The assessment of pain-related physical function for clinical trials in chronic pain

Jennifer A. Haythornthwaite, Ph.D.

Associate Professor

Johns Hopkins University School of Medicine

Contact Information:

Jennifer A. Haythornthwaite, Ph.D
101 Meyer, 600 N. Wolfe St.
Baltimore, MD 21287
(410) 614-9850 (voice)
(410) 614-3366 (FAX)
jhaytho1@jhmi.edu

Background/Overview

This paper will address three important and related dimensions of pain-related physical function. The first dimension, **perceived interference**, is typically measured with global ratings of the extent to which pain interferes with various key activities. Individuals are asked to make ratings in which they, in many cases, isolate the impact of pain from other aspects of their illness or lifestyle that interfere with daily activities. Not surprisingly, these ratings not only correlate with pain, but also correlate with other psychological factors such as depression. The second dimension, **activity level**, is typically measured with ratings of what specific activities the individual participates in on a regular basis. These ratings are not tied to pain and do not take into account, in general, whether that is an appropriate activity for the individual. And finally, the third dimension is **sleep**. Sleep is measured either with diaries or summary scales, and often ratings are made regarding the extent to which pain interferes with sleep.

There are a number of challenges that need to be addressed in selecting a measure of pain-related physical function. First, most measures of pain-related physical function are correlated with ratings of pain intensity. Although correlated, the relationship has been shown to be non-linear (157) and a number of factor analyses that have combined measures of pain with measures of physical function often find distinct factors (e.g., (151;167)). There is some indication from the literature reviewed below that ratings of interference made within specific domains – sleep, recreation, etc – are easier for people to make and show more independence from ratings of pain intensity than more global ratings (e.g., "daily activities"; (185)). While some widely used scales such as the SF-36 and the Graded Chronic Pain Scale (188) combine pain severity and interference into one scale, the potential for losing important information is great, particularly in the context of evaluating a treatment for chronic pain and potentially making a inaccurate conclusion (87). However, the Graded Chronic Pain Scale has also been used to examine differential treatment responses in groups of patients (51), an application of a combined scale that may be particularly appropriate.

The second challenge pertains to the inherent limitations of self report. Response biases need to be considered whenever using self-report measures. Some of the measures reviewed have been examined for the influence of response biases, such as social desirability or the tendency to present oneself in a positive or more socially acceptable light (41). Similarly when disability determinations are being made or litigation is a factor, measures of physical function may be particularly vulnerable to response biases. While self report measures have limitations, the value of self-reported function is well established and should not be discarded for observer reports, since providers' ratings of function do not correlate well with patients' self-reports (38), a finding that is common with ratings of pain severity.

The third challenge in selecting a measure, at least for some measures, is the potential change in the properties of the measure that may occur when it is removed from its original context. Only one measure reviewed below is a stand-alone measure of pain-related physical function – the Pain Disability Index (171). Another measure – the Brief Pain Inventory (36) – includes an assessment of pain in a different (previous) section before the patient reports on pain-related interference. The other two measures – the West Haven Yale Multidimensional Pain Inventory (96) and the Sickness Impact Profile (9) - have pain-related physical function scales embedded in other scales. Some have hypothesized that the items surrounding an item impact on ratings of the item, thereby contributing to high cross-loadings in factor analyses (110). The context of any single question, including both the subject's perceptions of the orientation of the questioner as well as adjacent questions, influence subjects' responses as much as scaling and question format (155).

Measures that are widely or predominantly used in one literature, such as the Oswestry Disability Index (e.g., low back pain) and measures that combine pain intensity and a dimension of physical function, such as the Graded Chronic Pain Scale or the SF-36 Bodily Pain scale, were excluded from the review. A number of studies in the chronic pain treatment literature have used scales designed for the study (104;106;121) or physician ratings of disability (193) and these procedures will also not be included in the review.

Four measures that include five scales assessing pain-related physical function are reviewed in detail below, and a final recommendation is made. The next section addresses the assessment of sleep, where the scaling is quite heterogeneous, and a recommendation is also made regarding the measurement of sleep in future clinical trials. And the final section suggests some future directions for research in the area of pain-related physical function. Each measure is reviewed separately by providing some background on the development of the scale and the extent to which it is currently used, discussing the scale itself and its psychometric properties, reviewing briefly validity data on the scale, and finally presenting available literature addressing the sensitivity of the scale to treatment effects, both from observational studies and randomized trials when available. Each of the selected scales shows adequate psychometric properties, although some have been more extensively studied than others. Table 1 summarizes some of the characteristics of each scale reviewed below.

