Measurement instruments of pain-related avoidance in chronic pain: A systematic review of psychometric properties

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Abstract

Avoiding harmful events is adaptive in the short term but eventually may compromise functioning in daily life. Therefore, assessing pain-related avoidance is important in both pain research and treatment. Despite a variety of available measurement instruments, a systematic analysis of their quality and limitations is lacking. We evaluated the measurement properties of instruments used to assess pain-related avoidance in individuals with chronic pain. A systematic review following COSMIN guidelines was conducted (PROSPERO registration: CRD42020181461), including an electronic search of Cochrane, PsycArticles, PubMed, PubPsych, Scopus, and Web of Science as well as grey literature from inception to January 2024. Eligible studies were English, German, or French publications that explicitly claimed to evaluate one or more psychometric properties of measurement instruments assessing pain-related avoidance in adults with chronic pain. Of 703 screened records, 140 original articles were included, covering 20 self-reported questionnaires, one therapist-reported outcome measure, and one performance-based measure. Based on the current evidence, only the Brazilian Portuguese language version of the Chronic Pain Coping Inventory (CPCI) and the Italian version of the CPCI-42 fulfilled criteria to be recommended for use. While the commonly used Fear-Avoidance Beliefs Questionnaire and Tampa Scale of Kinesiophobia were the most extensively studied, the study quality was mixed. The review further highlights extensive research on internal consistency, reliability, and construct validity but reveals a lack of high-quality evidence on measurement error and criterion validity. This work was supported by funding from the Flemish Government (METH/15/011).

Introduction

Pain avoidance is a common and adaptive response to aversive stimuli. Avoidance has been described as "the most prominent component of pain behavior" ([148], p. 274) and occurs in many different forms, ranging from painful movement, activities and daily mobility over housework and work-related contexts to social life [148]. Despite being adaptive, avoidance frequently becomes persistent, even habitual, beyond the regular recovery period. It then may interfere with daily functioning, may lead to withdrawal from valued activities and social life, and may have a detrimental impact on quality of life [3; 149; 153]. Hence, persistent pain-related avoidance behavior is considered maladaptive [107] and according to the Fear Avoidance Model (FAM [201]) contributes to depression, negative affect and, in the long-term, to the transition to chronic pain.

Avoidance can be broadly defined as the prevention of an aversive experience, including the worsening of that experience (e.g., not lifting objects anymore) [176]. It needs to be distinguished from *escape behaviors*, which terminate exposure to the aversive stimulus or situation (e.g., ending a task prematurely because of pain increase), and from *safety behaviors*, referring to actions performed to prevent or minimize harm while enduring the aversive situation (e.g. continuing a task with a supportive device or person) [150].

A variety of questionnaires (e.g., [58; 205]) and behavioral tasks (e.g., [72; 119]) to assess avoidance behavior have been employed in research. However, these instruments have not yet been systematically evaluated and compared, particularly in the light of the challenges associated with measuring avoidance. One challenge is that avoidance can be subtle and may often occur without conscious awareness, making it difficult for individuals to accurately report on it. Additionally, behavioral tasks designed to elicit or model pain-related avoidance may not adequately mimic natural circumstances and may overlook contextual factors. Notwithstanding, accurately measuring avoidance remains highly relevant both for research aimed at understanding the mechanisms underlying avoidance in chronic pain, and for clinical practice aimed at reversing the disabling effects of pain by specifically targeting individual avoidance behavior [37]. These complexities underscore the need for careful deliberation when selecting measurement instruments for assessing pain-related avoidance behavior. Vlaeyen and Linton [202] called for sound assessment techniques for escape and avoidance behavior. Although new instruments have emerged since (e.g., [22; 72]), no attempts have been made to evaluate them systematically. This systematic review identifies available measurement instruments assessing avoidance in adults with chronic pain, and critically appraises their psychometric properties. The goal is to assist researchers and clinicians in choosing an appropriate measurement instrument of pain-related avoidance.

Methods

A systematic literature search for instruments designed to measure pain-related avoidance behavior was conducted. It was conducted and reported according to a protocol registered and published on the International Prospective Register of Systematic Reviews (PROSPERO; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=181461, registration number: CRD42020181461) prior to the formal screening of the search results. For reasons of feasibility, the inclusion criteria have been further refined, and the study population has been limited to persons with chronic pain after the initial search (all amendments have been registered in PROSPERO). The updated COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN; [126]) guidelines for systematic reviews of patient-reported outcome measures was used and the PRISMA-COSMIN reporting guideline [49] was followed. The COSMIN framework is used for evaluative purposes (for an overview and comparison of this and other frameworks, see [109; 167]).

Search Strategy & Eligibility Criteria

The databases searched included Cochrane, PsycArticles, PubMed, PubPsych, Scopus, and Web of Science, without restriction by publication period. The searches were conducted in April and June 2020 and were re-run prior to the final analysis in January 2024.

The search strategy is described in detail in Appendix A. The search categories *avoidance behavior*, *pain*, and *psychometric properties* were combined, while filtering out animal, pharmacological, and pediatric population studies. Articles were eligible if they (a) reported on the development, or on one or more psychometric properties of at least one measurement instrument of pain-related avoidance behavior; (b) studied an adult human population (> 18 years) with chronic pain, except for headaches, migraine, and cancer pain; (c) were written in English, French or German, and (d) were available in full-text. Exclusion criteria comprised: (a) reviews and meta-analyses; (b) conceptual and narrative papers discussing pain-related avoidance behavior without adding significant information on measurement properties; (c) studies that used the instrument purely as an outcome measure [151]; (d) pharmacological studies. A post hoc decision was made to exclude studies that exclusively focused on avoidance in headache/migraine due to feasibility and the different types of triggers involved in these pain conditions.

Preliminary searches were conducted by JT to establish the need for and timeliness of a review on this topic, and to determine the study selection process, which was piloted subsequently. References and citing references of included studies were manually searched. After duplicate removal, titles and abstracts from the definite database search were screened for their eligibility by two independent reviewers (AW and RVP). In case of disagreement between the reviewers, a third reviewer (JT) was consulted to reach a final decision. Next, the full texts were screened. If full texts could not be retrieved, study authors were contacted (n = 3). An expert panel was consulted to ensure that all relevant instruments were included.

Data Extraction

One reviewer (JT) extracted the following information from the included studies: author(s) and year of publication, study population and demographics, pain characteristics, and characteristics and psychometric properties of measurement instruments. Data were extracted onto a bespoke data extraction table. A second reviewer (CK, EG) cross-checked the accuracy of the extracted information of a random 50% of included records, stratified for each instrument. Disagreements were resolved through discussion. Data extracted from included studies and used for all analyses can be found in Tables 1 and 2 and Appendix E.

Evaluation of Measurement Properties and Risk of Bias Assessment

The measurement properties of self-report instruments were evaluated according to the guidelines by [151] for systematic reviews of patient-reported outcome measures (PROMs) consisting of three steps: first, the methodological quality of individual studies was appraised for each measurement separately based on the COSMIN Risk of Bias checklist [1] using a four-point rating system (very good, adequate, doubtful, inadequate). The "worst score counts" principle was applied [187]. Next, the psychometric properties of measurements instruments reported in each included study were rated as sufficient (+), insufficient (-) or indeterminate (?) using the COSMIN updated criteria for good measurement properties ([186], see Table 3). These steps were first applied by two independent reviewers (JT, CK) to evaluate content validity. In case of disagreements, consensus was reached through discussion. Subsequently, following the steps described, one reviewer (JT) assessed the internal structure of the PROMs (i.e., structural validity, internal consistency, cross-cultural validity) – for which a reflective measurement model was assumed, unless otherwise specified in the instrument development paper - and the remaining measurement properties test-retest reliability, measurement error, criterion validity, hypothesis testing for construct validity, and responsiveness to change [125]. Twenty percent of these assessments were cross-checked by an independent reviewer (EG).

Criterion validity is tested by comparing an instrument to a criterion measure that is known to accurately assess the construct of interest. According to COSMIN, the gold standard should be used but this does not exist for PROMs, except if a shortened version is compared to the original instrument. Comparisons to, for instance, other widely used instruments are considered hypothesis testing for construct validity [125]. Given both the variety in the included PROMs and the large variability in study designs, we did not define global a priori hypotheses against which all study results would be compared to evaluate construct validity and responsiveness to change but instead followed the approach of [76]. We extracted hypotheses relating to these measurement properties from the articles or, if the authors had not specified a priori hypotheses, we deduced hypotheses from the authors' descriptions (Appendix B and C). This approach was slightly modified for use with performance-based outcomes measures [77].

[insert Table 3 here]

Data Synthesis

Evidence from multiple studies on the same measurement instrument was summarized per measurement property. A qualitative synthesis of the evidence per psychometric property was performed for each measurement instrument by one reviewer, resulting in a rating of sufficient (+), insufficient (-), inconsistent (±) or indeterminate (?), and graded following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach: quality of evidence was down-graded due to risk of bias, inconsistency, imprecision, and/or indirectness, resulting in "high", "moderate", "low" or "very low" quality [151]. When results of studies on the same measurement instrument were inconsistent, sources for inconsistency such as differences in populations were explored. When inconsistency could not be explained, results were summarized based on the consistent majority findings, if possible, or rated as inconsistent (±) without summarizing. Based on the evaluation of measurement properties, recommendations for the use of instruments assessing pain-related avoidance behavior were formulated according to the guidelines by [151] by sorting each PROM into one of three categories:

A: PROM can be recommended for use [evidence for sufficient content validity (any level), and at least low-quality evidence for sufficient structural validity and internal consistency];

B: PROM has potential to be recommended for use, but further validation is needed (PROM cannot be categorized into A or C);

C: PROM should not be recommended for use (high-quality evidence for insufficient measurement criteria).

Results

The database search and the manual search identified 658 and 182 articles, respectively. After removing 170 duplicates, 669 records were screened, of which 303 were excluded and 366 records were retrieved. Of these, 227 records were ineligible (for a list of excluded records with reasons for exclusion according to the inclusion criteria, see Appendix D): 5 records could not be retrieved, 151 did not report data on psychometric properties of relevant instruments, 24 were not original articles, 27 addressed a different target group, 13 did not address avoidance, and 6 were published in a language other than English, French, or German. A flow chart illustrating the selection of articles is presented in Figure 1.

The 140 eligible articles comprised 20 different PROMs [Table 1; Avoidance Daily Activities Photo Scale (ADAP; n = 2); Avoidance-Endurance Questionnaire (AEQ; n = 3); Activity Patterns Scale (APS; n = 1); Burn Survivor Fear-Avoidance Questionnaire (BSFAQ;

n = 1); Catastrophizing Avoidance Scale D-65+ (CAS-D-65+; n = 1); Chronic Pain Coping Inventory (CPCI; n = 7); Fear-Avoidance Beliefs Questionnaire (FABQ; n = 50); Fear-Avoidance Components Scale (FACS; n = 9); Negative Responsivity to Pain Scale (NRP; n = 1); Pain and Activity Relations Questionnaire (PARQ; n = 1); Pain Anxiety Symptoms Scale (PASS; n = 2); Pain-Coping Inventory (PCI; n = 1); Psychological Inflexibility in Pain Scale (PIPS; n = 7); Patterns of Activity Measure - Pain (POAM-P; n = 2); Tampa Scale of Kinesiophobia (TSK; n = 32); Tampa Scale of Kinesiophobia-Temporomandibular Disorders (TSK-TMD; n = 4)], four abbreviated versions of original PROMs [Table 1; CPCI-42 (n = 6); PASS-20 (n = 5); TSK-11 (n = 15); TSK-13 (n = 5)], and two behavioral measures [Table 2; Behavioral Avoidance Test-Back (BAT-Back; n = 2); clinician-reported fear avoidance beliefs (n = 1)], with some studies investigating more than one instrument. The studies investigated content validity (n = 37), structural validity (n = 59), internal consistency (n = 99), test-retest reliability (n = 85), measurement error (n = 27), criterion validity (n = 4), construct validity (hypothesis testing; n = 113), and responsiveness to change (n = 24). In the following, results will be described only for the original language version of each instrument and notable differences with other language versions will be pointed out. Characteristics of the included measurement instruments are displayed in Tables 1 and 2, respectively. Individual study characteristics are presented in Table 4. The risk of bias assessments and rating against measurement properties of included studies can be found in Tables 5 (content validity) and 6 (all other measurement properties); the evidence synthesis including rating of results and overall level of evidence are shown in Table 7. Figure 2 shows the number of studies investigating each of the measurement properties, including the risk of bias (RoB) ratings.

