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Pain and physical functioning in neuropathic pain: a systematic review of psychometric properties of various outcome measures

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ABSTRACT

Introduction: A range of outcome measures across various domains are used to evaluate change following an intervention in clinical trials on chronic Neuropathic pain (NeP). However, in order to capture a real change in the variable of interest, the psychometric properties of a particular measure should demonstrate appropriate methodological quality. Various outcome measures in the domains of pain and physical functioning have been used in the literature for NeP, for which individual properties (e.g., reliability/validity) have been reported. To date, there is no definitive synthesis of evidence on the psychometric properties of those outcome measures, thus the aim of this systematic review was to evaluate the methodological quality [COnsensus based Standards for the selection of health status Measurement INstruments (COSMIN) guidelines] of studies that evaluated psychometric properties of pain and physical functioning outcome measures used for NeP.

Methods: Specific MeSH/key-words related to three areas (pain and/or physical functioning, psychometric properties, and NeP) were used to retrieve relevant studies (English language) in key electronic databases (Medline (Ovid), CINAHL (EBSCO), Scopus, AMED and Web of Science) from database inception- July 2012. Articles retrieval/screening and quality analysis (COSMIN) were carried out by two independent reviewers.

Results: 24 pain and 37 physical functioning outcome measures were identified, varying in methodological quality from Poor-Excellent.

Conclusion: Although a variety of pain and physical functioning outcome measures have been reported in the literature, few have demonstrate methodologically strong psychometric properties. Thus, future research is required to further investigate the psychometric properties of existing pain and physical functioning outcome measures used for clinical and research purposes.

Keywords: neuropathic pain; systematic review; pain; physical function; outcome measures; psychometric properties; reliability; validity; responsiveness

1. INTRODUCTION

Neuropathic pain (NeP) is defined by the International Association for the Study of Pain's Neuropathic Pain Special Interest Group (NeuPSIG) as "*pain arising as a direct consequence of a lesion or disease affecting the somatosensory system*".¹ A range of assessment guidelines have been developed from the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT),² the European Federation of Neurological Societies (EFNS),³ and the NeuPSIG⁴ for NeP clinical trials and for clinical practice. These guidelines advocate a range of measures for assessing the core domains of pain, quality of life, mood, sleep, and functional capacity (physical, cognitive, emotional, and social). This notwithstanding, a variety of outcome measures are available for the above stated domains.² In order to evaluate the applicability of these measures, a systematic review of psychometric properties of available outcome measures used in published trials may provide a useful basis for selecting the best measurement instrument for a specific purpose.^{5,6}

Individual assessment of psychometric properties of available outcome measures is important.^{7,8} As part of this, in reviewing the evidence on available outcome measures, it is important to assess the methodological quality of those studies that investigated psychometric properties.⁹ While in clinical practice adoption of outcome measures will depend on feasibility of use (speed, ease of use, and limited need for an overly sophisticated instrument),¹⁰ emphases should also be given to measures which are proven to be reliable, valid, and responsive/interpretable for a given population.

Pain remains a leading cause of disability at the individual level, associated with functional losses as well as mood disturbances.¹¹ Thus the focus of this systematic review will be in evaluating the psychometric properties of various outcome measures used in the domains of pain and physical functioning in NeP. On examination of the literature, a number of outcome measures have been identified in which have been used to measure pain intensity and physical function in NeP trials,^{5,7,8,12} however, there is limited conclusive evidence on their psychometric properties. Use of reliable and valid outcome measures can help to better evaluate the patient's outcomes in terms of

