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Patient Reported Outcomes and Fibromyalgia

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Abstract

Fibromyalgia (FM) is classified as a chronic pain condition accompanied by symptoms of fatigue, sleep problems, problems with cognition, negative mood, limited functional status, and the presence of other chronic overlapping pain conditions (COPCs). Comprehensive assessment of all of these components can be challenging. This paper provides an overview of patient-reported approaches that can be taken to assess FM in the contexts of diagnosis, symptom monitoring, phenotyping/characterization, and for purposes of clinical trials.

Keywords

Fibromyalgia; Diagnosis; Phenotyping; Multi-modal assessment; Self-report; Pain

Introduction

Fibromyalgia (FM) is considered to be a chronic pain condition characterized by chronic widespread pain (CWP) along with accompanying symptoms of fatigue, sleep difficulties, diminished physical functioning, mood disturbances, and cognitive dysfunction that can include problems with memory, concentration, and mental clarity. (1, 2) Globally, the mean prevalence of FM is 2.7% with females having a global mean prevalence of 4.2% and males having a mean prevalence of 1.4% (female to male ratio = 3:1).(3) Individuals with FM

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Dr. Williams serves as a consultant to Community Health Focus Inc. and to Pfizer Inc. He is also on the Board of Directors of the American Pain Society. There is no conflict associated with the content or preparation of this manuscript.

often report diminished quality of life, (4) diminished functional status, (5) and higher-than-expected healthcare utilization. (6)

Fibromyalgia is currently considered to be a central pain state suggesting that while peripheral input may be playing a role, central factors (e.g., central sensitization) likely account for much of the symptomatology. (7) In FM, aberrant activity in both central afferent (8) as well as descending modulatory mechanisms (9) contribute to symptoms and can be targeted therapeutically with some success. (10–12)

Currently self-report measures, increasingly referred to as patient-reported outcomes (PROs), remain the best method for characterizing the multiple facets of FM. While numerous attempts to identifying biomarkers have produced mixed results (e.g., genetics, autoantibodies, cytokines, hematological findings, oxidative stress, neuroimaging, neuropathology), (13) pathophysiological indices with sufficient sensitivity and specificity to serve as a FM biomarker remain elusive. (14) The use of PROs in the context of FM can take several forms depending upon the purpose of assessment: (a) Diagnostics, (b) Symptom Monitoring, (c) Phenotyping/Characterization, and (d) as outcomes for clinical trials. The remainder of this manuscript focuses upon these four uses of PROs for FM and describes instruments that can be used to support each use.

Diagnostics

In 1990 the American College of Rheumatology (ACR) developed research classification criteria so that standardized selection of individuals likely to have FM could be identified in support of conducting research on the condition. These criteria required the presence of tender points and widespread pain over a prolonged period of time. (15) While the ACR 1990 criteria was useful in promoting research, the tender point concept was flawed as a means of identifying FM. (16) Women generally report more musculoskeletal tenderness compared to men and thus defining FM by tenderness lead to the erroneous conclusion that FM was predominantly a “female” condition. When tenderness was replaced with widespread pain, the distribution still favored females but not nearly as much. (17)

In 2010, the ACR released for the first time, Clinical Diagnostic Criteria for FM. These new criteria retained the need to have widespread pain but eliminated the tender point concept for the reasons discussed above. The new diagnostic criteria included other symptoms in addition to pain that are commonly experienced by people with FM such as cognitive dysfunction, fatigue, and sleep problems. These new criteria also require a physician to rule out a number of other diagnoses that could account for the symptoms. (18)

Again, in the interest of conducting research on FM with the new clinical criteria, a PRO survey containing most of the diagnostic criteria was published in 2011. (19) There are a number of practical differences between the actual diagnostic criteria and the survey criteria in that the survey can be mailed to people, completed online via internet-based survey, and/or completed in a research setting without a physician present. The survey criteria also permit the calculation of a continuously scaled Fibromyalgia Score (0–31) allowing an individual to have a lot or a little of FM – consistent with the experience reported by

individuals with FM that FM tends to be variable over time and with the observation that some individuals have greater disease (symptom) burden compared to others. Scores on this continuous measure can provide an indication of “fibromyalginess,” or degree of augmented sensory (most prominently pain sensation) processing. (20, 21)