Table 1: Summary of key dimensions for 4 scales of interest

Scale	Number of items	Time (mins)	Scoring procedure	Comments
BPI	7	<5	Sum of items	
PDI	7	<5	Sum of items	
SIP Physical Function	136	15	Weighted sum of items	Embedded in other scales
WHYMPI/MPI Interference	11	<5	Average of items	Embedded in other scales
General Activity	18	<5	Average of items	

Brief Pain Inventory – Interference Scale

Background. The Brief Pain Inventory (BPI;(3)) was originally developed by the Pain Research Group of the WHO Collaborating Center for Symptom Evaluation in Cancer Care (32) to measure pain severity and pain-related interference in patients with cancer. This scale has been widely used in the assessment of cancer pain (3;87) in many different countries (25;31;66;102;137;153;190). Recently its use has been extended to non-cancer pain assessment, including heterogeneous pain conditions (132), osteoarthritis (147;173), neuropathic pain (63;88;116;160) including HIV/AIDS (15), and cerebral palsy (185).

Scales. The Brief Pain Inventory includes two primary dimensions: pain intensity and pain interference (32). The original Brief Pain Inventory, called the Wisconsin Brief Pain Inventory (36), was developed on patients with four different sites of cancer pain and patients with rheumatoid arthritis (36). Administered in either interview or questionnaire form, the original interference scale included ratings on 5-point scales (0-not at all to 4-extremely) of the extent to which pain interferes with the six domains listed above. The most widely used version of the pain interference scale uses 11-point numeric rating scales (0-no interference to 10-interferes completely) to assess pain-related interference in seven areas: general activity, mood, walking ability, normal work including outside the home and housework, relations with other people, enjoyment of life, and sleep (32). Some investigators have added additional domains: self-care, recreational activities, and social activities (88;185) or changed walking to general mobility for disabled individuals (185); for the purposes of this review, this scale will be referred to as the modified BPI Interference scale. The time frame for assessment can vary from "the past week" (32) to "the past 24 hours" (3). Factor analyses of the pain intensity and pain interference scales support a two-factor structure that is robust across cultures (32).

Using data from the four country BPI database (157), multidimensional scaling analyses designed to control for response biases inherent to self-report questionnaires demonstrated two dimensions to the BPI Interference scale after controlling for worst pain intensity: affect (relations with others, mood, enjoyment of life) and activity (walking, work, general activity, sleep; (31). A recent factor analysis of the modified BPI Interference scale items measuring phantom limb pain indicated a single factor (88) that accounted for 70% of the variance in the items. Other factor analyses of the original BPI Interference scale, one with HIV-infected adults (160) and one validating a Hindi version (153) found a two factor solution - affect (enjoyment of life, mood, and relationships with others) and daily activity (work, walking, and general activity) – similar to that found with multidimensional scaling (31).

Psychometrics. The psychometric properties of the BPI Interference scale have been examined by a number of investigators with a variety of painful conditions. Analyses of the BPI Interference scale used in four different countries – U.S., France, China, and the Phillipines – yielded excellent internal stability coefficients (ranging from 0.86 to 0.91; (157). These authors (157) demonstrated remarkable internal consistency of the BPI Interference scale across different levels of pain – mild, moderate, and severe (ranging from 0.80 to 0.91 across the four countries and levels of pain). Similar results have been found in patients with AIDS (16). In patients with cerebral palsy, a slightly modified BPI Interference scale showed excellent internal consistency (alpha = 0.89; (185)), considerably better than the 3-item interference scale (alpha = 0.59; (185) from the Chronic Pain Grade Scale (188). Among individuals with phantom limb pain, the ten item modified BPI Interference scale showed excellent internal consistency (alpha = 0.95; (88)). Test-retest stability of the BPI Interference scale has not been systematically examined, although the validation of the German version included examining 30 minute stability, which was excellent ($r = 0.97$).

Validity: General. The wide use of the BPI Interference scale with cancer pain has created a large literature demonstrating the validity of this scale. Work on the BPI has demonstrated strong correlations between pain intensity ratings and pain interference ratings across different diseases (36;134;146). Detailed analyses indicate that the relationship between pain intensity and pain-related interference is non-linear, providing additional support for separating these two dimensions (157). Analyses using the BPI Interference scale have used both the total score and individual items. Total BPI Interference scores are correlated with other measures of disability, negative mood, and level of hope in the expected directions (103;134;136;146). Multivariate analyses indicate independent contributions of pain severity and mood in predicting total BPI Interference scores (134). Total BPI Interference scores correlate with overall quality of life (QOL) and show a stronger and more consistent relationship with QOL than pain severity over a period of three weeks (84). The German version of the BPI Interference scale correlates significantly with deteriorated performance scores and relevant SF-36 scales, including bodily pain, physical function, vitality, and general health (137).