[please insert Figure 1 here]

[please insert Figure 2 here]

[please insert Table 1 here]

[please insert Table 2 here]

[please insert Table 4 here]

Content validity

Quality of PROM development studies

Table 5 provides an overview of the overall results and quality of the 16 available development studies and the content validity studies. As no patients were involved in the development process, concept elicitation was judged to be inadequate for all PROMs, except for the Avoidance Daily Activities Photo scale (ADAP) [8]. The concept elicitation of the ADAP was described superficially and resulted in a "doubtful" rating. Furthermore, only the development studies of APS, FACS, PIPS and TSK-TMD included cognitive interviews with patients. The process for PIPS was deemed inadequate because too few patients were involved. The quality of cognitive interviews for APS and TSK-TMD was doubtful since relevant information was not reported in the papers. For instance, information on whether interviews were based on appropriate guides and recorded and if at least two researchers were involved in the analysis was not presented. The cognitive interview for FACS was of doubtful quality as it was purely based on a quantitative approach. No development studies could be retrieved for BSFAQ, PCI, TSK, or TSK-13.

Quality and results of content validity studies

The 37 articles on content validity comprised 35 studies involving patients, of which all assessed comprehensibility, five additionally addressed relevance, and none examined comprehensiveness, and ten studies involving professionals, of which nine assessed relevance and five assessed comprehensiveness. Thirty-two were cross-cultural adaptations that pretested the translated PROM. One study [135] was of inadequate quality as the method asking patients about the relevance of the FACS was inappropriate; the quality of all other studies was deemed doubtful as relevant information was not reported. No content validity studies on AEQ, BSFAQ, CAS-D-65+, NRP, PARQ, PASS, PCI, and TSK-13 were found.

Evidence synthesis

Overall, no high-quality evidence on content validity was available for any of the instruments. For CAS-D-65+, the quality of evidence for indeterminate results was “moderate” based on the reviewers’ ratings and the development study. For TSK, the quality of evidence for sufficient content validity was “moderate” based on the reviewers’ ratings and content validity studies.

There was “low” evidence for sufficient relevance for ADAP, CPCI, CPCI-42, PCI, and TSK-TMD. The quality of evidence for relevance was “very low” for all other instruments, often because the rating was solely based on reviewers’ ratings [26]. Regarding comprehensiveness, quality of evidence was “moderate” for FABQ and TSK with sufficient results based on the reviewers’ ratings and content validity studies. For all other instruments, quality of evidence for comprehensiveness was “very low”. Lastly, there was “moderate” quality evidence for sufficient comprehensibility for FABQ, FACS, PASS-20, PAOM-P, TSK, TSK-11, and TSK-TMD, “low” quality evidence for sufficient comprehensibility for ADAP, APS, CPCI, and CPCI-42, and “very low” quality evidence for sufficient comprehensibility for AEQ, PARQ, PASS, and PCI. “Very low” evidence pointed to inconsistent results for CAS-D-65+ and NRP, and to indeterminate results for PIPS.

As no high-quality evidence supporting insufficient content validity was found for any of the PROMs, the other psychometric properties were assessed.

[please insert Table 5 here]

Structural validity

Eighty studies assessed structural validity of the included PROMs in persons with chronic pain. Most of the studies (40%) were of very good quality, 41.25% were of adequate quality, 5% of doubtful quality, and 13.75% of inadequate quality. Inadequate ratings were mostly due to small sample sizes.

Sufficient structural validity was found for APS, NRP, PIPS (all language versions except Greek), TSK-TMD, the Brazilian Portuguese and French versions of CPCI, the English version of CPCI-42, the Dutch and German versions of TSK-11, and the Serbian version of FACS (all high evidence), the Dutch version of the TSK-13 and the Italian version of the CPCI-42 (both moderate evidence). There was high quality evidence for insufficient structural validity for the PASS-20, TSK (English, Dutch), TSK-11 (English, Swedish), TSK-13, and for the Swiss-German and Chinese versions of the FABQ. Lastly, structural validity was indeterminate for TSK (high quality evidence), ADAP, FABQ, FACS and PARQ (moderate evidence), and AEQ and PCI (low to very low evidence). No studies were retrieved that tested structural validity of BSFAQ, CAS-D-65+, PASS, PCI, or POAM-P.

Internal consistency

One hundred-eleven studies assessed internal consistency, covering all the included PROMs, except for BSFAQ. The vast majority of studies (90.09%) were of very good quality, while the quality of 11 studies (9.91%) was rated as inadequate because they did not calculate an internal consistency statistic for each unidimensional (sub)scale separately.

Internal consistency was sufficient for CPCI-42, NRP, PIPS, TSK-TMD and the Dutch version of the TSK-13 (all high evidence). High quality evidence was found for insufficient internal consistency for the Dutch and German versions of TSK-11 and the Dutch and Italian versions of TSK. For APS, internal consistency was considered inconsistent as the two available high-quality studies in one publication [51] found contrasting results, despite comparable samples. For all other PROMs, internal consistency was rated indeterminate as the prerequisite of at least low-quality evidence for sufficient structural validity was not met, even if Cronbach's alpha > 0.7.

Reliability

Eighty-five studies assessed test-retest reliability of most PROMs. There is no information on test-retest reliability available for the APS, BSFAQ, PARQ and PASS. Only two studies (2.35%) were of very good quality, 16.47% were of adequate quality while 63.53% were of doubtful and 17.65% of inadequate quality. Poor quality ratings were mostly due to inappropriate time intervals and uncertainty about whether patients were stable in the interim period and/or whether test conditions were similar at both measurement time points.

Reliability was deemed sufficient for TSK-11 (high evidence), CPCI-42, FABQ, TSK (all moderate evidence), ADAP, PASS-20, POAM-P (French version; all low evidence), and CAS-D-65+ (very low evidence). For CPCI, FACS, NRP, PCI, and TSK-TMD, test-retest reliability was considered indeterminate.

Measurement error

Twenty-seven studies assessed measurement error of ADAP, AEQ, FABQ, FACS, TSK, TSK-11, TSK-13 and TSK-TMD. Of these, two studies each (7.41%) were of very good [48; 127] and adequate [16; 81] quality, 70.37% were of doubtful quality and the remaining studies (14.81%) were of inadequate quality. Again, poor quality ratings can be ascribed to uncertainty about or dissimilarity between test conditions for the measurements in all of these studies, and the uncertainty about whether patients were stable in the interim period.

One study provided high [127] and low [128] quality evidence, respectively, for sufficient measurement error for the Italian version of the TSK. Two studies provided low evidence for insufficient measurement error for the Igbo version of the FABQ [74] and the Dutch version of the TSK [155]. In all other cases, measurement error was rated as indeterminate because none of the studies defined the minimal important change.

Criterion validity

Four studies assessed criterion validity of CPCI-42 [166], FABQ [80], PASS-20 [113] and TSK-11 [174]. Evidence for FABQ was indeterminate, while high quality evidence for sufficient criterion validity was found for the other three instruments.

Hypothesis testing for construct validity

Construct validity via hypothesis testing (convergent validity) was assessed in 111 studies for all instruments. 14.41% were of very good quality, 26.13% were of adequate quality, 13.51% were of doubtful quality, and 45.95% of studies were of inadequate quality. Known-groups validity was assessed in 18 studies for AEQ, BSFAQ, FABQ, FACS, PCI, TSK, and TSK-11. 33.33% of studies were of very good quality, 16.67% were of adequate quality, 38.89% were of doubtful quality, and 11.11% were of inadequate quality. Insufficient description of important characteristics of the subgroups accounted for most of the low-quality ratings (doubtful, inadequate).

Convergent validity and known-groups validity coupled together, there was high quality evidence for sufficient construct validity for the English language versions of CPCI and TSK. For most other instruments, more than 75% of hypotheses were confirmed as well but at lower quality evidence levels. Construct validity was insufficient with moderate to high-quality evidence for FABQ (Greek), TSK (Gujarati), and TSK-11 (Brazilian Portuguese, Chinese, Spanish), and with low to very low-quality evidence for ADAP, CPCI-42 (Korean), FABQ (Dutch, Gujarati, Hausa, Igbo, Marathi, Swedish, Swiss-German, and Yoruba language versions), PASS (Dutch), and TSK-13. It was inconsistent for TSK-11 (moderate evidence). Lastly, construct validity was indeterminate for FABQ (Arab, English, and Hindi language versions), and TSK-TMD (Chinese and Dutch language version).

Responsiveness to change

Responsiveness to change was assessed in 25 studies for CPCI-42, FABQ, FACS, POAM-P, TSK, and TSK-11, some of which used more than one approach. 28.21% of studies were of very good quality, 10.26% were of adequate quality, 30.77% were of doubtful quality, and 30.77% were of inadequate quality.

Responsiveness to change was deemed sufficient for CPCI and CPCI-42 (very low evidence), and FABQ, TSK (English and Italian versions) and TSK-11 (high quality evidence). However, results were not in line with at least 70% of a priori hypotheses for other language versions of the FABQ (Brazilian Portuguese, Chinese, Greek, Turkish), FACS, the Dutch version of the TSK, TSK-11 (Brazilian Portuguese), and TSK-13 (Portuguese version), indicating low responsiveness to change. Lastly, there was very low evidence for indeterminate responsiveness to change for POAM-P.

[please insert Table 6 here]

[please insert Table 7 here]

Recommendations

Only the Brazilian Portuguese language version of the CPCI and the Italian version of the CPCI-42 fulfilled all criteria of category A to be recommended for use. Importantly, these scales do not include an avoidance subscale but two subscales called "resting" and "guarding", which were considered here. Based on the current evidence, the Chinese, Gujarati and Swiss-German versions of the FABQ, the Chinese version of the PASS-20, the Greek version of the PIPS, the Chinese, Dutch and Italian versions of the TSK, the English, Dutch, German and Swedish versions of the TSK-11 and the English version of the TSK-13 cannot be recommended due to high-quality evidence for insufficient structural validity and/or internal consistency (category C). All other instruments and language versions have the potential to be recommended for use, pending further validation (category B): While several language versions of APS, CPCI-42, FACS, NRP, PIPS, TSK-13 and TSK-TMD performed well in terms of most psychometric properties, their content validity could not clearly be classified as sufficient and requires further assessment.

Non-validated measures of avoidance behavior

In addition to the self-report instruments described above, a plethora of instruments are used to measure pain-related avoidance in research that have not been formally validated according to classic test theory, and thus did not meet the inclusion criteria of this review. These comprise predominantly behavioral tasks, most of which operationalize avoidance in terms of response rate [11; 82; 195] or repetitions of certain movements [147]. Other instruments assess avoidance by measuring the willingness to repeat a painful task, such as the cold-pressor test [28] or an ischemic pain task [41]. Moreover, response latency (e.g., Voluntary Joystick Movement paradigm [120]), overall task duration [82], range of motion [147] or the deviation from a painful movement as used in the HapticMaster paradigm [119] are means of measuring avoidance. Lastly, rather than avoidance of painful movements or experimental pain stimuli, the Approach Avoidance Task [137] is based on pain-related images that can be avoided by zooming out. Although none of these tasks have been psychometrically validated yet, evidence of construct validity is often reported, and they bear great potential as most of them do not rely on self-report and have a comparatively high ecological validity due to their use of actual movements. Notwithstanding, many of these paradigms bear different limitations. As stated by Meulders et al. [118], the tasks rely on dichotomous responses or examine adaptive and/or low-cost avoidance which may ultimately limit their utility.

Proxy measures of pain-related avoidance

The expert panel suggested several instruments for potential inclusion in this review, including the Acceptance and Action Questionnaire II – Pain Version (AAQ-II-P) [159], the Coping Strategies Questionnaire (CSQ) [168], the Chronic Pain Acceptance Questionnaire (CPAQ) and its revised version (CPAQ-R) [115], the Pain and Impairment Relationship Scale (PAIRS) [160], and the Pain Interference Index (PII) [85]. However, after careful deliberation, these instruments were excluded as they primarily measure related yet distinct constructs: experiential avoidance (AAQ-II-P), acceptance (CPAQ, CPAQ-R), coping (CSQ), or interference (PII; assessing the extent to which pain has made certain activities difficult) rather than avoidance behavior per se. The PAIRS includes some items that could arguably reflect aspects of avoidance; however, to our knowledge, it has not been specifically utilized for this purpose. Additionally, apart from the AAQ-II-P and the CSQ, none of these instruments were identified in the literature search.