Disease Monitoring

Until the mid-1990s there was little uniformity in the assessment of pain in clinical settings. In his presidential address to the American Pain Society (APS), Jim Campbell observed that “...if pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly.” Following this address, the APS advanced the concept of pain being the 5th vital sign. In subsequent years, both the Veteran’s Administration (VA) and the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) adopted the concept of pain being the 5th vital sign. In clinical settings this is often operationalized by having patients rate their pain on a 0–10 numeric rating scale (NRS) which then gets transferred to the electronic medical record (EMR). Typically, pain greater than 4/10 triggers more comprehensive pain assessment and management.

Given pain is only one aspect of FM, use of the NRS as a means of monitoring the condition is likely to be insufficient. (22) One instrument that has been used to monitor diverse FM symptomatology and impact overtime has been the Fibromyalgia Impact Questionnaire-Revised (FIQR). (23) The FIQR, one of the few PROs developed specifically for FM, covers three domains relevant to FM: function, overall impact, and multi-dimensional symptomatology. Containing 21 items, this questionnaire can be given weekly (i.e. recall period is defined as 1 week), and only takes 3–5 minutes to administer. Its development was rigorous and numerous studies support its validation (for review see (24)). Whether used to monitor disease or as an outcome in clinical trials, a 14% change in the FIQR total score, which is the sum of the three domain scores, appears to represent a clinically meaningful change in FM. (25) Although more recently developed, the survey criteria for FM described above for epidemiological purposes (19) can also be used to monitor disease variability when the continuous Fibromyalgia scale (as described) is utilized.

Phenotyping and FM Characterization

Despite pain being the cardinal symptom of FM, to be “well” with FM requires far more than pain improvement. When characterizing FM it is helpful to think in terms of six assessment domains: (1) Pain, (2) Co-morbidities, (3) Affective vulnerability, (4) Beliefs and attitudes, (5) Behavior, and (6) Environmental/social. Next we provide a non-exhaustive listing of standardized PRO instruments that can be used to assess these domains in the context of FM.

Pain

Historically only pain intensity was assessed routinely for FM using visual analogue scales (VAS), numeric rating scales (NRS) or a “faces” approach. (26) There are, however, other aspects of pain that can hold relevance to FM. These include the quality of pain, its location

(e.g., how wide-spread it is), and its temporality (e.g., constant vs. intermittent). (See Table 1) One of the first measures of pain quality was the McGill Pain Questionnaire (MPQ;(27)). This questionnaire provided 78 pain descriptors grouped into 20 categories indicative of various types of pain (e.g., “stinging,” “aching,” “pounding”) that could be scored along 3 dimensions of painful experiences: sensation, affect, and evaluative components of pain. The MPQ also offers a body map to assess pain location and captures a NRS for present pain. The Brief Pain Inventory (BPI; (28)) is another commonly used pain question that captures both pain intensity and pain interference (i.e., elements of functional status). Like the MPQ, it uses a body map to assess location and queries about the effectiveness of treatment. Body maps are becoming increasingly important in the identification of single versus multiple comorbid pain conditions and are helping to identify individuals with just a primary condition versus multiple overlapping pain conditions (e.g., (29)). A newer questionnaire, the painDETECT (30) combines many of the important elements of pain assessment by offering an index of pain intensity assessment similar to the BPI, an abbreviated assessment of pain quality similar to the MPQ, a body map like both the MPQ and the BPI, as well as assessment of pain temporality. The painDETECT can also be scored to help differentiate the presence of musculoskeletal vs. neuropathic pain which in FM can present in the same individual to differing degrees.