The presence of breakthrough pain is associated with higher BPI Interference ratings (135). And patients with cancer still reporting breakthrough pain one week following aggressive implementation of the WHO analgesic ladder reported greater BPI Interference as compared to patients not experiencing breakthrough pain (85). In extending work on factors associated with concerns about pain management in patients with cancer, path analyses indicate that greater concerns were associated with lower analgesic use, which was associated with higher levels of pain and higher levels of BPI Interference (192). The BPI may be particularly suited in the assessment of episodic or fluctuating pain states, such as can occur with pain due to cancer. Patients with neoplastic disease who report no pain at the time of a medical visit but pain during the past week report higher levels of interference in every domain measured by the BPI Interference scale as compared to patients who reported no pain at either the visit or during the past week (131).

Validation of the BPI Interference scale comes from other populations, including patients with HIV/AIDS, phantom limb pain, and cerebral palsy. Pain intensity ratings correlate with ratings of BPI Interference in diabetic neuropathy (63) and post-amputation pain (116), and patients with complex regional pain syndrome report a “substantial” (at least 5/10) degree of interference all but one area (i.e., sleep) assessed by the

modified BPI (64). Concerns about pain management are associated with higher levels of pain and pain-related interference among patients with AIDS (14), and despite higher levels of distress and poorer overall quality of life, AIDS patients with a history of injection drug use do not report higher pain intensity or pain-related interference (15). Patients with HIV/AIDS reporting moderate to severe pain for the past two weeks and symptoms of post-traumatic stress disorder (PTSD) not only report higher levels of distress and lower QOL, but also report higher BPI Interference scores as compared to individuals who do not report significant PTSD symptoms (160). This effect was observed on the two dimensions of BPI Interference – affect and activity – and remained significant across a six-month period (160). The modified BPI Interference scale has been used to track outcome following a recent limb amputation (88). At one month following amputation, a variety of important psychosocial predictors – catastrophizing, perceptions of control over pain, and social environmental factors – were associated with level of pain-related interference, independent of average level of pain (88). Five months later, increases in pain-related interference were predicted by baseline levels of the same factors, again independent of baseline pain intensity (88).

Sensitivity: Pre-Post Changes. The BPI Interference scale has been used to track responses to a variety of pain management interventions. In a small descriptive investigation of sodium valproate in reducing pain and interference due to cancer-related neuropathic pain, pain-related interference scores decreased to a similar extent as pain intensity scores, except in the area of sleep (77). Radio-frequency ablation of a single painful osteolytic metastasis reduced pain and pain-related interference four weeks later in a group of 12 adults (24). One Veterans hospital that tracked patients with severe pain following implementation of the AHCPR pain guidelines for cancer pain management found that within one week patients achieved significant reductions in pain and pain-related interference ratings and that these reductions maintained for two additional weeks (28). Fourteen patients with intractable cancer pain treated with transdermal fentanyl reported reduced pain-related interference with sleep within one week and broader reductions in pain-related interference after two weeks, including reduced pain-related interference with general activity, mood, work, sleep, and enjoyment of others (201)

In the context of evaluating an extended release formulation of hydromorphone, patients on long-term opioid therapy for either cancer or non-cancer related pain reported significant decreases in pain intensity and pain-related interference during a large, multi-center open-label study (132). An open-label trial of transdermal fentanyl for chronic pain in patients with AIDS taking stable doses of previously prescribed opioids demonstrated a significant reduction in pain and pain-related interference following 15 days of treatment (125).

Sensitivity: RTC. Randomized clinical trials evaluating cancer pain treatments have not been widely conducted, although a few trials are available which included use of the BPI Interference scale. A randomized, prospective trial of a cancer pain treatment algorithm – including a comprehensive assessment and evidence-based analgesic guidelines – did not demonstrate a significant reduction in pain intensity, pain relief, or pain-related interference compared to a standard pain management program, although patient satisfaction scores were higher in the intervention group (49). The intervention yielded higher adherence to "best practice" guidelines, although there was no significant difference between groups in total 24-hour opioid dosing (49). Across both groups, though, opioid dosing was significantly correlated with reductions in pain interference (49). A brief pilot intervention to reduce women's concerns about pain management did not show a differential effect on perceived barriers to pain management or level of pain-related interference as compared to usual care, although all subjects reported fewer barriers and lower pain-related interference at the one-month follow-up (191).