Several other instruments used as proxy measures should be highlighted as well: The Photograph Series of Daily Activities (PHODA; [98]) and its shortened electronic version (PHODA-SeV; [108]) primarily examine the perceived harmfulness of daily activities and movements as shown in a set of photographs. The German scale Ältere Menschen in körperlicher Aktion (eng.: "Elderly people in physical action", AMIKA [156]) and its short 8-

item version, AMIKA-K [158], are based on the PHODA but adapted for use in people aged 65 and older with low back pain. Similarly, the Pictorial Fear of Activity Scale-Cervical (PFActS-C; [193]) uses photographs of various activities that specifically strain the neck to assess a person's worry or fearfulness about carrying out the displayed activities.

While these measurement instruments are occasionally used as proxy measures for avoidance and the instructions could be adjusted for this purpose, they do not explicitly target avoidance behavior. To maintain a focused and feasible scope, the review was narrowed to instruments specifically designed to measure avoidance.

Discussion

The purpose of this review was to systematically evaluate and compare the quality of instruments used to measure pain-related avoidance behavior, with the aim of providing recommendations for their use in evaluative clinical and research settings. Given that measurement properties may greatly affect study results, the use of high-quality instruments is pivotal to ensure reliable conclusions in both research and treatment contexts. To achieve trustworthy results, this review followed the COSMIN guidelines for systematic reviews. While two recent COSMIN reviews have been conducted on the measurement properties of specific instruments assessing pain-related avoidance – the TSK [47] and the cross-culturally adapted versions of the TSK-11 [7] – this is, to our knowledge, the first comprehensive COSMIN review of all available validated instruments addressing pain-related avoidance.

We identified 21 versions of 16 unique instruments. Of these, only the Brazilian Portuguese language version of the Chronic Pain Coping Inventory (CPCI) [179; 180] and the Italian version of the CPCI-42 [130] show sufficient content validity, structural validity, and internal consistency [151] and can be recommended for use based on the evidence currently available. However, it should be noted that these recommendations are based on just two and one publication, respectively. Although according to the COSMIN guidelines, a single high-quality study is sufficient to rate psychometric properties, a low number of publications means a lower chance for inconsistent findings compared to well-studied instruments like the FABQ or TSK. While some of the other instruments show insufficient structural validity and/or internal consistency and, therefore, cannot be recommended for use, most instruments require further validation with respect to their content and structural validity before they can be recommended or advised against.

As content validity is considered the most important measurement property [152], the lack of adequate evidence across instruments is concerning. In fact, content validity has been examined in most PROMs to some degree; however, most development studies did not include people with lived experience (PWLE) of pain in PROM development or the concept elicitation. Many PROM developments did not include a cognitive interview. The relevance, comprehensibility and especially comprehensiveness were often not investigated. It is, therefore, highly recommended to adhere to modern standards and include PWLE for the development of new instruments, to continue testing relevance, comprehensiveness, and comprehensibility in existing PROMs, and to update and improve instruments, if necessary.

Apart from content validity, the most frequently reported psychometric properties include internal consistency, reliability, and construct validity, whereas measurement error, responsiveness to change and criterion validity – according to the gold standard approach by COSMIN – received little attention. Importantly, quality of evidence was mixed, largely due to shortcomings in reporting, e.g. a lack of information about whether patients were stable in the interim period and/or whether test conditions were similar at both measurement time points (test-retest reliability, measurement error), or an insufficient description of subgroup characteristics (known-groups validity) or of the intervention used in responsiveness to change studies.

We would like to highlight some general challenges associated with measuring pain-related avoidance behavior, which may affect the validity and reliability of measurement instruments. First, avoidance is not necessarily a conscious behavior and can be subtle, so that people may lack insight. Second, an additional common problem of self-report is recall bias, as people may fail to correctly reproduce the degree of and circumstances under which they engage in avoidance behavior. Third, patients may be reluctant to report on avoidance behaviors for fear of stigmatization and instead give socially desirable answers. These problems complicate the use of self-report instruments to reliably measure avoidance behavior [204]. Most behavioral tasks, on the other hand, do not adequately reflect everyday life. They usually constitute a comparatively safe, predictable, and controllable context, often employ a simple operationalization of avoidance [95; 118] and tend to disregard competing motivations [202]. Research in people living with chronic pain [50; 84; 143] and pain-free participants [29-31; 195] demonstrated that goals and competing motivations can attenuate avoidance, even when pain-related fear remains high. People living with chronic pain may have reasons to avoid a movement, posture or activity in their daily life but not in the clinic, and vice versa. For example, holding an arm overhead to hold on to a grab handle on the bus that may stop abruptly is more consequential and more likely to be perceived as threatening than performing the same movement in isolation on a stable office floor. Conversely, a patient may be reluctant to lift a heavy object as part of a clinical assessment, which bears low intrinsic value, but not hesitate to pick up their grandchild. Furthermore, avoidance may be influenced by mood states [83; 203] and, thus, fluctuate over time [205]. The dynamics of avoidance behavior are also well demonstrated from the perspective of the exploitation-exploration trade-off [96] and Pavlovian-Instrumental Transfer literature [97]. These findings suggest that assessment of avoidance behavior in one specific context or even in a decontextualized way using one of the recommended questionnaires may not capture an accurate picture of a person's pain avoidance behavior. Alternatives to these assessments are observations of patients' avoidance behavior in everyday life. As this is usually not feasible for clinicians and researchers alike, avoidance can be measured in real life using ecological momentary assessment (EMA; see e.g. [178]). The advantages of this methodology are that a person's behavior is assessed repeatedly in real-time and in the person's natural environment, thus minimizing recall bias [57]. Hence, EMA offers a highly flexible and ecologically valid approach, although the challenges of lack of insight and potential reluctance to report avoidance remain. Considering the shortcomings of each approach, we recommend keeping these limitations of even well-validated self-report instruments in mind and basing clinical decisions not on a single measurement but using different types of assessment and sources of information where possible. One should also keep in mind that self-reports may only provide valid information in the context of a non-stigmatizing, trusting and empathic relationship.

Several limitations related to both the evidence included in this review and the review process warrant attention. First, several of the included studies were of questionable or insufficient quality, often due to poor or unclear reporting, resulting in low-quality evidence or inconclusive findings. Importantly, although not all studies specified the medium through which the PROMs were completed (e.g. paper-based vs. digital formats), it is likely that most were administered in a paper-based format. Therefore, future research should also assess the validity and reliability of computerized versions of these instruments [108]. Second, aside from the FABQ, the TSK and the TSK-11, most measurement instruments have been translated and culturally adapted into only few or no non-Western languages. This lack of translation limits research and clinical attention to avoidance behaviors in diverse populations across the globe. Third, we noted that psychometric terminology is often used incorrectly in the literature, which may be misleading for readers. Consequently, we recommend further research into the psychometric properties of measurement instruments of pain-related avoidance using terminology and frameworks consistently and encourage efforts to translate and validate more instruments in other languages, in particular, in African and Asian languages. As a side note, the included studies almost exclusively used Cronbach's alpha to measure internal consistency. Although this is the most common approach, the use of this measure has been criticized because the assumptions are often not met, and alternatives such as McDonald's omega have been proposed [117].

Regarding the review process itself, we only included studies that specifically aimed at testing one or multiple instruments' psychometric properties. Many other empirical studies provide information on internal consistency and construct validity. As reviewing and integrating all these records was not possible, this review should be considered a start that can be built upon. Similarly, for feasibility reasons, only one reviewer conducted the risk of bias and measurement property assessments, with an independent cross-check of a subset of publications by one of two researchers. While no frequent or systematic mistakes were identified in the randomly selected subset, we acknowledge that a small risk for error may remain. Moreover, we used the "worst score counts" method, adhering to the COSMIN guidelines. This may not sufficiently distinguish between subtle differences in the methodological quality of the included studies [181]. As highlighted above, the number of publications available for each individual instrument and language version may have influenced the recommendations for use. Both recommended instruments as well as most of those that could explicitly not be recommended were supported by evidence from only one or two studies. The instruments categorized as needing further validation were often more extensively studied, with inconsistent evidence. Hence, we strongly advise further investigation of the Brazilian Portuguese version of the CPCI and the Italian version of the CPCI-42. In addition, we evaluated the instruments for their evaluative purpose, and we assumed that measures were designed using a reflective measurement model. The evaluation of the psychometric properties in this paper reflects these assumptions. However, other purposes and measurement models are possible, requiring different psychometric standards [196]. For instance, good responsiveness to change is critical if an instrument is used to evaluate changes in avoidance behavior in response to an intervention but may be unnecessary in the context of diagnosis and screening, where known-groups validity and the availability of cut-off scores play an important role instead [37; 39; 196].

Future studies may extend this work with records published in languages other than English, French or German. Furthermore, we recommend systematic reviews on measurement instruments for use in (1) pain-free research participants and (2) children and adolescents experiencing chronic pain.

The clinical implications of this review are two-fold. Firstly, even though only two instruments can be recommended based on the current evidence, this overview of measurement properties of available instruments enables researchers and clinicians to select an instrument based on their specific goals. For example, even if not all measurement properties are well-tested, an instrument with good content validity, internal consistency, and responsiveness to change may be a viable option for evaluating treatment outcomes. Secondly, as stated before, we highly recommend complementing standardized questionnaires with EMA and/or observations, for example using movement tasks like the BAT-Back or through report by family members, to capture a person's behavior in different contexts. Importantly, to facilitate interpretation of assessment results and inform clinical decision making, norms and cut-off scores are needed (for example using regression modelling, e.g. [194]). These are available for only few of the instruments reviewed, including the FABQ [165] and TSK [54], and were established in specific languages and populations, limiting their generalizability. Hence, more work on norm scores and cut-offs is needed.

This review is the first to systematically capture all instruments commonly used to measure avoidance behavior in adult patients with chronic pain and to comprehensively evaluate their psychometric properties in accordance with the COSMIN guidelines. We hope this overview and the recommendations may aid researchers and clinicians in choosing the best-suited instruments. Furthermore, our findings reveal a notable lack of high-quality evidence supporting key measurement properties, even among the most frequently utilized PROMs. Addressing this critical gap through robust validation studies is essential to ensure the reliability and validity of clinical and research findings that rely on these measures.

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Figures

Figure 1. Flow chart illustrating the selection of articles for the review according to the PRISMA guidelines [124].