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3 pain and physical functioning, enabling better management, including the earliest appropriate
4
5 management to minimize risks of co morbidities and disabilities.
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8 Existing evidence on the psychometric properties of pain and physical functioning outcome
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10 measures used in NeP trials have not previously been systematically reviewed. The aim of this
11
12 systematic review was to systematically review and identify the gaps in literature for the evaluated
13
14 psychometric properties (reliability, validity, responsiveness, and interpretability) of identified
15
16 outcome measures for 'pain and physical functioning' as recommended by the IMMPACT guidelines
17
18 in NeP population. This review involved a systematic search of the literature. The findings of the
19
20 current study may assist in outlining the effective intervention strategies for patients with NeP. The
21
22 objectives of this systematic review were:
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26 • Systematically review and identify the type of established psychometric properties for the
27
28 identified outcome measures quantifying pain and physical functioning in neuropathic pain
29
30 populations.
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- 32
33 • Evaluate the methodological quality of the included studies investigating the psychometric
34
35 properties of the identified outcome measures in the domain of pain and physical
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37 functioning in neuropathic pain populations in accordance with the Consensus-based
38
39 Standards for the selection of Health Measurement Instruments (COSMIN) checklist with 4-
40
41 point scale.
42

43 44 2. METHOD

45 46 2.1 Information sources

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49 A systematic search was conducted following the Preferred Reporting Items for Systematic
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51 reviews and Meta-Analyses (PRISMA) guidelines. The following electronic databases were searched:
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53 Ovid Medline, CINAHL, Scopus, AMED, and Web of Science (WOS) (from database inception to 31st
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3 July 2012). The search update engine from the available databases was activated in order to be
4
5 familiar with the new searches in the current field, since the original search.
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8 2.2 Search strategy 9

10
11 The key words and MESH headings in three broad areas (pain and/or physical functioning
12
13 outcome measures, psychometric properties, and NeP) were used in the development of a search
14
15 strategy (Table I). Several strategies were used to develop a comprehensive list of keywords/MeSH
16
17 terms/subject headings representing each area. For outcome measures, all pain and physical
18
19 functioning outcome measures that were used in clinical trials of NeP were chosen. For
20
21 psychometric properties, we chose the standardised terminologies used by the COSMIN frame
22
23 work.⁶ For the terms relating to NeP, MESH terms/ key words indexed for neuropathy, neuralgia,
24
25 and neurodynia were used. Words within each theme were combined with OR and across themes
26
27 with AND. This search strategy was amended for different databases as necessary.
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31 *Insert Table I about here.*
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34 2.3 Study selection 35

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37 Articles identified in the search underwent a series of screening processes. Firstly, duplicate
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39 articles were removed. Two reviewers (PM and LC) independently selected and screened articles for
40
41 potential eligibility at the title and abstract stages. Full text articles of all potentially eligible abstracts
42
43 were retrieved for application of the eligibility criteria. Disagreements between the reviewers
44
45 regarding inclusion of individual studies were discussed during a consensus meeting and, when
46
47 unresolved, were resolved by discussion with other reviewers (PH, CC, and GDB). References of the
48
49 selected papers were further explored for relevant articles.
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51

52 2.4 Eligibility criteria 53 54 55 56 57 58 59 60

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3 Cross sectional studies and longitudinal cohort studies, which included at least one
4
5 assessment of a psychometric property of a pain or functional outcome measure in a NeP population
6
7 (Nep as defined by the Clinical Resource Efficiency Support Team- CREST)¹³ were included. The
8
9 adopted search strategy revealed two distinct categories of evaluations: one intended for screening
10
11 or diagnosis, and the other developed to measure outcomes. Since the focus of this review was to
12
13 investigate the psychometric properties of tools used to measure changes in the status of either pain
14
15 or functional outcomes over time: screening or diagnostic tools were excluded. Studies published as
16
17 case report, editorial, or reviews were also excluded. Only articles published in the English language
18
19 and on humans were selected.
20
21