The BPI Interference scale has been used to measure outcome in five additional randomized clinical trials involving non-cancerous painful conditions. In a randomized trial comparing cognitive-behavioral therapy (CBT) for HIV-related neuropathic pain to supportive psychotherapy, both groups showed reductions in pain and pain-related interference over the course of the trial (56). In patients with osteoarthritis pain, higher doses (20 mg BID) of controlled-release oxycodone reduced pain and interference of pain on mood, sleep, and enjoyment of life as compared to placebo (147). In temporomandibular joint osteoarthritis, glucosamine sulfate and ibuprofen both reduced pain and pain-related interference, with a tendency for the glucosamine sulfate to accomplish greater

improvements (173). In a placebo-controlled crossover study, buroprion sustained release significantly reduced neuropathic pain and pain-related interference ratings after 6 weeks of treatment (156). Patients with Fabry disease showed a significant reduction in pain and pain-related interference in response to enzyme replacement therapy as compared to placebo treatment (154).

Pain Disability Index.

Background. The Pain Disability Index (PDI) was specifically developed to be a brief measure of the degree to which chronic pain interferes with normal role functioning and consistent with the IOMs Committee on Pain, Disability and Illness Behavior's definition of disability (29;171). While most data come from patients with heterogeneous pain conditions (4;41;93;167), the PDI has been used to measure function/disability in a number of specific painful conditions, including low back pain (71-73), post-herpetic neuralgia (78), diabetic neuropathy (53), spinal cord injury (76), and cancer (123;180)

Scale. The PDI includes 7 items assessing perceived disability in each of seven areas of normal role functioning: family/home responsibilities, recreation, social activity, occupation, sexual behavior, self-care (e.g., taking a shower, driving, getting dressed), and life-support activity (e.g., eating, sleeping, breathing). Each item is rated on an 11-point scale (0-no disability to 10-total disability) and the responses are summed.

Early factor analyses of the PDI yielded first a two-factor solution (171) and then a one-factor solution (169). More recent analyses of a large group of patients (N=1361) with heterogenous pain conditions presenting for care at a hospital-based pain clinic support a single factor that accounts for 49% of the variance in items (29). A recent factor analysis of the PDI in combination with multiple other scales found that the last PDI item (life-support activity) did not meet criteria for convergent and discriminant validity and was removed from further analyses (167).

Psychometrics. The PDI shows excellent internal consistency (alpha = 0.85-86; (29;171) and test-retest stability (70;73;171), although a later analysis suggested poorer stability over a 2-month period following an inpatient admission (169).

Validity. As is seen with other measures of physical function, PDI scores correlate with pain intensity (71;73;93), but the moderate level of these correlations indicates only partial overlap (70). Early work with the PDI showed that scores correlated with other indices of physical function, such as the frequency of lying down or staying in bed (168) and nurse ratings of pain behaviors (169). Validation of the PDI has included comparisons with other accepted measures of physical function, such as the Oswestry Disability Questionnaire frequently used to measure function in patients with back pain (142). In addition to correlating with the Oswestry (70), PDI scores showed expected correlations with physical tests of function (72). Total PDI and factor 1 scores (discretionary activities) showed stronger correlations with the Oswestry (r's of 0.83 and 0.84, respectively) than with factor 2 scores (obligatory activities; r=0.41; (70)). As seen with other measures of physical function, response biases may influence responses to the PDI. Social desirability, or the tendency to present oneself in a positive light, correlates with PDI scores only after controlling for depressive symptoms, a factor that often inflates disability ratings (41).

Other correlates of PDI ratings include depressive symptoms (93), work-related factors (29;71;93;170), litigation status (29;170) and medication use (93).

Sensitivity: Pre-Post. The sensitivity of the PDI to the beneficial effects of SCS for treating post-herpetic neuralgia were recently documented in a consecutive case series (78). Twenty three long-term responders to SCS (long-term pain relief with a median rating of 1/10) reported concurrent reductions in pain-related disability (78).

Sensitivity: RTC. Following 7 days of treatment with controlled-release codeine in a placebo-controlled crossover clinical trial, a heterogeneous group of patients with painful conditions reported a significant reduction in pain intensity that was associated with a significant reduction in PDI score(4). Analyses of individual items indicated significant improvements in total PDI and in each area of role functioning, except life-support activities (4). The PDI was also used in a randomized clinical trial evaluating lamotrigine in reducing pain due to diabetic neuropathy (53). While significant reductions in pain intensity occurred following treatment with lamotrigine relative to placebo, no significant effects were observed on the PDI (53), although a preliminary report of the same trial suggested a trend for PDI scores to decline in response to lamotrigine (112). In a small group of patients with pain following a spinal cord injury, topiramate reduced pain ratings after the highest dose (800 mg) was accomplished for 3 weeks, but no concomitant change in PDI score was observed (76).