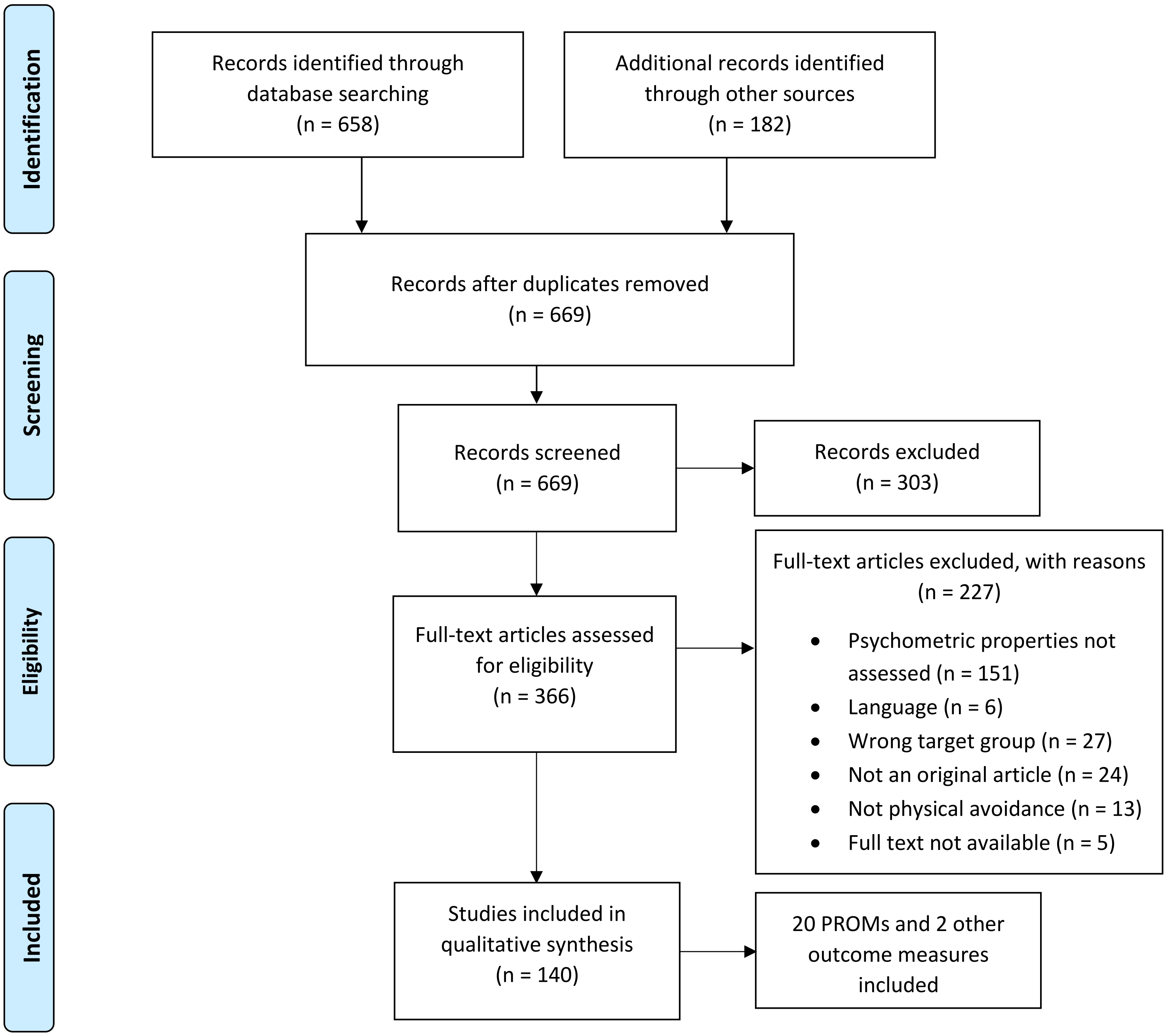
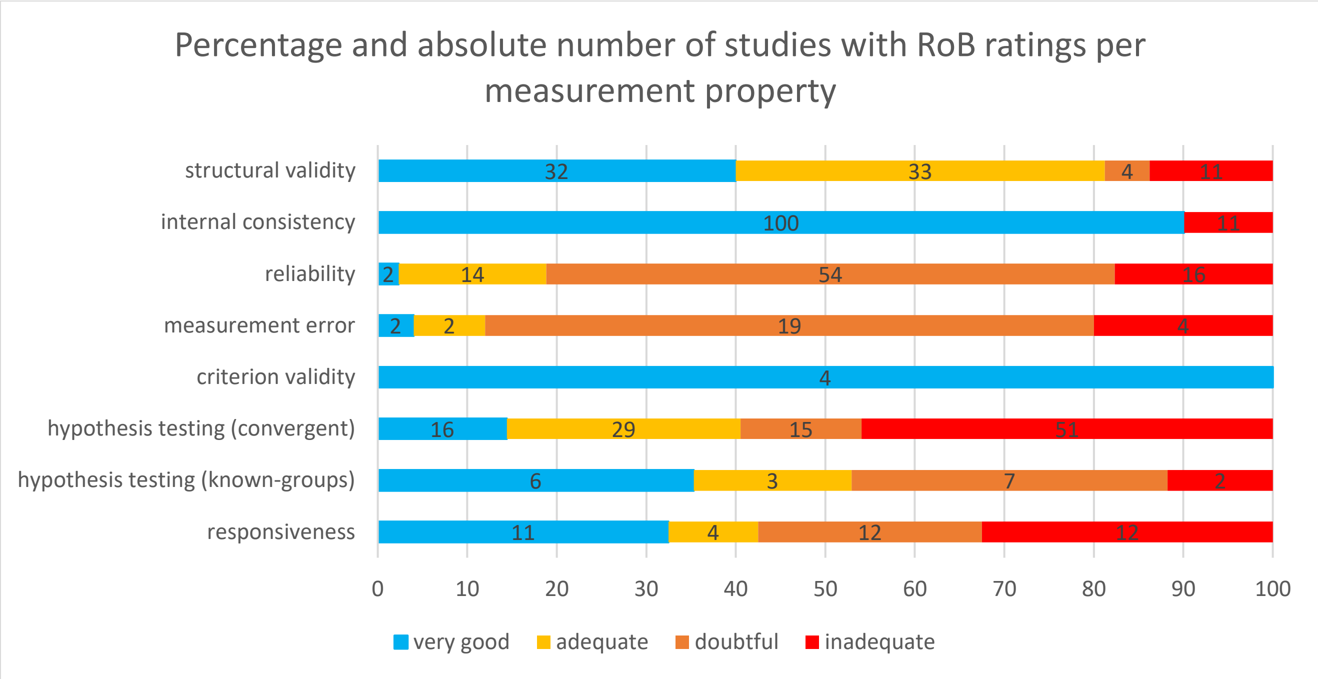


Figure 2. Percentage and absolute number of studies with the different Risk of Bias ratings per measurement property.



Tables

Table 1. Characteristics of patient-reported outcome measures (PROMs).

PROM* [development study]	Target population	Mode of administration	Recall period	Subscales (number of items)	Response options	Original language	Available translations
ADAP [8]	persons with shoulder pain	Rating of photographs of activities	now	free movement, high effort, self-care (15 items)	0 (not avoid at all) – 10 (avoid extremely)	Brazilian Portuguese	
AEQ [68]	persons with LBP	Self-report	undefined	anxiety/depression, help-/hopelessness, catastrophizing, avoidance of social activities scale, avoidance of physical activities scale, positive mood, thought suppression, behavioral endurance scale with two sub-scales humor/distraction scale and pain persistence scale (49 items)	10 affective items & 16 cognitive items: 0 (never) – 6 (always), 23 behavioral items: 0 (never) – 5 (always)	German	Korean, Persian, Spanish
APS [51]	chronic pain patients	Self-report	undefined	pain avoidance, activity avoidance, task-contingent persistence, excessive persistence, pain-contingent persistence, pacing to increase activity levels, pacing to conserve energy for valued activities, and pacing to reduce pain (24 items)	0 (not at all) - 4 (always)	Spanish	
BSFAQ [103]	burn patients	Self-report	now	(5 items)	0 (strongly disagree) – 3 (strongly agree)	English, French	
CAS D-65+ [157]	elderly (65+) with LBP	Self-report	undefined	catastrophizing, avoidance (11 items)	0 (never) – 5 (always)	German	

CPCI [78]	chronic pain patients	Self-report	past week	guarding, resting, asking for assistance, medication use relaxation, task persistence, exercise/stretch, coping self-statements, seeking social support (65 items)	number of days: 0-7	English	Brazilian Portuguese
CPCI-42 [166]	chronic pain patients	Self-report	past week	guarding, resting, asking for assistance, relaxation, task persistence, exercise/stretch, coping self-statements, seeking social support, opioid medication use, non-steroidal medication use, sedative-hypnotic medication use (42 items)	number of days: 0-7	English	Chinese, Italian, Korean, Polish, Spanish
FABQ [206]	persons with LBP	Self-report	undefined	fear-avoidance beliefs about work, fear-avoidance beliefs about physical activity (16 items)	0 (completely disagree) – 6 (completely agree)	English	Arabic, Brazilian Portuguese, Chinese, Danish, Dutch, Finnish, French, German, Greek, Gujarati, Hausa, Hindi, Igbo, Italian, Japanese, Kannada, Norwegian, Persian, Spanish, Swedish, Tamil, Turkish, Yoruba
FACS [135]	chronic musculoskeletal pain	Self-report	last week	(20 items)	0 (completely disagree) – 5 (completely agree)	English	Brazilian Portuguese, Dutch, French, Gujarati, Mandarin, Persian, Serbian, Spanish (European & Central American), Turkish
NRP [79]	general population	Self-report	undefined	NRP scales: despondent, fear, avoidant (12 items) PR scales: happy/hopeful, approach (8 items)	0 (I never feel this way) – 4 (I feel this all the time)	English	

PARQ [114]	chronic pain patients	Self-report	undefined	avoidance, pacing, confronting (21 items)	0 (never) – 5 (always)	English	
PASS [116]	chronic pain patients	Self-report	undefined	cognitive, escape and avoidance, fear, physiological anxiety (40 items)	0 (never) – 5 (always)	English	
PASS-20 [113]	chronic pain patients	Self-report	undefined	cognitive, escape and avoidance, fear, physiological anxiety (20 items)	0 (never) – 5 (always)	English	Arabic, Chinese, Dutch, German, Korean, Persian, Spanish
PCI [92]	chronic pain patients	Self-report	undefined	pain transformation; distraction; reducing demands; retreating; worrying; resting (33 items)	1 (hardly ever) - 4 (very often)	Dutch	
PIPS [209]	chronic pain patients	Self-report	now	avoidance, cognitive fusion (16 items)	1 (never true) – 7 (always true)	Swedish	Dutch, English, German, Greek, Japanese, Persian, Spanish
POAM-P [22]	chronic pain patients	Self-report	undefined	avoidance, overdoing, pacing (30 items)	0 (not at all) – 4 (all the time)	English	French, Japanese, Spanish, Turkish
TSK [121]	chronic pain patients	Self-report	undefined	somatic focus, activity avoidance (17 items)	1 (strongly disagree) – 4 (strongly agree)	English	Arabic, Brazilian Portuguese, Cantonese, Chinese, Dutch, Finnish, French, German, Greek, Gujarati, Iranian, Italian, Japanese, Norwegian, Persian, Portuguese, Spanish, Swedish, Thai
TSK-11 [210]	chronic pain patients	Self-report	undefined	somatic focus, activity avoidance (11 items)	1 (strongly disagree) – 4 (strongly agree)	English	Brazilian Portuguese, Chinese, Japanese, Malay, Marathi, Spanish, Swedish, Thai

TSK-13 [32]	chronic pain patients	Self-report	undefined	somatic focus, activity avoidance (13 items)	1 (strongly disagree) – 4 (strongly agree)	English	
TSK-TMD [198]	temporomandibular pain patients	Self-report	undefined	somatic focus, activity avoidance (12 items)	1 (strongly disagree) – 4 (strongly agree)	Dutch	Brazilian Portuguese, English, French, Korean, Mandarin, Spanish

* Each version of a PROM is considered a separate PROM.

Table 2. Characteristics of other measurement instruments.

Instrument	Target population	Mode of administration	Rating	Original language	Available translations
BAT-Back [72]	persons with CLBP	physical test	0 (no avoidance/safety behavior), 1 (safety behavior), 2 (avoidance of movement)	German	Turkish
Clinician-reported fear-avoidance beliefs [21]	persons with LBP	therapist assessment	0 (no fear-avoidance) – 10 (very high fear-avoidance)	English	

Table 3. COSMIN definitions and criteria for good measurement properties of measurement instruments.