22 23 2.5 Data extraction and synthesis 24 25

26 A systematic approach to data extraction was carried out by independent reviewers (PM and
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28 LC/ PH/ CC/ GDB), with equal number of articles randomly distributed among the team members.
29
30 Each member extracted the data from the allotted articles, which were then checked for accuracy,
31
32 with consensus meetings and opinions from other reviewers to resolve any disagreements. The
33
34 following data were collected and tabulated from each of the included articles: study reference,
35
36 participant characteristics, outcome measures studied, and type of psychometric properties tested
37
38 (reliability and/or validity) (Table II). Further summary of identified outcome measures with their
39
40 published psychometric properties and COSMIN grading were synthesized (Table IV & V). Results
41
42 from excellent and good methodological quality studies based on COSMIN criteria (as stated in Table
43
44 VI) were used to formulate recommendations for acceptable psychometric properties scores (for
45
46 definitions of acceptable, good and excellent scores see Table VI).
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50 51 2.6 Methodological quality of individual studies reporting on psychometric properties 52 53

54 Whereas a variety of tools are available to measure the methodological quality of studies that
55
56 report on scale development and assessed psychometric properties, the Consensus-based Standards
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3 for the selection of Health Measurement Instruments (COSMIN)⁶ checklist; developed by an
4
5 international group of experts, is unique and preferred because it allows for individual assessment of
6
7 each psychometric domain within a study.
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10 The COSMIN checklist¹⁴ (Table III) consists of 'A to J' nine boxes (Internal consistency- Box A;
11 Reliability- Box B; Measurement error- Box C; Content validity- Box D; Structural validity- Box E;
12 Hypotheses testing- Box F; Cross-cultural validity- Box G; Criterion validity- Box H; Responsiveness-
13 Box I; Interpretability- Box J), with 5–18 items concerning methodological standards for how each
14 measurement property should be assessed. According to COSMIN guidelines, the methodological
15 quality of a study is considered adequate if all items in a box (A to J) were considered adequate. For
16 this, each item was scored on a 4-point rating scale (i.e., "poor", "fair", "good", or "excellent"). The
17 primary investigator (PM) independently scored all articles and the results were discussed and
18 consensus obtained with each relevant team member. Methodological quality was determined using
19 the 'lowest rating score'⁶ achieved by any item for the representative psychometric property.
20 Therefore, if one criterion for any property scored 'poor', the methodological quality for that
21 particular property was rated as 'poor' overall, irrespective of the scores that other criteria achieved.
22 Disagreements regarding COSMIN scoring were resolved by discussion between reviewers.
23 Reviewers were not blinded to the journal affiliation or authors of the included articles.
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41 *Insert Table III about here.*
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44 3. RESULTS

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47 Figure 3.1 illustrates the study selection process. The search resulted in 10,913 articles. After
48 accounting for duplicate removal, title screening, and abstract screening, 80 articles were identified
49 and retrieved as potentially eligible for the review. While checking the eligibility of full text articles, a
50 further 16 articles were excluded from the review as two articles were editorial papers; two were
51 commentary papers; five articles were based on cancer pain; three papers were PhD publications;
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3 and for the remaining four, full text article were not available. Thus total of 64 articles satisfied our
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5 eligibility criteria and were included in this review.
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8 *Insert Figure I about here*
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10 3.2 Characteristics of included studies 11

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14 In total, 64 studies reporting 61 different outcome measures were identified. The included
15
16 studies evaluated the psychometric properties of pain outcome domains (n=24) and physical
17
18 function outcome domains (n= 37), (Table II). For the 24 pain intensity outcome measures, fifteen
19
20 (63%), measures were patient-reported/self-reported measures, and the rest nine (37%) were the
21
22 therapist/ clinician completed measures. For the 37 physical function outcome measures, seventeen
23
24 (46%) measures were patient-reported/ self-reported measures i.e. symptomatic assessment
25
26 (subjective), nine (24%) measures were performance based measures, and the rest of the eleven
27
28 (30%) measures were therapist completed measures i.e. symptoms and signs (subjective and
29
30 objective testing). The synthesis of results per/ outcome measure, their published psychometric
31
32 properties, and quality assessment scores for studies, are detailed in Table IV and V. Data on the
33
34 characteristics of the study population and sample population were extracted on the interpretability
35
36 and generalizability boxes provided by the COSMIN checklist. Information regarding the sample size
37
38 and gender distribution is reported in Table II.
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42 *Insert Table II about here.*
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45 3.2.1 Pain intensity outcome measures 46

