and services										1						
d6200 Shopping	1															
d630 Preparing meals	1										1					
d640 Doing housework	3			1			2			1		1				
d6401 Cleaning cooking area and utensils	1															
d6403 Using household appliances	2											1				
d6505 Taking care of plants, indoors and outdoors	1															
d7 Interpersonal interactions and relationship				1			1							1		
d750 Informal social relationship												1				
d7500 Informal relationships with friends							1					1				
d7501 Informal relationships with neighbors												1				
d760 Family relationships							3	1				1				
d770 Intimate relationships							1									
d7702 Sexual relationships							1			1						
d850 Remunerative employment	2			1			2	1				3		1		3
d9 Community, social, and civic life						1	1	1		1						1
d920 Recreation and leisure									1	1					1	
d9201 Sports										1		3				
d9204 Hobbies																1
d9205 Socializing	1									1		1				
Environmental factors																
e1101 Drugs				5												
e1150 General products—for personal use in daily living					1											
e1151 Assistive products—for personal use in daily living				2												
e3 Supports and relationships						1	1									
e310 Immediate family							1			1						
e315 Extended family																
e320 Friends							1			1						
e410 Individual attitudes of immediate family members							1									
e5800 Health services				3												
Not covered																2
Personal factor	1						3		1			3		3		1
Personal factor-subjective														1		
Health condition	2			1												7
Not definable		1		3			7	2								6
Not definable health condition				3			1									1
Not definable activities and participation				2		1	1		2	1		2				
Not definable general health							1					4		1		
Not definable quality of life							1									
Not definable physical health												3				
Not definable body function																1

* This table shows the linking of the concepts contained in the items of the instruments using the ICF categories as a reference and ordered by component. Values are the frequencies with which the ICF categories were found to be addressed in the different instruments. A higher number indicates that several concepts from a specific instrument were linked to the same ICF category. See Table 2 for definitions.

listed in Table 2. Tools currently used are FM specific and symptom specific. The number of items of each questionnaire is presented in Table 3. The FIQ was the only FM-specific instrument in this literature search. Because psychiatric symptoms may influence pain and dysfunction as well as provide a sense of the impact of pain, fatigue, and other symptoms, assessments of depression were included (10).

Instrument item linkage to ICF codes. The linking of the concepts contained in the items of the instruments using the ICF categories as a reference and ordered by components is shown in Table 4 (a–d). The numbers in the table represent the frequencies with which the ICF categories were addressed in the different instruments. A higher number indicates that several concepts from a specific instrument were linked to the same ICF category. For example, the category d760 family relationship was linked to the following 3 concepts of the FACIT-F: “having troubles to meet the needs of the family,” “family well-being,” and “satisfaction with family communication about illness.”

In 296 items of all instruments, 447 concepts were identified, which were then linked to 52 ICF categories of the component body functions, 1 category of the component body structure, 40 categories of the component activities and participation, 9 categories of the component environmental factors, and 13 concepts to personal factors (Table 4 [a–d]). Ten concepts were considered to be related to health condition and were not linked to any ICF category. Forty-four concepts were not definable, and the following 2 concepts were found to be not covered by the ICF: suicides and attempts at suicides (concept in item 3 of the HRSD).

The frequencies of items and concepts of the instruments and ICF categories in relation to each other are shown in Table 3. The total number of the ICF categories linked to the concepts of the questionnaires shows remarkable differences. While some instruments showed a considerable diversity in their content (such as the Short Form 36 [SF-36], which includes 36 items from which 57 concepts were extracted and linked to 44 ICF categories), other instruments were linked to few or only 1 ICF category (such as the Arizona Sexual Experience Scale [ASEX], which includes 5 items from which 5 concepts were extracted and linked to 5 ICF categories).

The kappa statistic for agreement between the 2 investigators was 0.74 ($P < 0.0001$). The kappa coefficient exceeded 0.61 and thus was regarded as good.

DISCUSSION

For clinicians and researchers who wish to select an instrument for measuring a specific end point, it is important to know which domains are covered by which instruments and which areas receive no coverage at all. The findings of this study suggest that many areas of health are covered by the most commonly used measures, and that each instrument differs in the breadth of content that items cover.

One-third of the items of the FIQ, the only FM-specific

instrument, were linked to body functions and two-thirds were linked to activities and participation. The remaining concepts were linked to health condition or personal factor, such as the item “How many days last week did you miss work, including housework, because of fibromyalgia?” in which the meaningful concept “because of fibromyalgia” was linked to health condition. This instrument clearly links to health condition itself and is therefore not etiologically neutral (16). Because a lack of a clinical basis by which FM might be identified as a separate entity is evident (17), one might argue whether it is possible to have a special instrument in FM or whether a special instrument is required at all. Although it would be desirable for daily clinical practice to have 1 instrument covering the diversity of symptoms in FM, this might raise psychometric difficulties such as insensitivity associated with the multidimensionality, and differential item functioning associated with sex, as occurred in the FIQ (18).