Sickness Impact Profile and its modifications

Background (countries/languages/conditions). The Sickness Impact Profile (SIP) was originally developed as a behaviorally-based outcome measure of overall health status. It was developed and refined with randomly selected samples of patients with different types of disease, using different assessment methods and interviewers (133). After extensive refinement, the final version includes 136 items in 12 categories of function, yielding 3 summary scores – psychosocial/physical/ other impairment (9). Its earliest applications in chronic pain were to the assessment of function in rheumatoid arthritis (45;46) and chronic low back pain (62;181) and The SIP has been translated into a number of languages, including Swedish (6), Dutch (37), and Spanish (67), although Mexican Americans did not produce clearly valid responses when responding to either the English or the Spanish versions (42). As with some of the other scales reviewed in this paper, the SIP has been used as a standard against which other scales are evaluated (57). The SIP has been used in older patients with pain (57) and in an extremely broad number of painful conditions, including heterogeneous pain conditions (89;124;145), rheumatoid arthritis (45;46;111), osteoarthritis (37), and joint pain (82), low back pain (5;108;183), facial pain (81), and fibromyalgia (26;187).

Scales (description/variations). The SIP includes a list of 136 statements (e.g., “I do not do any of the shopping that I would usually do” or “I do not walk at all”). Respondents mark only those statements that describe the respondent “today” and are related to health, and its instructions are typically changed from “your state of health” to “your pain.” Each statement is weighted and percentage scores for 3 areas are computed as weighted sums: Physical Function (personal care, mobility, and walking), Psychosocial Function (emotions, cognitive function, social interactions, and communication), and Other Function (sleep/rest, household, work, recreation, and eating). A Total score is calculated as a weighted sum of these 3 scales. The distribution of SIP scores can be quite skewed, necessitating transformations to normalize the distribution prior to conducting parametric analyses (e.g., (144)).

Alterations to the SIP: Early in its application, 24 of the original SIP items were developed as a measure of function in back pain by adding the stem to each statement “because of my back pain” - the Roland Morris Disability Scale (142;143). Items were selected based on the likely impact back pain would have on the physical function, however not all items are from the SIP Physical Function scale. Items include assessment of irritability, appetite, and housework. This measure has become one of a select group of standard outcome measures in the back pain literature (43;44). Although primarily used for the assessment of function in low back pain, some investigators have used this shorter scale to assess function in heterogeneous groups of patients seen through multidisciplinary programs (89;90). A later analysis identified 20 items that were most sensitive to change in patients with low back pain, only 7 of which were included in the Roland-Morris scale (105;164). Since this paper will not review in detail such condition-specific measures of physical function, interested readers should refer to a recent review of this measure that provides comprehensive review of the usefulness of the Roland (142).

Psychometrics. The SIP was originally developed and refined on randomly selected group practice enrollees through a series of field trials. Enrollees were selected to represent a range of characteristics and sampling was weighted towards inclusion of the sick and disabled. The internal consistency of the overall score is excellent (alphas in the range of 0.81 to 0.94) and test-retest stability is also good (r's in the range of 0.87 to 0.97; (9)). In a sample of Dutch OA patients, the internal consistency of the SIP Physical Function was reported as good (alpha = 0. 81; (37)).

Validity: General. As is the case with other measures of physical function, the SIP physical function scale correlates with pain intensity ratings (91). Early work with the SIP validated the Physical Function scale against daily activity logs, demonstrating a significant inverse correlation between uptime and SIP physical function score (62). SIP Physical Function scores correlate with clinical ratings of knee function and self-selected walking speed (118) and clinician ratings of physical disability and morning stiffness (37). The SIP Physical Function scale was further validated in a sample of women with RA and found to correlate significantly with a variety of measures of disease activity, joint involvement and joint function (166).

SIP physical function scores show expected increases in community OA patients in comparing groups with sporadic vs. episodic vs. chronic joint pain (82). SIP physical function correlates with depression, particularly somatic symptoms of depression, and moreso than pain severity (81), and abnormal personality profiles are associated with poorer physical function among patients with fibromyalgia (26). Consistent with a behavioral/operant model of pain expression, directly observed attentive responses from spouses to patients' non-verbal expressions of pain are associated with lower physical function in those patients who also report high levels of depressive symptoms (145). And finally, overall SIP scores predicted the transition from acute to chronic pain (55).

Sensitivity: Pre-Post Change. The SIP has been used widely to evaluate function in a variety of different pain conditions and with a range of different types of treatment. Although many of these studies used the total score from the SIP (e.g., (161;162), the Physical Functioning scale does show sensitivity to change across treatments and painful conditions. Early work with a small group of patients participating in a multidisciplinary rehabilitation program demonstrated significant changes in SIP Physical Function following treatment (62), and its sensitivity to change with multidisciplinary rehabilitation has been shown repeatedly since (e.g., (92). Changes in SIP Physical Function scores correlated with changes in pain severity, joint involvement and joint function in a group of women with RA followed over a one-year period (166).