Comorbidities

Comorbidities refer to both diagnosable conditions as well as to co-aggregated symptoms that tend to accompany chronic pain. (31) (See Table 2) The concept of coexisting chronic pain conditions was mentioned in the 2011 Institute of Medicine report on *Relieving Pain in America* (32) and is now recognized by both the National Institutes of Health and the U.S. Congress as a set of co-aggregating disorders that share symptomatology and putatively common mechanisms despite residing in anatomically distinct regions of the body. Currently labeled as “Chronic Overlapping Pain Conditions (COPCs) this collective of pain conditions includes but is not limited to fibromyalgia (FM), temporomandibular disorders (TMD), irritable bowel syndrome (IBS), chronic tension type headache (cTTH), migraine (MI), chronic low back pain (cLBP), myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), interstitial cystitis/painful bladder syndrome (IC/PBS), endometriosis (ENDO), and vulvodynia (VVD). (33) Currently one of the best means of assessing for the presence of one or more COPCs in a given individual is through the use of the Complex Multi-Symptom Inventory (CMSI; (34)). The CMSI contains two parts, (1) a 41-item symptom screener and (2) the published diagnostic criteria for six of the ten COPCs listed above. Rather than administering all diagnostic criteria to all patients, patients first complete the screener which contains specific items that trigger the administration of the full diagnostic criteria for COPCs that are relevant for that individual, effectively limiting response burden by only administering relevant questions. An updated version of the CMSI is in development that includes all 10 COPCs. The CMSI symptom screener can also be used as a tally of functional somatic burden much like a similar measure, the Pennebaker Inventory of Limbic Languidness (PILL; (35)) or the FM survey criteria described above. (19) Such co-aggregated symptom tallies have demonstrated utility in predicting both the onset and chronification of COPCs. (36)

Despite pain being the cardinal symptom of FM, an internet-based survey of 2,596 individuals with FM revealed that the intensity of fatigue, sleep problems, and difficulties with memory, concentration, and mental clarity (i.e. dyscognition) are often more severe and problematic than pain. (1) Brief instruments for assessing both sleep quality and sleep-related impairment can be obtained through the Patient Reported Outcomes Measurement Information System (PROMIS) administration and information website, AssessmentCenter™ (37). Other measures of sleep disturbances that have been more commonly used with FM populations include the Medical Outcomes Study (MOS) sleep scale (38) or the Pittsburgh Sleep Quality Index (PSQI; (39)). Fatigue can also be assessed via PROMIS measures that provide a single fatigue score reflecting a combination of fatigue intensity and fatigue interference/impact, (37) or with the Multidimensional Fatigue Inventory (MFI; (40)). The latter instrument allows for the assessment of general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity. To assess perceived cognitive difficulties across several dimensions, the Multiple Ability Self-Report Questionnaire (MASQ;(41)) has been used with FM samples. (42) This questionnaire assesses perceived cognitive difficulties across several dimensions: language ability, visual-perceptual ability, verbal memory, visual memory, and attention/concentration. One drawback of this questionnaire however is its length. At 38-items, it can represent considerable response burden to patients. Recently a new measure of perceived dyscognition, based upon the PROMIS item banks, was developed via classical and item response theory methods (IRT) specifically for FM and widespread pain conditions. Entitled the Multidimensional Inventory of Subjective Cognitive Impairment (MISCI;(43)) this 10-item inventory provides indices for cognitive concerns in the areas of mental clarity, memory, attention/concentration, executive functioning, and language, and is highly correlated ($r = 0.82$) with the lengthier MASQ.

Affective Vulnerability

Pain is defined as *both* a sensory and affective experience. (44) Thus, emotion is not a confounder or downstream by-product of pain, but is central to the very experience. Historically the phenotype of FM included the high prevalence of comorbid affective disorders in individuals with FM (45, 46). As such it became common to identify the presence of negative affective symptoms using such measures as the Beck Depression Inventory-II (BDI-II; (47, 48)) the Center for Epidemiological Studies Depression Scale (CESD, CESD-R; (49, 50)) or the PHQ-9 (51) for depression and the State-Trait Anxiety Inventory (STAI; (52)) or General Anxiety Disorder-7 (GAD-7; (53)) for anxious affect. Some measures such as the Hospital Anxiety and Depression Scale (HADS; (54) assess both constructs. Each of these measures can be scored to reveal either a probable diagnosis of an affective disorder or a continuous measure of negative affect. One need not be psychiatrically ill however to have FM; which is why the continuous measurement of emotion is preferable when assessing the role of affect in a pain condition. Other measures of negative affect (i.e., not diagnostic of disorders) include the PROMIS negative emotions scales (e.g., depressed affect, anxious affect, and anger). (37) and the Positive and Negative Affect Scale (PANAS; (55)). In addition to characterizing pain by negative affect, this latter scale introduces the ability to assess positive emotion, which is thought to represent an element of resilience that can serve to buffer or even diminish the perception of pain(56);

deficits in the balance between positive and negative affect in FM have been discovered and highlight the importance of a comprehensive assessment of affect in this condition.(57, 58) The PANAS can be scored to derive an index of affect balance, a ratio between positive and negative emotion that is associated with well-being in FM. (59)