Domain	Measurement property	Definition	Rating	Criteria
Reliability	Internal consistency*	The degree of the interrelatedness among the items	+	At least low evidence[a] for sufficient structural validity[b] AND Cronbach's alpha(s) ≥ 0.70 for each unidimensional scale or subscale[c]
			?	Criteria for "At least low evidence[a] for sufficient structural validity[b]" not met
			-	At least low evidence[a] for sufficient structural validity[b] AND Cronbach's alpha(s) < 0.70 for each unidimensional scale or subscale[c]
	Reliability	The proportion of the total variance in the measurements which is due to 'true' differences between participants	+	ICC or weighted Kappa ≥ 0.70
			?	ICC or weighted Kappa not reported
			-	ICC or weighted Kappa < 0.70
	Measurement error	The systematic and random error of a participant's score that is not attributed to true changes in the construct to be measured	+	SDC or LoA < MIC[b]
			?	MIC not defined
			-	SDC or LoA > MIC[b]
Validity	Content validity	The degree to which the content of an instrument is an adequate reflection of the construct to be measured		No objective criteria
	Structural validity*	The degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured	+	**CTT** CFA: CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08[d]

			IRT/Rasch No violation of <u>unidimensionality</u>[e]: CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08 AND no violation of <u>local independence</u>: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 AND no violation of <u>monotonicity</u>: adequate looking graphs OR item scalability > 0.30 AND adequate <u>model fit</u> IRT: $\chi^2 > 0.001$ Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > −2 and < 2
		?	CTT: not all information for '+' reported IRT/Rasch: model fit not reported
		-	Criteria for '+' not met
Hypothesis testing for construct validity	The degree to which the scores of an instrument are consistent with hypotheses (based on the assumption that the instrument validly measures the construct to be measured)	+	The result is in accordance with the hypothesis[f]
		?	No hypothesis defined (by the review team)
		-	The result is not in accordance with the hypothesis[f]
		+	No important differences found between group factors (such as age,

Cross-cultural validity/ measurement invariance*	The degree to which the performance of the items on a translated instrument or a version adapted to a different culture or patient group are an adequate reflection of the performance of the items of the original version of the instrument		gender, language) in multiple group factor analysis OR no important DIF for group factors (McFadden's $R^2 < 0.02$)
		?	No multiple group factor analysis OR DIF analysis performed
		-	Important differences between group factors OR DIF was found
Criterion validity*	The degree to which the scores of an instrument are an adequate reflection of a 'gold standard'	+	Correlation with gold standard ≥ 0.70 OR AUC ≥ 0.70
		?	Not all information for '+' reported
		-	Correlation with gold standard < 0.70 OR AUC < 0.70
Responsiveness	The ability of an instrument to detect change over time in the construct to be measured	+	The result is in accordance with the hypothesis[f] OR AUC ≥ 0.70
		?	No hypothesis defined (by the review team)
		-	The result is not in accordance with the hypothesis[f] OR AUC < 0.70

The criteria are based on [186], [126] and Prinsen et al. [151; 152]

AUC area under the curve, *CFA* confirmatory factor analysis, *CFI* comparative fit index, *CTT* classical test theory, *DIF* differential item functioning, *ICC* intraclass correlation coefficient, *IRT* item response theory, *LoA* limits of agreement, *MIC* minimal important change, *RMSEA* root mean square error of approximation, *SEM* standard error of measurement, *SDC* smallest detectable change, *SRMR* standardized root mean residuals, *TLI* Tucker–Lewis index

"+" = sufficient, "–" = insufficient, "?" = indeterminate

* relevant for patient-reported outcome measures (PROMs) but not for performance-based outcome measures.

[a] As defined by grading the evidence according to the GRADE approach; [b] This evidence may come from different studies; [c] The criteria 'Cronbach alpha < 0.95' was deleted, as this is relevant in the development phase of a PROM and not when evaluating an existing PROM; [d] To rate the quality of the summary score, the factor structures should be equal across studies; [e] Unidimensionality refers to a factor analysis per subscale, while structural validity refers to a factor analysis of a (multidimensional) patient-reported outcome measure; [f] The results of all studies should be taken together and it should then be decided if 75% of the results are in accordance with the hypotheses.

Table 4. Characteristics of included studies.

Instrument	Author (year)	Sample Characteristics			Country	Language	Psychometric properties
		N	Demographics	Pain type			
ADAP	Ansanello 2022 [8]	156	mean age = 47.8, SD = 17.2; 59% female	shoulder pain	Brazil	Brazilian Portuguese	content validity, structural validity, internal consistency
	Ansanello 2023 [9]	100	mean age = 44.9, SD = 15.9; 57% female	shoulder pain	Brazil		reliability, measurement error, construct validity
AEQ	Hasenbring 2009 [68]	191	mean age = 44.96, SD = 11.3; 55% female	LBP	Germany	German	structural validity, internal consistency, construct validity
	Abad 2020 [2]	123	mean age = 34.85; SD= 11.29; 76% female	non-specific neck pain	Iran	Persian	internal consistency, reliability, measurement error, construct validity
	Ruiz-Párraga 2015 [170]	150	mean age = 48.27, SD = 6.7; 62% female	musculoskeletal	Spain	Spanish	structural validity, internal consistency, construct validity
APS	Esteve 2016 [51]	402	unclear, different samples mixed	fibromyalgia, rheumatic diseases	Spain	Spanish	content validity, structural validity, internal consistency, construct validity
BAT-Back	Holzapfel 2016 [72]	128	64.9% female	LBP vs HC	Germany	German	internal consistency, reliability, construct validity
	Küçükakkaş 2020 [100]	155	mean age = 44.4, SD = 13.2; 48.7% female	LBP vs HC	Turkey	Turkish	structural validity, internal consistency, reliability, construct validity
BSFAQ	Chen 2023 [24]	31	mean age = 50.1, SD = 14.8; 25.5% female	burns	Canada	French	construct validity

CAS-D-65+	Quint 2011 [157]	68	mean age = 74.1; 76.5% female	back pain	Germany	German	internal consistency, reliability, construct validity
Clinician-rep. FAB	Calley 2010 [21]	80	mean age = 46.6, SD = 11.5; 57.5% female	LBP	US	English	reliability, construct validity
CPCI	Hadjistavropoulos 1999 [66]	210	mean age = 40, SD = 10.4; 39% female	mixed	Canada	English	structural validity, construct validity
	Jensen 1995 [78]	254	unclear, different samples mixed	mixed	US		internal consistency, reliability, construct validity
	Tan 2005 [184]	564	mean age = 50.8, SD = 11.4; 9.7% female	mixed	US		structural validity, construct validity
	Souza 2018 [179]	59	66% female	mixed	Brazil	Brazilian Portuguese	content validity, internal consistency
	Souza 2021 [180]	705	mean age = 53.8, SD = 14.26; 68.4% female	nonspecific, mixed	Brazil		structural validity, internal consistency
	Truchon 2006 [191]	827	mean age = 44, SD = 12.6; 70% female	mixed	Canada, France	French	structural validity, internal consistency
CPCI, CPCI-42	Romano 2003 [166]	154	mean age = 43.46, 51% female	mixed	US	English	internal consistency, reliability, criterion validity, construct validity, responsiveness
CPCI-42	Wong 2010a [211]	208	mean age = 40.95, SD = 11.28; 54.3% female	musculoskeletal	China	Chinese	content validity, structural validity, internal consistency, construct validity
	Monticone 2013 [130]	270	mean age = 55.4, SD = 14.6; 55.9% female	non-specific (musculoskeletal)	Italy	Italian	content validity, structural validity, internal consistency, reliability, construct validity

	Ko 2010 [88]	142	mean age = 47.9, SD = 11.9; 73% female	LBP	Korea	Korean	content validity, structural validity, internal consistency, reliability, construct validity
	Misterska 2014 [123]	90	mean age = 43.47, SD = 10.21; 60% female	LBP	Poland	Polish	content validity, internal consistency, reliability, construct validity
	Garcia-Campayo 2007 [55]	402	mean age = 45.3, SD = 6.8; 89.8% female	fibromyalgia	Spain	Spanish	structural validity, internal consistency, reliability, construct validity
FABQ	Cleland 2008a [33]	263	51.8% female	LBP	US	English	construct validity
	Riley 2019 [161]	30	mean age = 48.1, SD = 15.6; 24 female	shoulder pain			structural validity, construct validity, responsiveness
	Inrig 2012 [75]	187	mean age = 45.2, SD = 9.68; 46% female	upper extremity	Canada		internal consistency, reliability, measurement error, construct validity
	Waddell 1993 [206]	184	mean age = 39.7, SD = 11.7; 44.3% female	LBP and/or sciatica	UK		structural validity, internal consistency, reliability, construct validity
	Laufer 2012 [105]	113	unclear, different samples mixed	LBP	Israel	Arabic	content validity, internal consistency, reliability, construct validity
	Alanazi 2017 [5]	110	mean age = 47.3, 35.2% female	LBP	Saudi Arabia		reliability, construct validity
	Salama 2020 [173]	80	mean age = 47, SD = 13.4; 67.5% female	LBP	Egypt		construct validity
	Cheung 2018 [25]	100	mean age = 57, SD = 12.5; 57% female	LBP	China	Chinese	content validity, internal consistency, construct validity

Pei 2010 [142]	245	mean age = 47.5, SD = 14.1, 63% female	LBP			content validity, structural validity, internal consistency, reliability, construct validity, responsiveness
Lee 2006 [106]	476	unclear, different samples mixed	neck pain	Hong Kong		content validity, structural validity, internal consistency, reliability, construct validity, responsiveness
Trolle 2019 [189]	45	mean age = 48.1, SD = 15; 40% female	shoulder impingement syndrome	Denmark	Danish	reliability, measurement error, construct validity, responsiveness
Sørensen 2021 [183]	52	mean age = 57.4, SD = 10.1; 50% female	shoulder pain			responsiveness
Terho 2016 [185]	66	mean age = 45.8 SD = 12.9; 57.6% female	LBP	Finland	Finnish	content validity, structural validity, internal consistency, reliability
Chaory 2004 [23]	244	mean ages = 46.0, SD = 7.5 / 45.3, SD = 9.2 /42.5 = 7.5 (range 26–54)	LBP	France	French	structural validity, reliability, measurement error, construct validity, responsiveness
Pagels 2023 [139]	49	mean age = 41.8, SD = 12.8; 48.98% female	shoulder pain	Germany	German	internal consistency, construct validity
Pfingsten 1997 [146]	87	mean age = 40.9, SD = 9.6; 57.5% female	LBP			structural validity, internal consistency, reliability, construct validity
Pfingsten 2000 [145]	302	mean age = 44.6, SD = 10.6; 47.7% female	LBP			structural validity, internal consistency, reliability, construct validity
Pfingsten 2004 [144]	302	mean age: 44.6, SD = 10.6; 47.7% female	back pain			internal consistency, construct validity

Staerkle 2004 [182]	255	mean age = 56.9, SD = 15.5; 55.69% female	LBP			structural validity, internal consistency, reliability, construct validity
Georgoudis 2007 [60]	70	mean age = 42.2, SD = 12; 82.9% female	LBP	Greece	Greek	content validity, structural validity, internal consistency, reliability, construct validity, responsiveness
Bid 2016 [18]	30	mean age = 41.8, SD = 11.36; 63.3% female	LBP	India	Gujarati	content validity, internal consistency, reliability, measurement error, construct validity
Bid 2019 [15]	128	mean age = 41.23, SD = 7.48; 60.9% female	LBP	India	Gujarati	structural validity, construct validity, responsiveness
Ibrahim 2019 [73]	200	unclear, different samples mixed	LBP	Nigeria	Hausa	content validity, structural validity, internal consistency, reliability, measurement error, construct validity, responsiveness
Kaka 2015 [80]	54	mean age = 39.3, SD = 10.86; 33.3% female	neck pain			content validity, reliability, criterion validity, construct validity
Igwesi-Chidobe 2019 [74]	50	mean age = 45.2, SD = 11.55; 64% female	LBP		Igbo	content validity, structural validity, internal consistency, reliability, measurement error, construct validity
Panhale 2019 [140]	100	mean age = 36.89, SD = 7.78	LBP	India	Hindi	content validity, structural validity, internal consistency, reliability, construct validity
Franchignoni 2020 [52]	155	mean age = 43, SD = 11; 43% female	LBP	Italy	Italian	structural validity, internal consistency
Monticone 2020 [131]	129	mean age = 48, SD = 16; 66.66% female	LBP			internal consistency, reliability, measurement error, responsiveness

Monticone 2012 [129]	180	mean age = 44.1, SD = 11.3; 43% female	LBP			content validity, structural validity, internal consistency, reliability, measurement error, construct validity
Pruneti 2014 [154]	250	mean age = 41.84, SD = 11.06; 48% female	back pain			structural validity, internal consistency, reliability
Matsudaira 2014 [111]	178 6	mean age = 48.7, 49.6% female	LBP	Japan	Japanese	structural validity, internal consistency, construct validity
Kumar 2020 [99]	60	mean age = 41.5, SD = 10.59	LBP	India	Kannada	content validity, internal consistency, reliability
Panhale 2018 [141]	100	mean age = 33.97, SD = 11.54; 45% female	LBP	India	Marathi	content validity, internal consistency, reliability, construct validity
Grotle 2006 [64]	173	unclear, different samples mixed	LBP	Norway	Norwegian	structural validity, internal consistency, reliability, measurement error, construct validity, responsiveness
Rostami 2014 [169]	136	mean age = 48.7, SD = 13.13; 47.7% female	LBP	Iran	Persian	structural validity, internal consistency, reliability, construct validity
Kovacs 2006 [91]	156	mean age = 45.7; 60.9% female	LBP	Spain	Spanish	content validity, internal consistency, reliability
Dayalan 2022 [42]	50	mean age = 39.9, SD = 15.5; 60% female	LBP	India	Tamil	internal consistency, reliability, construct validity
Korkmaz 2009 [90]	150	mean age = 44.7, SD = 13.06; 64% female	LBP, leg	Turkey	Turkish	structural validity, internal consistency, reliability, construct validity, responsiveness