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49 Pain domain outcomes (Table II, and IV) included: Brief Pain Inventory Scale for Diabetic
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51 Peripheral Neuropathy;¹⁵ Complex Regional Pain Syndrome Severity Score;¹⁶ Diabetes Symptom
52
53 Checklist Type-2;¹⁷ Foot Function Index (pain subscale);¹⁸ Italian Neuropathic Pain Symptom
54
55 Inventory;¹⁹ McGill Pain Questionnaire;²⁰ modified Toronto Clinical Neuropathy Score;²¹ Neuropathic
56
57 Pain Scale;²²⁻²⁴ Neuropathic Pain Sensory Inventory;^{25,26} 0-10 Numerical Rating Scale;²⁷ Neuropathy
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3 Total Symptom Score-6;²⁸ 0-10 point Pain Intensity- Numerical Rating Scale;²⁹ Pain Quality
4
5 Assessment Scale;^{30,31} Portuguese version of the Neuropathic Pain Symptoms Inventory;³²
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7 Quantitative Sensory Testing (hot and cold pain threshold);³³⁻³⁵ Sensory evaluation with Semmens-
8
9 Weinstein Monofilaments;³⁶ Short-form McGill Pain Questionnaire-2;³⁷ Spanish Neuropathic Pain
10
11 Symptom Inventory;³⁸ Toronto Clinical Scoring System;³⁹ Total Neuropathy Score;⁴⁰ Trauma Related
12
13 Neuronal Dysfunction Symptoms Inventory;⁴¹ Utah Early Neuropathy Scale;⁴² Visual Analog Scale;⁴³
14
15 and Zoster Brief Pain Inventory.^{44,45}
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18 19 3.2.2 Physical functioning outcome measures

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21 The range of physical functioning outcome measures was equally extensive, and included
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23 (Table II, and V): Alderson-McGall Hand Function questionnaire;⁴⁶ Barthel Index;⁴⁷ Berg Balance
24
25 Measure;⁴⁸ Brief Pain Inventory Facial;⁴⁹ Charcot-Marie-Tooth disease Neuropathy score;^{50,51}
26
27 Charcot-Marie-Tooth disease Neuropathy Score-2;⁵² Disabilities of Arm, Shoulder and Hand
28
29 Questionnaire;⁵³⁻⁵⁶ Deambulation Index;⁴⁷ Dellon-modified Moberg pick-up test;⁵⁷ Facial Disability
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31 Index;⁵⁸ Functional Dexterity test;⁵⁹ Human Activity Profile;⁶⁰ INCAT The Overall Disability Sum
32
33 Score;⁶¹ Inflammatory neuropathy Sensory Score;⁶² Levine-Katz Questionnaire;⁵⁶ Michigan Hand
34
35 Outcome Questionnaire;⁵³ modified Neuropathy Disability Score;⁶³ 10-Meter walking test;^{48,64} Nine-
36
37 Hole Peg test;⁶⁴ Neuropathy Impairment Score;⁵¹ Overall Disability Sum Score;⁶⁵ Overall Neuropathy
38
39 Limitations Scale;^{64,66} Patient Evaluation Measure;⁵³ Physical Performance Measures (6 minute walk
40
41 test, Timed up and go test);⁶⁷ Questionnaire Rising and Sitting down;⁶⁸ Radboud skills
42
43 Questionnaire;⁶⁹ short form Screening of Activity Limitation and Safety Awareness Scale;^{70,71} Step
44
45 Activity Monitor;⁷² Step Activity Monitor (4 min walk test);⁷³ Sheehan Disability Scale;⁷⁴ Sollerman
46
47 Hand function test;⁵⁹ Turkish version of the Boston Questionnaire;⁷⁵ Ulnar Neuropathy at the Elbow
48
49 Questionnaire;⁷⁶ 12-Item Multiple Sclerosis Walking Scale;⁷⁷ Walking Stairs Questionnaire;⁶⁸ Work
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51 stimulation tasks (knob turn, Linear motion, and Lever arm);⁷⁸ and Zoster Impact Questionnaire.⁴⁵
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3 3.3 Methodological quality of studies evaluating psychometric properties of pain intensity and
4
5 physical functioning outcome measures
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8 3.3.1 Reliability 9