Constructs related to affective vulnerability also include stress/trauma and personality. Stress is a state-like phenomena with influences on pain perception that can be assessed with measures such as the Perceived Stress Scale (PSS; (60)). Longer and more stable affective influences on pain can emerge from trauma (e.g. assessed with measures such as the Childhood and Recent Traumatic Events Scales (CTES/RTES; (61)) or personality characteristics. The latter, personality characteristics often utilize measures that assess the big 5 personality domains: neuroticism, extroversion, openness, conscientiousness, and agreeableness (e.g., NEO-PI, NEO PI-R; (62, 63), the International Personality Item Pool; (IPIP) (64–66), or the Ten-Item Personality Inventory (TIPI; (67)). (See Table 3 for a review of Affective scales).

Beliefs/Attitudes

Beliefs and attitudes about pain can directly influence a patient's affect and functional status. (68) Further, a single detrimental belief such as “catastrophizing” has been shown to account for up to 47% of the variance in chronification in low back pain (69) and is a common cognitive style for individuals with FM. (70) Several measures are used to assess catastrophizing; the Pain Catastrophizing Scale (PCS; (71)) and the Catastrophizing subscale of the Coping Strategies Questionnaire (CSQ; (72)). Other beliefs and attitudes associated with pain and subsequent outcomes in FM include locus of control (i.e., assessed by the Beliefs in Pain Control Questionnaire (BPCQ;(73))), self-efficacy to control pain (i.e., assessed by the Perceived Self-Efficacy Scale (PSE; (74))), coping resources (e.g., the full version of the above mentioned CSQ; (72)) and multidimensional measures of pain beliefs (e.g., the Survey of Pain Attitudes (SOPA; (75) or the Pain Belief and Perceptions Inventory (PBPI; (76))). (See Table 4 for a listing of Belief/attitudes scales).

Behavior

There are a number of behavioral domains that can hold relevance for individuals with FM but perhaps the most common is physical functioning. (See Table 5) In many studies, the SF-36 (77) (or one of the shorter versions of this instrument) has been used for assessment. (78) Other measures of physical functioning with relevance for FM include the PROMIS physical functioning scales (37), the Pain Disability Index (PDI; (79)) and as mentioned previously, the pain interference scale from the BPI. (28) Underscoring the importance of assessing behavioral responses to pain, outcomes such as health care utilization have shown stronger relationships with demand for services and disability than with indices more specifically tied to symptomatology such as illness severity, prognosis or treatment status. (80)

Environmental/Social

For rheumatologic forms of pain, both the quality and quantity of social support at the initial diagnosis of a condition can be predictive of pain and functional status 3–5 years later. (81)

For this reason, social factors are often considered in the phenotypic assessment of FM. Measures of family functioning (e.g., the Dyadic Adjustment Scale (DAS; (82)), work place activities (e.g., Workplace Productivity and Activity Impairment (WPAI; (83)) and measures of social engagement with friends and others (e.g., Participation Enfranchisement (PE); (84)) capture three highly relevant components of individuals' social world. A more general multidimensional measure, the West Haven-Yale Multidimensional Pain Inventory (WHYMPI; (85)) also provides multidimensional indices of constructs relevant to the social/environmental influences on pain: interference, support, pain severity, life-control, affective distress, negative responses, solicitous responses, distracting responses, household chores, outdoor work, activities away from home, social activities, and general activities. (See Table 6)