	Namli 2022 [134]	195	mean age = 62.67, SD = 4.57; 79% female	knee osteoarthritis			internal consistency, construct validity
	Ozuberk 2023 [138]	175	mean age = 43.41, SD = 10.96; 79.4% female	neck pain			internal consistency, reliability, construct validity
	Mbada 2021 [112]	131	mean age = 53.6, SD = 11.6; 45.8% female	LBP	Nigeria	Yoruba	content validity, structural validity, internal consistency, reliability, measurement error, construct validity
FABQ, PASS, TSK	Crombez 1999 [38]	104	unclear, different samples mixed	LBP	Belgium	Dutch	internal consistency, construct validity
FABQ, TSK	Cleland 2008b [34]	78	mean age = 42, SD = 11.3; 68% female	neck pain	US	English	reliability, construct validity
FABQ, TSK	de Souza 2008 [44]	50	mean age = 45.9, SD = 12; 54% female	LBP	Brazil	Brazilian Portuguese	internal consistency, reliability, construct validity, responsiveness
FABQ, TSK	Askary-Ashtiani 2014 [12]	166	45% female	neck pain	Iran	Persian	internal consistency, reliability, construct validity
FABQ, TSK	Saadat 2023 [172]	100	mean = 42.01, SD = 10.18; 69% female	neck pain	Iran	Persian	responsiveness
FABQ, TSK	Dedering 2013 [45]	41	60.97% female	cervical radiculopathy	Sweden	Swedish	internal consistency, reliability, construct validity
FABQ, TSK-11	George 2010 [59]	53	mean age = 44.3, SD = 18.5; 80% female	LBP	US	English	reliability, measurement error, construct validity
FABQ, TSK-11	Kamonseki 2021 [81]	178	mean age = 39.7, SD = 14.01; 41.6% female	shoulder pain	Brazil	Brazilian Portuguese	structural validity, internal consistency, reliability, measurement error, responsiveness

FABQ, TSK-11	Mintken 2010 [122]	80	mean age = 41.2, SD = 13.2, 60% female	shoulder pain	US	English	structural validity, internal consistency, reliability, construct validity
FACS	Neblett 2016 [135]	788	unclear	musculoskeletal	US	English	content validity, internal consistency, reliability, construct validity
	Neblett 2017 [136]	426	mean age = 47.1, SD = 10.9; 39% female	musculoskeletal			structural validity, responsiveness
	De Baets 2023 [43]	224	mean age = 48.6, SD = 16; 66.07% female	musculoskeletal pain	Belgium	Dutch	structural validity, internal consistency, reliability, measurement error, construct validity
	Duport 2023 [46]	55	mean age = 51.15, SD = 16.47; 45.5% female	musculoskeletal pain	France	French	internal consistency, reliability, construct validity
	Bid 2020 [16]	150	mean = 47.36, SD = 9.85; 68.67% female	musculoskeletal pain	India	Gujarati	content validity, internal consistency, reliability, measurement error, construct validity
	Knezevic 2018 [87]	322	mean age = 52.98, SD = 12.33; 67.1% female	musculoskeletal pain	Serbia	Serbian	structural validity, internal consistency, reliability, measurement error, construct validity
	Cuesta-Vargas 2020 [40]	330	mean age = 55.04, SD = 12.7; 45.2% female	musculoskeletal pain disorders	Spain	Spanish	structural validity, internal consistency, construct validity
	González Aroca 2023 [62]	208	mean age = 48.45, SD = 6.05; 52.9% female	unilateral subacromial shoulder pain			construct validity
	Turan 2023 [192]	208	mean age = 46.2, SD = 11.4; 55.8% female	musculoskeletal pain	Turkey	Turkish	structural validity, internal consistency, reliability, construct validity

NRP	Jensen 2017 [79]	395	75.95% female	various	US	English	structural validity, internal consistency, reliability, construct validity
PARQ	McCracken 2007 [114]	276	mean age = 46.6, SD = 13.7; 65.6% female	mixed	UK	English	structural validity, internal consistency, construct validity
PASS	McCracken 1992 [116]	104	mean age = 45, SD = 13.4, 53.8% female	mixed	US		internal consistency, construct validity
PASS-20	Coons 2004 [35]	201	mean age = 41.5,SD =15.5, 55% female	mixed	Canada	English	structural validity, internal consistency, reliability, construct validity
	McCracken 2002 [113]	282	mean age = 46.5, SD = 13.8; 66% female	mixed	UK		internal consistency, criterion validity, construct validity
	Kreddig 2015 [94]	195	mean age = 42.45, SD = 11.29; 55% female	LBP	Germany	German	structural validity, internal consistency, construct validity
	Cho 2010 [27]	166	mean age = 48.7, SD = 13.04; 70.5% female	mixed	Korea	Korean	structural validity, internal consistency, reliability, construct validity
	Zhou 2017 [213]	249	mean age = 58.4, SD = 13.4; 66.7% female	?	China	Chinese	content validity, structural validity, internal consistency, reliability, construct validity
PCI	Kraaimaat 2003 [93]	1055	unclear, different samples mixed	mixed	Dutch	Dutch	internal consistency, reliability, construct validity
PIPS	Trompetter 2014 [190]	428	mean age = 43.7, SD = 12.5; 72.2% female	mixed, musculoskeletal	the Netherlands	Dutch	structural validity, internal consistency, construct validity
	Barke 2015 [13]	182	mean age = 51.0, SD = 10.5; 70.3% female	back pain	Germany	German	content validity, structural validity, internal consistency, construct validity

	Vasiliou 2019 [197]	394	unclear, different samples mixed	musculoskeletal and other (incl. headache)	Greece	Greek	structural validity, internal consistency, reliability, construct validity
	Nagasawa 2021 [133]	120	mean age = 73.8, SD = 7.8; 61.7% female	LBP, knee pain	Japan	Japanese	structural validity, internal consistency, reliability, construct validity
	Rodero 2013 [162]	259	mean age = 52.4, SD = 8.5; 95.6% female	fibromyalgia	Spain	Spanish	structural validity, internal consistency, reliability, construct validity
	Wicksell 2008 [209]	203	mean age = 45.5, SD = 10.15; 80.8% female	fibromyalgia, migraine, whiplash, LBP	Sweden	Swedish	structural validity, internal consistency, construct validity
	Wicksell 2010 [208]	611	mean age = 49, SD = 12.8; 74.8% female	whiplash			structural validity, internal consistency, construct validity
POAM-P	Cane 2013 [22]	559	unclear, different samples mixed	mixed	Canada	English	internal consistency, construct validity, responsiveness
	Benaim 2017 [14]	595	mean age = 43, SD = 12	musculoskeletal	Switzerland	French	content validity, internal consistency, reliability, construct validity
TSK	French 2007 [53]	200	mean age = 40, SD = 10.6; 54% female	back / neck	Canada	English	reliability
	Alanazi 2021 [6]	82	mean age = 29.7; SD= 9.6; 29.3% female	LBP	Saudi Arabia	Arabic	internal consistency, reliability, measurement error, construct validity
	Siqueira 2007 [177]	50	mean age = 41.98, SD = 13.76; 76% female	LBP	Brazil	Brazilian Portuguese	structural validity, internal consistency
	Wong 2010b [212]	325	mean age = 39.72, SD = 13.88; 52.3% female	any	China	Cantonese	structural validity, internal consistency, construct validity

Lamé 2008 [102]	50	mean age = 54.7, SD = 13.1; 60% female	mixed			internal consistency, reliability
Pulles 2020 [155]	359	mean age = 45.28, SD = 11.02; 66.3% female	musculoskeletal pain			measurement error, construct validity, responsiveness
Roelofs 2004 [163]	616	unclear, different samples mixed	LBP, fibromyalgia			structural validity, internal consistency, construct validity
Vlaeyen 1995a [199]	103	mean age = 39.0/42.9, SD = 7.7/8.9; 56.3% female (only S1)	LBP			internal consistency, construct validity
Vlaeyen 1995b [200]	162	unclear, different samples mixed	LBP			structural validity, internal consistency, construct validity
Koho 2014 [89]	94	mean age = 47, SD= 8; 58.5% female	musculoskeletal pain	Finland	Finnish	internal consistency, reliability
Georgoudis 2022 [61]	70	mean age = 42.2, SD = 12; 82.9% female	LBP	Greece	Greek	internal consistency, reliability, construct validity
Bid 2018 [17]	160	mean age = 43.26, SD = 14.51; 67.5% female	LBP	India	Gujarati	content validity, structural validity, internal consistency, reliability, construct validity
Monticone 2016a [127]	180	mean age = 55.4, SD = 10.5; 59.44% female	LBP	Italy	Italian	measurement error, responsiveness
Monticone 2016b [128]	205	mean age = 50.9, SD = 9.1; 58.54% female	LBP			measurement error, responsiveness
Monticone 2010 [132]	178	mean age = 61.5, SD = 13.2; 70.2% female	LBP			internal consistency, construct validity

	Haugen 2008 [69]	466	mean age = 43.6, SD = 11.5; 42.5% female	sciatica	Norway	Norwegian	structural validity, internal consistency, reliability, construct validity, responsiveness
	Lundberg 2004 [110]	102	mean age = 45.3, SD = 12.5; 50.98% female	LBP	Sweden	Swedish	structural validity, internal consistency, reliability, construct validity
	Areeudomwong 2017 [10]	80	mean age = 65.53, SD= 9.39; 66.25% female	knee pain	Thailand	Thai	internal consistency, reliability, construct validity
TSK, TSK-11	Woby 2005 [210]	111	mean age = 43.4, SD = 10.5; 48.65% female	LBP	UK	English	content validity, structural validity, internal consistency, reliability, construct validity, responsiveness
TSK, TSK-11	Roelofs 2007[a] [164]	3934	mean age = 41.7, SD = 8.7; 67% female	work-related upper extremity disorders	the Netherlands	Dutch	structural validity, internal consistency, construct validity
TSK, TSK-11	Kikuchi 2015 [86]	956	mean age = 45.5, SD = 10.4; 29% female	whiplash & LBP	Japan	Japanese	content validity, reliability, measurement error, construct validity
TSK, TSK-11, TSK-13	Eiger 2023 [48]	77	mean age = 49.9, SD = 14.4; 66.2% female	any	Denmark	Danish	reliability, measurement error
TSK, TSK-13	Burwinkle 2015 [19]	233	mean age = 43.79, SD = 10.83; 100% female	fibromyalgia	US	English	structural validity, internal consistency
TSK, TSK-13	Goubert 2004 [63]	277	mean age = 41.33, SD = 10.9; 66.4% female	LBP, FM	Belgium, the Netherlands	Dutch	structural validity, internal consistency
TSK, TSK-13	Heuts 2004 [71]	254	mean age = 51.7, SD = 5	osteoarthritis	the Netherlands		structural validity, internal consistency