The SIP Physical Function scale was used in an early study evaluating spinal cord stimulation (SCS), although the results were somewhat disappointing (6). In comparing SCS responders to non-responders based on reports of pain relief, no differences were observed on SIP Physical Function scores (6). However, a more recent and systematic evaluation of a group of patients undergoing SCS demonstrated significant improvements in SIP Physical Function one year following implantation (18).

Sensitivity: RTC. The SIP has been widely used in randomized clinical trials of various pain treatments, but many of these studies used the total score rather than subscales (108;126;127;181-184;198) or modified/shortened total scores (47;105;111). SIP Physical Function scores improved in a group of low back pain patients randomized to receive exercises for lumbar extensor muscles as compared to a waiting list control group (140). In the context of no apparent reductions in pain, SIP Physical Function scores also did not improve following biofeedback or fitness training for fibromyalgia patients (187)

In a randomized, crossover placebo-controlled study of opioids, the SIP Physical Function scale did not show any improvements, despite significant pain reduction(124). Similarly, significant changes in SIP Physical Function scores did not coincide with short-term benefits of amitriptyline and cyclobenzaprine in the treatment of fibromyalgia (26) or the pain reducing effects of nortriptyline in low back pain (5).

West Haven-Yale Multidimensional Pain Inventory

Background (countries, languages,conditions). The theoretically driven (174) West Haven-Yale Multidimensional Pain Inventory (WHYMPI; (96) and the slightly expanded version referred to as the Multidimensional Pain Inventory (MPI; (149) have provided an important tool for measuring the experience of pain. Use of this scale has contributed to the extensive knowledge base that has developed over the past two decades of pain research, particularly in understanding the psychosocial aspects of the pain experience. The WHYMPI/MPI has been translated into multiple languages, including Dutch (109;110), Swedish (11), German (61), and Italian (58). It has most widely been used to study non-cancerous, chronically painful conditions, including heterogenous groups (30;96), low back pain (119), headaches (8;107;114;115;117), knee osteoarthritis (68), fibromylagia (48;177), spinal cord injury (197), stroke (196)and recently in burning mouth syndrome (27) and pain due to polio (195). This scale has also been used in evaluating acute pain such as acute temporomandibular joint disorder (TMD; (54)), and is useful in the measurement of pain-related experiences across a broad range of ages (175;196). Despite its length, the WHYMPI/MPI has been applied in epidemiological studies of patients complaining of severe chronic pain in general medical practice (99).

Scales (description, variations). The perceived Interference scale is imbedded in the first section of the instrument, which includes items assessing pain severity, support, life control and affective distress. The perceived **Interference** subscale includes nine items rated on Likert-type scales (0-No to 6-Extreme) of interference (I), change (C), or change in satisfaction (CS) in day-to-day activities (I), work (C;CS), social/recreational activities (C), marriage/family activities (C; CS), household chores (C), friendships (C). Instructions do not include any specific time frame and "In general" precedes the first item (day-to-day activities) and "Since your pain began…" precedes the change in work item. The slightly expanded WHYMPI/MPI Interference scale includes 11 items, including one assessing sleep (I; (149).

A second scale from the WHYMPI/MPI that deserves consideration as a potential measure of pain-related function is the **General Activity** subscale. This scale is in its own section of the instrument and is a compilation of four activity scales (social activities, activities away from home, household chores, and outdoor work). Similar to the perceived Interference subscale, each of 18 items is rated on a Likert-type scale (0-never to 6-very often). Instructions include the following: "Listed below are 18 common daily activities. Please indicate *how often* you do each of these activities by *circling* a number on the scale listed below each activity. Please complete *all* 18 questions." (86).

Factor Structure. Analyses of the factor structure of the WHYMPI/MPI generally confirm the original subscales (12;39;139), even when translated into Dutch (110). A high correlation between pain severity and perceived Interference (165;197) is often seen with the WHYMPI/MPI, possibly due in part to the inclusion of pain-related suffering in the pain severity score, inclusion of a general interference item (In general, how much does your pain interfere with your day-to-day activities?), or item ordering effects (110). A smaller, but still significant correlation is typically seen with General Activities (40;165). But even a more general factor comprising multiple scales of physical function correlate with a pain severity factor also comprised of multiple scales (151), again suggesting a fundamental association between these two constructs. A recent factor analysis of all items from the WHYMPI/MPI found three factors, one of which was titled "suffering" and included items assessing pain severity, perceived interference, and punishing responses from a significant other, but confirmed the General Activity factor previously identified (40). Other work, consistent with the original development of the WHYMPI/MPI, found cross-loading of affective distress on a pain severity/interference factor (39).

Random responding to the WHYMPI/MPI can be detected using a scale derived from items expected to be highly intercorrelated including some items from the perceived Interference subscale (17). However, in some

clinical settings where exaggeration or frank malingering may be of concern, the WHYMPI/MPI, as well as other commonly used psychosocial measures, may be vulnerable to biases (141). Students told to present as someone "coping poorly" score higher on the perceived Interference and lower on the General Activity subscales than students told to present themselves as "coping well" (141).