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11 The majority of the instruments included in our review were not tested for all psychometric
12 properties listed on COSMIN checklist. Forty four of the sixty four studies (68%) assessed various
13 forms of reliability (Internal consistency, inter-rater reliability, intra-rater reliability, test-retest
14 reliability, and measurement error) and showed a mixed methodological quality of evidence
15 (excellent/good/fair/poor), when evaluated on COSMIN (Table IV and V). The key results for
16 reliability showed that the BPI-DPN, and the SF-MPQ2 have excellent ($\alpha > 0.90$) internal consistency.
17 The mTCNS has good internal consistency ($\alpha = 0.81-0.90$), inter-rater reliability, and intra-rater
18 reliability (ICC or K= 0.81-0.90). The hot and cold pain thresholds on the QST have good inter-rater
19 and test-retest reliability (ICC or K= 0.81-0.90). The Spanish NPSI has excellent internal
20 consistency ($\alpha > 0.90$) with good test-retest reliability (ICC or K= 0.81-0.90). Measurement error was
21 the least reported form of reliability, and the TRNSI had good test-retest reliability (ICC or K= 0.81-
22 0.90) and measurement error (see Table IV). These measures with excellent and good psychometric
23 properties scores also scored good/excellent on the COSMIN checklist (as according to COSMIN
24 criteria stated in Table VI).
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42 3.3.2 Validity 43

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45 Validity was the more frequently tested psychometric property, in forty nine of sixty four
46 studies (76%), there was face/content validity, structural validity, construct validity,
47 criterion/concurrent validity, convergent validity, discriminative validity, hypothesis testing, and
48 responsiveness. Similar to the findings for reliability, mixed methodological quality evidence
49 (excellent/good/fair/poor) was found when evaluated on COSMIN (Table IV and V). The key results
50 for validity showed that the NPSI, the SALSA, and the UNEQ have excellent content validity as there
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3 were no concerns raised by the patients or experts regarding the wording of questionnaires, and
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5 thus no further modifications were advised. The UENS has the best criterion validity followed by the
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7 HAP and the mNDS. Approximately one third of the studies (18/49, 36%) evaluated responsiveness
8
9 form of validity. The NPS has excellent responsiveness followed by the 0-10 PI NRS, and the ODSS.
10
11 Also the studies showing these evidences were of excellent/good methodological quality on the
12
13 COSMIN checklist (as according to COSMIN criteria stated in Table VI).
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16
17 *Insert Table IV and V about here.*
18