TSK, TSK-13	Wei 2015 [207]	142	mean age = 52.3, SD = 10.2; 47.9% female	LBP		Chinese	structural validity, internal consistency, reliability, construct validity
TSK-11	Hapidou 2012 [67]	74	mean age = 43.8, SD = 9.3; 61% female	any	Canada	English	reliability, measurement error, construct validity, responsiveness
	Santo Salvador 2021 [174]	130	mean age = 45.5, SD = 11.1; 98.5% female	fibromyalgia	Brazil	Brazilian Portuguese	internal consistency, reliability, measurement error, criterion validity, construct validity
	Cai 2019 [20]	254	mean age = 63.1, SD = 9.8; 56.3% female	total knee athroplasty	China	Chinese	structural validity, internal consistency, reliability, construct validity
	Rusu 2014 [171]	191	mean age = 50.1, SD = 11.3; 55% female	LBP	Germany	German	content validity, structural validity, internal consistency, construct validity
	Satpute 2019 [175]	100	mean age = 38.9, SD = 11.34; 47.9% female	LBP	India	Marathi	content validity, reliability, construct validity
	Gómez-Perez 2011 [65]	211	unclear, different samples mixed	mixed	Spain	Spanish	content validity, structural validity, internal consistency, reliability, construct validity
	Larsson 2014 [104]	433	mean age = 74.8, SD = 7.5; 63.5% female	mixed	Sweden	Swedish	structural validity, internal consistency, construct validity
TSK-11, TSK-13	Tkachuk 2012 [188]	276	mean age = 47.76, SD= 12.35; 65% female	mixed	Canada	English	internal consistency, reliability, measurement error, responsiveness
TSK-13	Geisser 2000 [56]	133	mean age = 41.7, SD = 8.5; 43.61% female	back pain	US	English	structural validity, construct validity

	Cordeiro 2013 [36]	166	mean age = 50.55, SD = 10.80; 63.3% female	LBP	Portugal	Portuguese	structural validity, internal consistency, reliability, construct validity, responsiveness
TSK-TMD	Aguiar 2017 [4]	100	mean age = 36.88, SD = 9.8; 100% female	temporo-mandibular pain	Brazil	Brazilian Portuguese	content validity, structural validity, internal consistency, reliability, measurement error, construct validity
	He 2016 [70]	160	mean age = 45.2, SD = 15.8; 54.4% female	temporo-mandibular pain	China	Chinese	content validity, internal consistency, reliability, construct validity
	Visscher 2010 [198]	301	mean age = 41.3, SD = 14.1; 81% female	temporo-mandibular pain	the Netherlands	Dutch	structural validity, internal consistency, reliability, construct validity
	LaTouche 2020 [101]	125	mean age = 45.58, SD = 12.92; 67.3% female	temporo-mandibular pain	Spain	Spanish	content validity, structural validity, internal consistency, reliability, measurement error, construct validity

[a]The study by Roelofs et al.[164] contained a sub-study in which several datasets (including multiple language versions of the TSK), some of which are part of this review, were pooled and re-analysed. Therefore, this sub-study was not considered here.

responsiveness = responsiveness to change.

Table 5. Evidence synthesis of the content validity of PROMs: rating of results and overall level of evidence.

PROM	PROM development		Relevance*		Comprehensiveness*		Comprehensibility	
	PROM design	CI study	RoR	QoE	RoR	QoE	RoR	QoE
ADAP	D		+	low	?	very low	+	low
AEQ	A		+	very low	+	very low	+	very low
APS	V	I	+	very low	-	very low	+	low
BSFAQ				N/A				
CAS-D-65+	V		+	moderate	+	very low	±	very low
CPCI	D		+	low	+	very low	+	low
CPCI-42	D		+	low	±	very low	+	low
FABQ	V		?	very low	+	moderate	+	moderate
FACS	I	I	±	very low	+	very low	+	moderate
NRP	D		+	very low	±	very low	±	very low
PARQ	I		+	very low	+	very low	+	very low
PASS	D		+	very low	+	very low	+	very low
PASS-20	V		+	very low	+	very low	+	moderate
PCI	N/A		+	low	-	very low	+	very low
PIPS	V	I	±	very low	?	very low	?	very low
POAM-P	D		+	very low	±	very low	+	moderate
TSK	N/A		+	moderate	+	moderate	+	moderate
TSK-11	I		+	very low	±	very low	+	moderate

TSK-13				N/A				
TSK-TMD	D	D	+	low	±	very low	+	moderate

CI = Cognitive interview; QoE = Quality of evidence; RoR = Rating of results; * combined for patient and expert opinion

“V” = very good, “A” = adequate, “D” = doubtful, “I” = inadequate; “+” = sufficient, “–” = insufficient, “±” inconsistent, “?” = indeterminate.

Table 6. Risk of Bias Assessments and Rating Against Measurement Properties of included studies.

Instrument	Reference	structural validity	internal consistency	reliability	measurement error	criterion validity	convergent validity†	responsiveness to change‡
ADAP	Ansanello 2022 [8]	? / A	+ / V					
	Ansanello 2023 [9]			+ / D	? / D		a. - / V	
AEQ	Hasenbring 2009 [68]	? / I	? / V				a. + / A	
							b. + / D	
	Abad 2020 [2]		+ / V	+ / D	? / D		a. - / D	
	Ruiz-Párraga 2015 [170]	? / I	? / V				a. + / D	
APS	Esteve 2016 - study 1 [51]	+ / V	- / V				a. + / A	
	Esteve 2016 - study 2 [51]		+ / V				a. + / A	
BAT-Back	Holzapfel 2016 [72]		+ / V	+ / V			a. + / A	
							b. + / V	
	Küçükakkaş 2020 [100]	? / A	+ / V	+ / A			a. - / I	
							b. + / V	
BSFAQ	Chen 2023 [24]						a. + / A	
							b. + / I	
CAS-D-65+	Quint 2011 [157]		? / V	? / D			a. + / A	
clinician-reported FAB	Calley 2010 [21]			- / V			a. - / V	

CPCI	Jensen 1995 [78]		? / V	+ / D		a. + / A	
	Hadjistavropoulos 1999 [66]	? / I				a. + / V	
	Tan 2005 [184]	? / I				a. + / A	
	Souza 2021 [180]	+ / V	+ / V				
	Truchon 2006 [191]	+ / D	+ / V				
	Romano 2003 [166]		? / V	+ / D		a. + / A	d. + / I
	Souza 2018 [179]		? / V				
CPCI-42	Ko 2010 [88]	? / I	? / V	+ / D		a. - / I	
	Monticone 2013 [130]	+ / A	+ / V	+ / A		a. + / I	
	Wong 2010a [211]	? / A	? / V			a. + / A	
	Romano 2003 [166]		+ / V	+ / D	+ / V	a. + / A	d. + / I
	Misterska 2014 [123]		? / V	+ / D		a. + / A	
	Garcia-Campayo 2007 [55]	+ / V	+ / V	? / A		a. + / I	
FABQ	Georgoudis 2007 [60]	? / I	? / V	+ / D		a. - / A	d. - / A
	Pei 2010 [142]	- / V	? / V	+ / A		a. ? / I	d. - / I
	Staerkle 2004 [182]	- / V	? / V	+ / D		a. - / I	
	Lee 2006 [106]	? / A	? / I	+ / A		a. + / A	b. - / I
						b. + / D	d. - / D
	Panhale 2019 [140]	? / A	? / V	+ / D		a. ? / I	
	Matsudaira 2014 [111]	? / V	? / V			a. + / A	

					b. + / I	
Monticone 2012 [129]	? / A	? / V	+ / D	- / D	a. + / I	
Terho 2016 [185]	? / I	? / V	+ / I			
Ibrahim 2019 [73]	? / A	? / V	+ / D	? / D	a. - / I	d. + / V
Igwesi-Chidobe 2019 [74]	? / A	? / V	+ / D	- / D	a. - / I	
Chaory 2004 [23]	? / A		+ / D	? / D	a. + / I	d. + / D
Pfingsten 2000 [145]	? / A	? / V	? / D		a. + / I b. + / D	
Rostami 2014 [169]	? / A	? / V	+ / A		a. + / I	
Pfingsten 2004 [144]	? / A	? / V	? / D		a. + / I	
Mintken 2010 [122]	? / D	? / V	? / A		a. - / V	
Waddell 1993 [206]	? / A	+ / V	+ / D		a. + / I	
George 2010 [59]			+ / I	? / I	a. + / I	
Pruneti 2014 [154]	? / A	? / I	? / I			
Cleland 2008a [33]					a. + / A	
Cheung 2018 [25]		± / V			a. - / D b. - / D	
Riley 2019 [161]			- / D		a. - / V	b. ? / I d. + / I
Inrig 2012 [75]		+ / V	- / I	? / I	a. - / I	

Laufer 2012 [105]		+ / V	- / I			a. + / V b. + / A	
Alanazi 2017 [5]			+ / D			a. - / I	
Trolle 2019 [189]			+ / D	? / D		a. ? / V	b. + / A
Bid 2016 [18]		- / V	+ /D	? / D		a. - / I	
Bid 2019 [15]	- / V					a. - / I	d. + / I
Kaka 2015 [80]			+ / D		+ / V	a. - / I	
Kumar 2020 [99]		? / V	+ / D				
Panhale 2018 [141]		+ / V	+ / D			a. - / I	
Grotle 2006 [64]	? / I	? /V	± / I	? / I		a. + / I	d. + / D
Kovacs 2006 [91]		? / I	+ / D				
Dayalan 2022 [42]		+ / V	+ / V			a. + / I	
Dedering 2013 [45]		+ / I	+ / I			a. - / I b. - / V	
Franchignoni 2020 [52]	? / A	? / V					
Kamonseki 2021 [81]	? / A	? / V	- / A	? / A			d. - / D
Monticone 2020 [131]		? / V	+ / D	+ / D			c. + / I d. + / V
Namli 2022 [134]		? / V				a. ? / V	
Ozuberk 2023 [138]		? / V	+ / D			a. - / D	

	Pagels 2023 [139]		? /V			a. - / I b. - / D	
	Saadat 2023 [172]						c. + / A d. + / V
	Salama 2020 [173]					a. + / A	
	Sørensen 2021 [183]						b . + / D d. + / V
	Korkmaz 2009 [90]	? / V	+ / V	? / D		a. + / I	d. - / V
	Mbada 2021 [112]	? / V	+ / I	+ / D	? / D	a. - / I	
	Cleland 2008b [34]			+ / I		a. + / V	
	de Souza 2008 [44]		? / V	+ / D		a. + / I	b. - / I d. - / I
	Pfingsten 1997 [146]	? / D	? / I			a. - / I	
	Askary-Ashtiani 2014 [12]		? / V	+ / D		a. + / I b. + / A	
	Crombez 1999 [38]		? / V			a. - / I	
FACS	Neblett 2016 [135]		? / V	? / D		a. + / I b. + / A	
	Cuesta-Vargas 2020 [40]	? / I	? / V			a. + / V	
	Aroca 2023 [62]					a. - / V	

	De Baets 2023 [43]	? / A	? / V	+ / D	? / D		a. + / V	
	Bid 2020 [16]		? / V	+ / A	? / A		a. + / A	
	Duport 2023 [46]		? / V	+ / A			a. + / V	
	Turan 2023 [192]	? / A	? / V	+ / D			a. - / D	
	Knezevic 2018 [87]	+ / V	+ / V	+ / D	? / D		a. + / I b. + / V	
	Neblett 2017 [136]	? / A						d. - / D
NRP	Jensen 2017 [79]	+ / V	+ / V	? / D			a. + / A	
PARQ	McCracken 2007 [114]	? / A	? / V				a. + / A	
PASS	McCracken 1992 [116]		? / V				a. + / I	
	Crombez 1999 [38]		? / V				a. - / I	
PASS-20	Coons 2004 [35]	? / A	? / V	? / I			a. + / D	
	Kreddig 2015 [94]	? / A	? / V				a. + / A	
	Zhou 2017 [213]	- / V	? / V	+ / D			a. + / D	
	Cho 2010 [27]	- / V	? / V	? / I			a. + / A	
	McCracken 2002 [113]		? / V			+ / V	a. + / D	
PCI	Kraaimaat 2003 [93]		? / V	? / I			a. + / I b. + / V	
PIPS	Vasiliou 2019 [197]	- / V	? / V	? / I			a. + / I	
	Wicksell 2010 [208]	+ / V	+ / V				a. + / I	

	Barke 2015 [13]	+ / V	+ / V			a. + / I	
	Trompetter 2014 184]	+ / V	+ / V			a. + / I	
	Nagasawa 2021 [133]	+ / V	+ / V	? / D		a. ? / D	
	Rodero 2013 [162]	? / A	? / V	+ / D		a. + / A	
	Wicksell 2008 [209]	? / A	+ / V			a. + / A	
POAM-P	Cane 2013 [22]		? / V			a. + / A	d. ? / I
	Benaim 2017 [14]		? / V	+ / D		a. + / I	
TSK	Lundberg 2004 [110]	? / A	? / I	+ / A		b. + / V	
	Goubert 2004 [63]	? / V					
	Bid 2018 [17]	? / A	? / I	- / D	? / D	a. - / A	
	Monticone 2010 [132]	? / A	? / V	+ / D		a. + / I	
	French 2007 [53]	- / V	? / V			a. + / D	d. ? / I
	Roelofs 2004 [163]	- / V	? / V			a. + / I	
	Wei 2015 [207]		? / V	+ / D		a. + / A	
	Roelofs 2007 [164]	+ / V					
	Areeudomwong 2017 [10]		? /V	+ / D		a. - / I	
	Alanazi 2021 [6]		? / V	+ / A		a. + / D	
	Dedering 2013 [45]		? / V	+ / I		a. - / I b. + / V	
	Koho 2014 [89]		? / V	+ / D			