Clinical Trials

The Outcome Measures in Rheumatology Clinical Trials (OMERACT) is an organization that seeks to refine outcomes measurement issues in part by identifying core sets of variables that should be collected and reported in any clinical trial involving rheumatological conditions. (86) Dating back to 2004, a task force within OMERACT focused upon FM, conducted two Delphi studies so as to establish consensus regarding the most relevant domains of assessment for clinical trials involving FM. One of these studies involved individuals with FM (87) and the second involved clinicians treating FM. (88) Despite some differences in the ordering of symptom priority between patients and clinicians (e.g., patients seemed more concerned with dyscognition than were clinicians), there was considerable consensus about the domains of relevance for clinical trials. (2) These OMERACT domains included: pain, fatigue, functional status, sleep, mood, tenderness, stiffness, and dyscognition (e.g., memory and concentration).

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) has similarly identified the domains of relevance for any clinical trial of a painful condition. IMMPACT recommends that four core areas be assessed: (1) pain intensity, (2) physical functioning, (3) emotional functioning, and (4) overall improvement/wellbeing. (89–91) Despite OMERACT and IMMPACT being two independent organizations, there was substantial agreement between organizations as to what domains to assess. It should be noted that while each organization identified relevant domains, neither organization dictated the specific instruments that needed to be used in the assessment of each domain leaving that up to individual investigators.

To date, clinical trials in FM have used many different questionnaires to assess the relevant domains. (24, 78) While this may seem problematic, at least one published study that combined datasets from across large clinical trials, assessment approaches, and differing pharmacological agents, empirically identified the phenotype of an “FM treatment responder”. This study suggested that regardless of the assessment instrument used, an FM treatment responder would demonstrate (1) a 30% improvement in pain, (2) a 10% improvement in physical functioning, and (3) a 30% improvement in at least two of the following domains: fatigue, sleep, depression, anxiety, or dyscognition. (78)

Conclusions

PROs remain the best approach for assessing the multiple facets of FM for the purposes of diagnosis, disease monitoring, phenotyping, and clinical trials. Through the use of PROs it is possible to classify individuals as having FM for both clinical and research purposes. Given FM is a highly variable condition with a variety of symptomatic manifestations, PROs that capture the waxing and waning of FM's multifaceted symptomatology are necessary for monitoring the condition. In order to better understand the mechanisms underlying FM it is necessary to characterize individuals with FM comprehensively. Depending upon the research question, this can require extensive exploration of putative mechanisms interacting across multiple domains of assessment. Assessments can be briefer in the context of clinical trials given that the "discovery" is related to the intervention rather than to the underlying mechanisms of FM. Still, a multifaceted assessment is needed in order to adequately identify the potential of the intervention to impact multiple domains of relevance to FM. While researchers continue to explore biomarkers for FM, it is likely that PROs will continue to be informative to this field for years to come.

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Key Points

- Physicians and/or PROs remain the most sensitive and specific means of diagnosing FM in clinical or research settings
- The primary uses of PROs for FM include diagnostics, disease monitoring, phenotyping/characterization and as outcomes for clinical trials.
- FM is a multifaceted condition requiring a multifaceted approach to assessment if the complexity of the condition is to be represented in a reliable and valid manner.

Table 1

Assessment of the Pain Domain

Domain	Instrument	Items	Score Range
Pain			
Intensity	Visual Analog Scale (VAS) and Numerical Rating Scales (NRS) (26)	1	0–10
Quality Intensity & Distribution	McGill Pain Questionnaire (MPQ) (27)	78	0–78
Intensity Distribution Interference	Brief Pain Inventory (BPI) (28)		16
	Subscales:	Pain Intensity	4
		Pain Interference	7
Quality Intensity Distribution Temporality	painDETECT (30)	9	–1 – 38