Although not included in this review, the WHYMPI/MPI has been used to identify subgroups of patients (21;178) that are generally consistent across diseases (e.g., (99;176;180) and that may differentially respond to behavioral and psychological treatments (152;172;176;179), although not in every setting (10;65;100).

Psychometrics. The psychometric properties of this instrument have been examined in a large variety of settings and pain conditions. The psychometric properties of the perceived Interference and General Activity subscales demonstrate good internal consistency (alphas ranging from 0.86-0.90 for Interference and 0.74-0.78 for General Activity) and 2-week stability (test-retest coefficients for 2 weeks ranging from 0.85 to 0.87 for Interference and 0.80 to 0.87 for General Activity; (11;96;110)).

Validity – General. The WHYMPI/MPI is so well respected and widely applied that its subscales often serve as criteria in the validation of new scales (e.g., (48;74;165;186). Validation of these two subscales is provided by an extensive literature from multiple countries and many different types of pain conditions documenting expected relationships with other measures of interference, activity level, disability, and function. An important **construct** validation study used experience sampling methods and daily diaries to examine the relationship between WHYMPI/MPI subscales and daily ratings of pain-related interference and daily activities (109). Eight ratings made each of six days on diary ratings of interference due to pain were highly correlated ($r=0.60$, $p < .001$) with WHYMPI/MPI perceived interference scores. Although diary ratings of household chores correlated with the relevant WHYMPI/MPI subscale ($r=0.40$, $p < .01$), diary recordings of overall activity level did not correlate with the similar WHYMPI/MPI subscale ($r=0.16$, $p > .05$; (109)). Similar results were reported in an earlier German study comparing diary data to WHYMPI/MPI reports (see Flor et al., 1990 reported in (109)). Bicycle ergometer performance correlates with WHYMPI/MI General Activity (110). The moderate correlation between the Interference and General Activity scales has lead some to combine them in a composite score (97). Confirmatory factor analysis of a sample of individuals with post-amputation pain or pain with paraplegia demonstrated a physical functioning factor - WHYMPI/MPI Interference and General Activity scores and SF-36 physical and role functioning scores – that was highly correlated with physical performance outcomes during lifting and wheel turning, as well as pain severity and emotional functioning (151). Improvements in treadmill capacity and reductions in downtime correlated with increases in General Activity in patients with musculoskeletal pain enrolled in a multidisciplinary rehabilitation program (20). Sleep quality is positively correlated with General Activity scores (159).

Further construct validation work using the WHYMPI/MPI has provided important information about the impact of negative moods such as anxiety (52), depression (80;95;150;175;199), and anger (19) on pain-related function, including both Interference and General Activity.

Another important **predictive** validation study demonstrated that WHYMPI/MPI Interference scores reported during a medical consultation for neck pain following a motor vehicle accident were significantly higher in the group of individuals who continued to experience residual pain from the accident one year later (129). The General Activity scores were not significantly different for these individuals, and multivariate analyses indicated that the Interference score was the single effective measure in identifying individuals who report continued pain one year following the initial accident (129). WHYMPI/MPI Interference scores also predict which acute TMD patients will have seek additional treatment for symptom relief in the next 6 months (54)

Sensitivity: Pre-Post Changes. Further validation of the WHYMPI/MPI Interference and General Activity subscales comes from studies that demonstrate change on these measures following treatment for pain. Multiple comprehensive, interdisciplinary pain treatment centers have used the WHYMPI/MPI as a measure of

treatment outcome, demonstrating reductions in Interference (22;30;69;74;95;110;114;119;120;165;200) and increases in General Activity (19;22;94;119;165;200). Specific psychological treatments, such as behavioral treatment of TMD have an impact on Interference ratings (152). WHYMPI/MPI Interference scores declined following interdisciplinary outpatient treatment (177) and following a brief (1.5 day) intensive treatment for fibromyalgia (200). Importantly, the Oswestry scale did not show significant improvement following interdisciplinary outpatient treatment for fibromyalgia when the WHYMPI/MPI Interference scale did (177). However, following effective cognitive-behavioral treatment of fibromyalgia that reduced pain behavior, worry and perceived control, Interference ratings were not reduced and General Activity scores were not increased (128).

Arthroscopic treatment of painful temporomandibular joints reduced Interference ratings (35), whereas laproscopic surgery for chronic pelvic pain increased General Activity (50).