Regarding the 4 instruments used to assess pain (McGill Pain Questionnaire [MPQ], Short Form MPQ [SF-MPQ], Brief Pain Inventory [BPI], and Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale [LANSS] [19–22]), considerable differences occurred in the ICF components covered. While the SF-MPQ was linked to body functions only, the MPQ and LANSS covered mainly body functions, and the BPI showed more diversity and was linked to body functions, activities and participation, and environmental factors. When assessing pain, the assessor must choose the instrument based upon what knowledge is desired (i.e., whether pain is affecting body function or activities and participation). In the literature, pain is described as both a symptom and a contributor to other symptoms such as fatigue, impairment of concentration, negative mood, degraded sleep, and diminished overall activity (9). Although it is evident that environmental factors have an impact on functioning in daily life from the perspective of patients (23–25), not all of the pain assessment instruments addressed these factors.

The Medical Outcomes Study sleeping scale (26) was only linked to body functions and the majority of concepts were linked to the ICF category b134 sleep functions. Many people with FM report sleep disturbances. Sleep impacts pain, fatigue, and social functioning (27,28); nevertheless, it is not clearly stated whether sleep disturbance is a symptom occurring itself or as a comorbidity. The relationship between sleep and pain was investigated by Affleck et al (29), who stated that the relationship might be bidirectional, meaning that pain might increase disturbance in sleep, and disturbed sleep could intensify pain, or even both. Sleep is rarely included in multidimensional assessment instruments; 2 exceptions are the BPI for assessing pain and the HRSD for depression, which include aspects of sleep. However, it might be recommended to assess sleep and pain in patients with FM.

Less than half of the concepts extracted from the fatigue-specific instruments (FACIT-FS, FACIT-F, Fatigue Severity Scale, Multidimensional Fatigue Inventory, Multidimensional Assessment of Fatigue [MAF] [30–33]) were linked to body functions. Activities and participation was covered by all fatigue instruments, whereas environmental factors only occurred in the FACIT-FS, the FACIT-F, and

the MAF. Coverage of fatigue in FM was considered by patients to be the second most important domain after pain (10), which is consistent with the relative importance of fatigue in the deterioration of activities and participation in other rheumatic diseases of long duration in general (24,33). As with pain, the relative lack of emphasis on environmental factors in the existing instruments assessing fatigue may indicate a gap that deserves future development.

The ASEX, an instrument that assesses sexual function, was only linked to body functions. The assessment of sexual function was considered important both as a domain of human function and because of the potential for adverse effects of medications on sexual function in patients with FM. Female patients with FM have distinct issues associated with sexual function compared with healthy controls (34). Tikiz et al (35) highlighted that the impact of FM on sexual function can be profound in addition to limiting one's ability to perform other essential life tasks and social roles. Sexual dysfunction may also cause significant personal distress and negatively impacts quality of life. In the ASEX, sexual function is assessed solely in the ICF component body functions. This has to be considered because assessing the dysfunction itself does not allow drawing any conclusions about the subjective meaning or choice of sexual function and thus the individual impact on quality of life.

The SF-36 (36,37) and the 3 depression instruments (Beck Depression Inventory, Hospital Anxiety and Depression Scale, HRSD [38]) were linked to body function as well as activities and participation. Because the impact of the syndrome profoundly influences the patient's normal life and daily activity pattern in work, home maintenance, and leisure activities (39), assessing concepts related to the component activities and participation in FM should be highlighted.

Visual analog scales for pain, fatigue, and disease activity or global health status are, per definition, self-report instruments. However, because they can be linked to a single ICF category only (b280 pain, b130 energy and drive functions) or to the health condition itself, they were not included in this analysis, which focused on a comparison of the content of instruments. Further research should focus on the psychometric properties of instruments and may suggest how to best measure specific concepts or categories. In terms of content, instruments that measure pain and fatigue not only within the ICF component body functions, but also within activities and participation may be preferable, as has been argued above.

The content of the questionnaires assessing health in patients with FM differs considerably, not the least due to the multidimensional nature of FM. Several instruments are available to assess pain, fatigue, and depression. All of them cover categories of the ICF concept body function, but not all could be linked to concepts regarding activities and participation and environmental factors. Thus, when selecting an instrument, careful consideration needs to be taken into account regarding which aspects of health should be covered. Based on the comparison made in this article, researchers and clinicians should be able to make a

more informed decision about which questionnaires best cover the content of the end points they wish to assess.

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AUTHOR CONTRIBUTIONS

Ms Prodingler had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Prodingler, Cieza, Mease, Boonen, Stucki, Stamm.

Acquisition of data. Prodingler, Cieza, Stamm.

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