Table 2

Assessment of the Co-Morbidities Domain

Domain	Instrument		Items	Score Range
Comorbidities				
Symptom burden Chronic Overlapping Pain Conditions (COPC) diagnostics	Complex Medical Symptom Inventory (CMSI)(34) (screener and measure of symptom burden) Includes diagnostic criteria for COPC's		41	0–41
Symptom burden	Pennebaker Inventory of Limbic Languidness (PILL) (35)		54	0–54
FM diagnostics Fibromyalgia-ness	FM survey criteria (19) “Fibromyalgia-ness” as a continuous construct		7	0–31
Sleep	PROMIS Sleep Disturbance Short Form 8a (37)		8	8–40
Waking	PROMIS Sleep-Related Impairment Short Form 8 (37)		8	8–40
Sleep	Medical Outcome Study (MOS) sleep scale(38)		12	-
	Subscales:	Sleep Disturbance	4	1–6
		Snoring	1	1–6
		Shortness of Breath	1	1–6
		Sleep Adequacy	2	1–6
		Somnolence	3	1–6
		Sleep Quantity (hours)	1	-
Sleep	Pittsburgh Sleep Quality Index (PSQI)(39)		19	-
	Subscales:	Sleep Quality	1	0–3
		Sleep Latency	2	0–3
		Sleep Duration	1	0–3
		Sleep Efficiency	2	0–3
		Sleep Disturbances	9	0–3
		Use of Sleep Medication	1	0–3
		Daytime Dysfunction	2	0–3
		Global Score	18	0–21
Fatigue	PROMIS Fatigue Short Form 8a (37)		8	8–40
Fatigue	Multidimensional Fatigue Inventory (MFI) (40)		20	-
	Subscales:	General Fatigue	4	4–20
		Physical Fatigue	4	4–20
		Mental Fatigue	4	4–20
		Reduced Motivation	4	4–20
		Reduced Activity	4	4–20
Dyscognition	Multiple Ability Self-Report Questionnaire (MASQ)(41)		38	38–190

Domain	Instrument		Items	Score Range
	Subscales:	Language	8	8–40
		Visual-Perceptual Ability	6	6–30
		Verbal Memory	8	8–40
		Visual-Spatial Memory	8	8–40
		Attention/Concentration	8	8–40
Dyscognition	Multidimensional Inventory of Subjective Cognitive Impairment (MISCI)(43)		10	10–50

Table 3

Assessment of the Affective Vulnerability Domain

Domain	Instrument		Items	Score Range
Affective Vulnerability				
Depression	Beck Depression Inventory-II (BDI-II)(47, 48)		21	0–63
Depression	Center for Epidemiologic Studies of Depression Scale Revised (CED-R)(49)		20	0–60
Depression	Patient Health Questionnaire – 9 (PHQ-9)(51)		9	0–27
Anxiety	State-Trait Anxiety Inventory (STAI)(52)		40	-
	Subscales:	State Anxiety Scale	20	20–80
		Trait Anxiety Scale	20	20–80
Anxiety	Generalized Anxiety Disorder –7 (GAD-7)(53)		7	0–21
Anxiety Depression	Hospital Anxiety Depression Scale (HADS)(54)		14	0–42
	Subscales:	Anxiety	7	0–21
		Depression	7	0–21
Depression	PROMIS Depression Short Form 8a (37)		8	8–40
Anxiety	PROMIS Anxiety Short Form 8a (37)		8	0–32
Stress	Perceived Stress Scale (PSS)(60)		10	0–40
Trauma	Childhood Traumatic Events Scale (CTES)/Recent Traumatic Events Scale (RTES)(61) *single items scored separately		13	-
Personality	NEO Personality Inventory –Revised (NEO-PI-R)(62, 63); Full scale has 243 items including 3 validity items		240	
	Subscales:	Extraversion	48	0–192
		Agreeableness	48	0–192
		Conscientiousness	48	0–192
		Neuroticism	48	0–192
		Openness to Experience	48	0–192
Personality	International Personality Item Pool (IPIP)(64–66)		120	
	Subscales:	Extraversion		
		Agreeableness		
		Conscientiousness		
		Neuroticism		
		Openness to Experience		
Personality	TIPI(67)		10	
	Subscales:	Extraversion	2	1–7
		Agreeableness	2	1–7
		Conscientiousness	2	1–7
		Neuroticism	2	1–7
		Openness to Experience	2	1–7

Domain	Instrument		Items	Score Range
Positive affect Negative affect	Positive and Negative Affect Schedule (PANAS)(55)		20	-
	Subscales:	Positive Affect	10	10–50
		Negative Affect	10	10–50