Sensitivity: RTC. The WHMPI Interference and General Activity subscales have been used to evaluate the efficacy of psychological and rehabilitative treatments in a number of chronic pain populations, including heterogeneous samples (98), TMD (60;179), musculoskeletal pain (105;163), chronic back pain (2;60;101), fibromyalgia (100), and phantom limb pain (83). Therapeutic touch differentially reduced Interference and increased General Activity in knee osteoarthritis patients relative to placebo touch and a usual care control group (68). One randomized clinical trial used the WHYMPI/MPI Interference and General Activity subscales to evaluate opioids and tricyclic antidepressants (TCAs) in the treatment of post-herpetic neuralgia (138), and a cross-over trial evaluated the effects of mexilitine on neuropathic pain with allodynia (189). While some of these interventions reduced perceived Interference (2;60;101;115), others did not demonstrate expected reductions in Interference scores with active treatment relative to an appropriate control (83;113;138;179). No study demonstrated a treatment effect on the WHYMPI/MPI General Activity subscale (101;138;163). The mexilitine trial was largely negative and results for Interference and General Activity were not reported (189).

Recommendations Regarding the Assessment of Pain-related Function

Based on this review it is recommended that the two WHYMPI/MPI scales - Interference and General Activity - be used as standard measures of pain-related physical function in future clinical trials. These scales are widely used, translated into multiple languages, have excellent psychometric properties, are convenient in terms of length and scoring, have a strong empirical foundation, and are sensitive to change. One caveat to consider is the potential change in properties that may occur when the WHYMPI/MPI Interference scale is removed from its original context. If resources are available, it is also recommended that the BPI Interference scale be included in the assessment to provide an accumulation of data on these scales so that they can be compared with respect to sensitivity. The SIP Physical Function scale is not recommended due to its length, its complex scoring requirements, the fact that it is embedded in a larger scale, and the “Other Function” scale includes important dimensions of physical function included in the other scales (e.g., sleep). The PDI is not recommended primarily because there are not as many data demonstrating either the validity or the sensitivity of this scale.

Measures of Sleep

High rates of sleep disturbance are noted among samples of patients with chronically painful conditions (79;159). Standardized measures of sleep used in the sleep literature, such as the Pittsburgh Sleep Quality Index (PSQI; (33;122;159) and sleep diaries (34;79), are not frequently used in the assessment of sleep disturbance in chronic pain, particularly the treatment outcome literature. Ratings more frequently focus on the extent to which pain interfered with sleep, either in diary form (7;148) or as part of the overall assessment of physical function using the scales described above, each of which does include some assessment of sleep (18;29;31;149). Single item sleep disturbance ratings are also used, and vary from using a 10 cm VAS (1;194) to an 11-point numerical rating (13;59).

Sensitivity. Two studies using sleep diaries found beneficial effects of pain treatment on sleep (7;148), as did one that used the SIP to evaluate SCS implantation (18) and one that used a single quality of sleep rating (194) or sleep interference (1). Cognitive-behavioral treatment of insomnia secondary to chronic pain improved an array of sleep measures, including diary measures of sleep onset latency, sleep efficiency, and minutes awake after sleep onset as well as overall sleep quality ratings (34).

Despite successful reduction in phantom limb pain with gabapentin, a single sleep interference rating did not show any significant change (13). A more extensive assessment of sleep quality in patients with diabetic neuropathy, including ratings of quantity of sleep, sleep adequacy, sleep disturbance, and somnolence, did not change in response to tramadol, which was effective in reducing pain and improving some areas of quality of life (75).

Recommendation Regarding the Assessment of Sleep

Based on these studies and current standards used in the sleep literature (158), it is recommended that investigators use both a sleep diary – either a single item (148) or a more complete assessment (79) – and the Pittsburgh Sleep Quality Index as a summary measure of overall sleep quality (23).

Recommendations for Future Work

As already mentioned, future studies need to include more than one measure of pain-related physical function – e.g., the WHYMPI/MPI Interference scale and the BPI Interference scale – so that comparisons are possible and the accumulation of knowledge and experience with these measures continues. There are few data comparing different measures in their ability to detect changes in response to effective pain treatments, so systematic use of multiple scales across trials will provide a valuable database for refining measurement of pain-related physical function. It is also recommended that the content of the General Activity scale be further investigated and developed so as to include activities common in modern times (e.g., work on a computer, talk on the telephone, work on a hobby, go shopping or to a mall, exercise or play sports, work on financial paperwork, work as a volunteer, go to church, attend classes, read a newspaper or magazine). And finally, the reliance on self-report remains a major challenge for the assessment of pain-related physical function. Measures of functional ability have been developed in many areas (e.g., for use in epidemiological studies of the elderly (130)). Unfortunately such measures, like walking speed, may not be affected by many pain conditions and are more appropriately applied within specific painful conditions (e.g., low back pain). However, this challenge needs to be addressed in future studies.

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