Monticone 2016a [127]				+ / V		b. + / I c. + / D
Monticone 2016b [128]				+ / D		b. + / I c. + / D d. + / V
Pulles 2020 [155]				- / D		c. - / D d. - / V
Cleland 2008b [34]			+ / I		a. + / I	
de Souza 2008 [44]		? / V	+ / D		a. + / I	b. + / I d. + / I
Wong 2010b [212]	- / V	- / V			a. + / D b. + / V	
Lamé 2008 [102]		+ / V	- / I			
Woby 2005 [210]		? / I	+ / I	? / I		b. + / V c. + / D d. + / V
Kikuchi 2015 [86]		+ / I			a. + / I b. + / D	
Vlaeyen 1995a [199]		+ / V			a. + / I	
Heuts 2004 [71]	- / V					

	Siqueira 2007 [177]	? / D	? / V					
	Georgoudis 2022 [61]		? / V	+ / D			a. + / D	
	Eiger 2023 [48]			+ / V	? / V			
	Vlaeyen 1995b [200]	? / A	- / V				a. + / I b. + / D	
	Crombez 1999 [38]		? / V				a. + / I	
	Burwinkle 2015 [19]	? / A	? / V					
	Askary-Ashtiani 2014 [12]		? / V	+ / D			a. + / I b. + / A	
	Saadat 2023 [172]							c. + / A d. + / V
	Haugen 2008 [69]	? / A	? / V	- / I			a. + / I	c. ? / D
TSK-11	Rusu 2014 [171]	+ / V	- / V					
	Gómez-Perez 2011 [65]	? / A	? / V	? / I			a. - / A b. - / V	
	Tkachuk 2012 [188]	- / V	? / V				a. + / A	
	Larsson 2014 [104]	- / V	? / V	+ / A			a. + / I	
	Mintken 2010 [122]	? / D	? / V	+ / A			a. - / V	
	Woby 2005 [210]		? / I	+ / I	? / I			a. + / V b. + / V

								c. + / D
								d. + / V
	Cai 2019 [20]	? / A	? / V	+ / D			a. - / A	
	Kamonseki 2021 [81]	? /A	? / V	+ / A	? / A			d. - / D
	Eiger 2023 [48]			+ / V	? / V			
	Santo Salvador 2021 [174]		? / V	+ / D	+ / D	+ / D	a. - / V	
	Kikuchi 2015 [86]		? / I				a. + / I	
							b. + / D	
	Satpute 2019 [175]		+ / H	+ / D			a. + / D	
	Roelofs 2007 [164]	+ / V	- / V				a. + / A	
	Hapidou 2012 [67]			+ / D	? / D		a. + / V	c. + / I
	George 2010 [59]			+ / D	? / D		a. - / I	
	Geisser 2000 [56]	? / V					a. - / I	
	Tkachuk 2012 [188]	- / V						
	Cordeiro 2013 [36]	? / I	+ / I	+ / D			a. + / I	d. - / D
TSK-13	Goubert 2004 [63]	? / V	+ / V					
	Heuts 2004 [71]	+ / V	+ / V					
	Burwinkle 2015 [19]	? / A	? / V					
	Eiger 2023 [48]			+ / V	? / V			
	Wei 2015 [207]	? / A	? / I	+ / D			a. + / A	

TSK-TMD	LaTouche 2020 [101]	+ / V	+ / V	+ / D	? / D	a. + / A
	Aguiar 2017 [4]	+ / V	+ / V	+ / D	? / D	a. + / D
	Visscher 2010 [198]	+ / V	+ / V	- / A		a. ? / A
	He 2016 [70]		? / V	+ / D		a. ? / I

“V” = very good, “A” = adequate, “D” = doubtful, “I” = inadequate; “+” = sufficient, “–” = insufficient, “±” inconsistent, “?” = indeterminate.

† a. convergent validity; b. known-groups validity.

‡ a. comparison with gold standard; b. comparison with other instruments; c. comparison between subgroups; d. comparison before and after intervention.

Table 7. Evidence synthesis of the validity of PROMs: rating of results, overall level of evidence and recommendation for use.

Rec.	PROM	Language	Validity			Reliability			Responsiveness
			Structural	Construct	Criterion	Internal consistency	Reliability	Measurement Error	
A	CPCI	Brazilian	+ (H)			+ (M)			
	CPCI-42	Italian	+ (M)	+ (VL)		+ (M)	+ (M)		
B	ADAP	Brazilian	? (M)	- (L)		? (H)	+ (L)	? (L)	
	AEQ	German	? (VL)	+ (M)		? (H)			
		Iranian		- (L)		? (H)	+ (L)	? (L)	
		Spanish	? (VL)	+ (M)		? (H)			
	APS	Spanish	+ (H)	+ (H)		± (M)			
	BAT-Back	German		+ (H)		? (H)	+ (H)		
		Turkish	? (M)	± (VL)		? (H)	+ (M)		
	BSFAQ	English / French		+ (VL)					
	CAS-D-65	German		+ (L)		? (H)	? (VL)		
	clin.-rep. FAB	English		- (H)			- (H)		
	CPCI	English	? (VL)	+ (H)		? (H)	+ (L)		+ (VL)
		French	+ (H)			+ (VL)			
	CPCI-42	English	+ (H)	+ (M)	+ (H)	? (H)	+ (M)		+ (VL)
		Chinese	? (M)	+ (M)		? (M)			
		Korean	? (VL)	- (L)		? (VL)	+ (L)		
		Polish		+ (M)		? (H)	+ (L)		
	FABQ	English	? (M)	? (M)		? (M)	+ (M)	? (L)	+ (M)
		Arab		? (M)		? (H)	? (L)		
		Brazilian	? (M)	+ (VL)		? (H)	+ (M)	? (L)	- (L)
		Danish							+ (L)
		Dutch		- (VL)		? (H)			
		Finnish	? (VL)			? (VL)	+ (VL)		
		French	? (M)	+ (VL)			+ (L)	? (L)	+ (L)
		German	? (H)	± (L)		? (H)	? (M)		
		Greek	? (VL)	- (M)		? (VL)	+ (L)		- (M)
		Hausa	? (M)	- (L)	+ (H)	? (M)	+ (M)	? (L)	+ (H)
		Hindi	? (M)	? (VL)		? (M)	+ (L)		

	Igbo	? (M)	- (VL)		? (M)	+ (L)	- (L)	
	Italian	? (H)	+ (VL)		? (H)	+ (M)	? (M)	+ (M)
	Japanese	? (H)	+ (M)		? (H)			
	Kannada				? (H)	+ (L)		
	Marathi		- (VL)		? (H)	+ (L)		
	Norwegian	? (VL)	+ (VL)		? (H)	± (VL)	? (VL)	+ (L)
	Persian	? (M)	+ (M)		? (M)	+ (M)		+ (M)
	Spanish	? (VL)				+ (L)		
	Swedish		- (VL)		? (VL)	+ (VL)		
	Tamil		+ (VL)		? (M)	+ (M)		
	Turkish	? (H)	± (M)		? (H)	+ (L)		- (H)
	Yoruba	? (H)	- (VL)		? (VL)	+ (L)	? (L)	
FACS	Dutch	? (M)	+ (H)		? (H)	+ (L)	? (L)	
	English	? (M)	+ (M)		? (H)	? (L)		- (L)
	French		+ (M)		? (H)	+ (L)		
	Gujarati		+ (M)		? (H)	+ (M)	? (M)	
	Spanish	? (VL)	± (M)		? (VL)			
	Serbian	+ (H)	+ (VL)		+ (H)	+ (L)		
	Turkish	? (M)	- (L)		? (H)	+ (L)		
NRP	English	+ (H)	+ (M)		+ (H)	? (L)		
PARQ	English	? (M)	+ (M)		? (H)			
PASS	English		+ (L)		? (H)			
	Dutch		- (VL)		? (H)			
PASS-20	English	? (M)	+ (M)	+ (H)	? (H)	? (VL)		
	German	? (M)	+ (M)		? (H)			
	Korean	- (VL)	+ (L)		? (H)	+ (VL)		
PCI	Dutch		+ (VL)		? (L)	? (VL)		
PIPS	Dutch	+ (H)	+ (VL)		+ (H)			
	German	+ (H)	+ (L)		+ (H)			
	Japanese	+ (H)	? (L)		+ (H)	? (L)		
	Spanish	? (M)	+ (L)		? (H)	+ (L)		
	Swedish	+ (H)	+ (M)		+ (H)			
POAM-P	English		+ (L)		? (H)			? (VL)
	French		+ (VL)		? (H)	+ (L)		
TSK	English	± (H)	+ (H)		? (H)	+ (M)	? (VL)	+ (H)

		Arabic		+ (VL)		? (M)	+ (L)		
		Brazilian		+ (VL)		? (H)	+ (L)		+ (VL)
		Danish					+ (H)	? (H)	
		Finnish				? (M)	+ (VL)		
		Greek		+ (L)		? (H)	+ (L)		
		Gujarati	? (M)	- (M)		? (VL)	- (L)	? (L)	
		Japanese		+ (M)		+ (VL)			
		Norwegian	? (M)	+ (VL)		? (H)	- (VL)		? (L)
		Persian		+ (M)		? (H)	+ (L)		+ (M)
		Swedish		- (VL)		? (L)	+ (VL)		
		Thai		- (VL)		? (M)	+ (VL)		
	TSK-11	Brazilian	? (M)	- (H)	+ (H)	? (H)	+ (M)	± (L)	- (VL)
		Chinese	? (M)	- (M)		? (H)	+ (L)		
		Danish					+ (H)	? (H)	
		Japanese		+ (M)		? (VL)			
		Marathi		+ (L)		+ (H)	+ (L)		
		Spanish	? (M)	- (M)		? (M)	? (VL)		? (VL)
	TSK-13	Danish					+ (H)	? (H)	
		Dutch	+ (M)			+ (H)			
		Portuguese	? (VL)	+ (VL)		? (VL)	+ (L)		- (L)
	TSK-TMD	Dutch	+ (H)	? (M)		+ (H)	± (M)		
		Brazilian	+ (H)	+ (L)		+ (H)	+ (L)	? (L)	
		Chinese		? (VL)		? (H)	+ (L)		
		Spanish	+ (H)	+ (L)		+ (H)	+ (L)	? (L)	
C	FABQ	Chinese	- (H)	+ (L)		? (H)	+ (H)		- (L)
		Gujarati	- (H)	- (H)		? (H)	+ (L)	? (L)	+ (VL)
		Swiss-German	- (H)	- (VL)		? (H)	+ (L)		
	PASS-20	Chinese	- (H)	+ (L)		? (H)	+ (L)		
	PIPS	Greek	- (H)	+ (VL)		? (H)	? (VL)		
	TSK	Chinese	- (H)	+ (H)		? (M)	+ (L)		
		Dutch	- (H)	+ (M)		- (H)		- (H)	- (M)
		Italian	? (M)	+ (VL)		- (H)	+ (L)	+ (H)	+ (H)
	TSK-11	English	- (H)	± (M)		? (H)	+ (H)	? (L)	+ (H)
		Dutch	+ (H)	+ (M)		- (H)			
		German	+ (H)			- (H)			

	Swedish	- (H)	+ (L)		? (H)	+ (M)
TSK-13	English	- (H)	- (VL)		? (H)	

Rec. = Recommendation; Responsiveness = Responsiveness to change; A = PROM can be recommended for use; B = PROM has potential to be recommended for use; C = PROM should not be recommended for use; “H” = high level of evidence, “M” = moderate level of evidence, “L” = low level of evidence, “VL” = very low level of evidence; “+” = sufficient, “−” = insufficient, “±” inconsistent, “?” = indeterminate.