Table 4

Assessment of the Beliefs/Attitudes Domain

Domain	Instrument		Items	Score Range
Beliefs/Attitudes				
Catastrophizing	Pain Catastrophizing Scale (PCS)(71)		13	0–52
	Subscales:	Rumination	4	0–16
		Magnification	3	0–12
		Helplessness	6	0–24
Locus of control	Beliefs About Pain Control Questionnaire (BPCQ)(73)		13	-
	Subscales:	Internal Control	5	5–30
		Powerful Others	4	4–24
		Chance	4	4–24
Self-efficacy	Arthritis Self Efficacy Scales (ASE) (74)		20	-
	Subscales:	Self-efficacy Pain	5	1–10
		Self-efficacy Function	9	1–10
		Self-efficacy other symptoms	6	1–10
Coping Strategies	Coping Strategies Questionnaire (CSQ) (72)		50	
	Subscales:	Diverting attention	6	0–36
		Reinterpreting Pain Sensations	6	0–36
		Coping Self-Statements	6	0–36
		Ignoring Pain Sensations	6	0–36
		Praying/Hoping	6	0–36
		Catastrophizing	6	0–36
		Increasing Behavioral Activity	6	0–36
		Ability to control pain	1	0–6
		Ability to decrease pain	1	0–6
Pain Beliefs	Survey of Pain Attitudes (SOPA)(75)		57	-
	Subscales:	Control	10	0–40
		Emotion	8	0–32
		Disability	10	0–40
		Harm	8	0–32
		Medication	6	0–24
		Solicitude	6	0–24
		Medical Cure	9	0–36
Pain Beliefs	Pain Beliefs and Perceptions Inventory (PBPI)(76)		16	-
	Subscales:	Mystery	4	-2 – +2
		Constant	4	-2 – +2
		Permanent	4	-2 – +2

Domain	Instrument		Items	Score Range
		Self-Blame	4	-2 – +2

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Table 5

Assessment of the Behavior Domain

Domain	Instrument		Items	Score Range
Behavior				
Physical function Mental function	Medical Outcomes Study Short Form Health Survey-36 (SF-36)(77)		36	
	Subscales:	Physical Functioning	10	0–100
		Role Physical	4	0–100
		Bodily Pain	2	0–100
		General Health	5	0–100
		Vitality	4	0–100
		Social Functioning	2	0–100
		Role Emotional	3	0–100
		Mental Health	5	0–100
Physical function	PROMIS Physical Function Short Form 10a (37)		10	10–50
Disability	Pain Disability Index (PDI)(79)		7	0–70
Pain interference	Brief Pain Inventory – Interference subscale (BPI)(28)		7	0–10
Physical function Multimodal FM	Fibromyalgia Impact Questionnaire- Revised (FIQR)(23)		21	0–100
	Subscales:	Function	9	0–30
		Symptoms	10	0–50
		Overall Impact	2	0–20

Table 6

Assessment of the Social/Environmental Domain

Domain	Instrument		Items	Score Range
Social/Environmental				
Home	Dyadic Adjustment Scale (DAS)(82)		32	0–151
	Subscales:	Dyadic Consensus	13	0–65
		Dyadic Satisfaction	10	0–50
		Dyadic Cohesion	5	0–12
		Affectional Expression	4	0–24
Work	Work Productivity and Activity Impairment (WPAI)(83)		6	
	Subscales:	Percent work missed due to health		0–100
		Percent impairment while working due to health		0–100
		Percent overall work impairment due to health		0–100
		Percent activity impairment due to health		0–100
Friends	Participation Enfranchisement (PE)(84)		19	
Multimodal	West Haven-Yale Multidimensional Pain Inventory (WHYMPI)(85)		54	
	Subscales:	Pain Interference	9	0–6
		Support	3	0–6
		Pain Severity	3	0–6
		Life-Control	2	0–6
		Affective Distress	3	0–6
		Negative Responses	4	0–6
		Solicitous Responses	6	0–6
		Distracting Responses	4	0–6
		Household Chores	5	0–6
		Outdoor Work	5	0–6
		Activities Away from Home	4	0–6
		Social Activities	4	0–6
		General Activity	18	0–6