19 20 **4. Discussion**

21
22 To our knowledge, this is the first systematic review to evaluate the evidence for the
23
24 psychometric properties of pain and physical functional outcome measures used in assessment in
25
26 NeP conditions, and to identify the methodological quality of the studies investigating the
27
28 psychometric properties of various outcome measures. A total of 61 different outcome measures
29
30 were identified related to the domains of pain and physical functioning. In this systematic review,
31
32 while most of the studies have shown good/excellent evidence of reliability and validity of the used
33
34 scales, only few are considered 'excellent to good' in terms of their methodological quality. Our
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36 review identified acceptable reliability and validity (for a few key properties) for the mTCNS, the
37
38 TRNDI, the 0-10 PI NPS, the QST, the SALSA, the Spanish NPSI, the ODSS, the SF-MPQL, the UNEQ,
39
40 the UENS, the HAP, the mNDS, the NDS and the BPI-DPN.
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46 The available studies investigating the psychometric property of reliability were rated in
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48 varying methodological quality from 'poor' to 'excellent' on the COSMIN checklist. However, the
49
50 majority of studies showed similar methodological shortcomings. In this review, smaller sample sizes
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52 were found to be associated with the majority of inconsistent results. According to COSMIN
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54 guidelines,⁶ a sample size of ≥ 100 is considered to be an adequate/ excellent sample size, given the
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56 need for precision in the overall estimates; these estimates are based on the power 0.80.^{79, 25} A
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3 sample size of 50 provides a 0.70 power (level of significance being 0.05), while 100 has a power of
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5 0.94.²⁵
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8 In the current systematic review, many outcome measures seem promising for different
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10 domains of reliability and validity (according to COSMIN criteria stated in Table VI), as the FFI, the
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12 NTSS-6, the AMHFQ, the DASH, the HAP, the ISS, the MHQ, the PEM, the SDS, the TBQ, the UNEQ,
13
14 and the Walk-12 scales have 'moderate' ($\alpha > 0.71-0.80$) to 'excellent' ($\alpha > 0.90$) published grades for
15
16 internal consistency. However, when the methodological quality of the studies were evaluated on
17
18 COSMIN, these were graded of 'poor/fair' quality because of the small sample size. These findings
19
20 are consistent with those of a recent systematic review on outcome measures in neck pain, where
21
22 smaller sample sizes frequently led to poorer results.⁸⁰ This current review recommends that future
23
24 research on a larger sample size ($n \geq 100$, as recommended by COSMIN) is needed to improve the
25
26 quality of research on these measures.
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30 Validity was the most frequently evaluated psychometric property in both pain and physical
31
32 functioning outcome domains. The majority of these studies demonstrated unsatisfactory (poor/fair
33
34 scores) results on COSMIN. The main reasons for this were inconsistencies in the following areas:
35
36 smaller sample sizes; hypotheses were not formulated; and expected direction/magnitude of
37
38 correlations was not stated in advance. Other common findings were a lack of information about
39
40 reporting of missing items, and measures adopted to handle missing data. Though these two items
41
42 did not contribute to the overall 'poor' grading on the COSMIN, it is expected that studies of 'good'
43
44 methodological quality should report this construct, as a high number of missing items can introduce
45
46 bias.
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49
50 A further interesting finding of this review was that responsiveness was the least frequently
51
52 studied psychometric property for the included pain and physical functioning outcome measures.
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54 There were a total of 18 studies which published the findings on responsiveness and only three
55
56 scales- the NPS, the 0-10 PI NRS and the ODSS proved satisfactory methodological quality on
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3 COSMIN. The remaining measures were graded 'fair to poor', and all the above stated shortcomings
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5 (small sample size, un-reporting of missing items, vagueness about how the missing data were
6
7 handled, not well formulated hypothesis etc.) equally contributed to the inconsistent results for the
8
9 studies reporting on this property.
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11
12 In the current systematic review, there were few measures identified which had promising
13
14 psychometric properties for key variables: the mTCNS (good internal consistency, inter-rater and
15
16 intra-rater reliability and criterion validity); the TRNSI, and the ZBPI (good test-retest reliability);
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18 the NPSI (excellent face/content validity); the 0 to 10 PI NRS (good responsiveness); the QST- pain
19
20 threshold (good intra-rater and test-retest reliability); the NPS (excellent responsiveness); and the
21
22 SALSA (excellent internal consistency and content validity), and were supported by a "excellent to
23
24 good' methodological quality on the COSMIN checklist. The future use of these measures can be
25
26 recommended based on their proven psychometric properties; however, it is imperative that other
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28 remaining psychometric properties of these outcome measures should also be established.
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33 We also identified a list of instruments which showed their best methodological quality for
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35 few psychometric properties on COSMIN, but at the same time good methodological quality
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37 evidence was lacking for other properties: the TCSS (good construct validity, but poor inter and intra-
38
39 rater reliability); the Short-form MPQ- 2 (excellent internal consistency, but fair construct validity
40
41 and responsiveness); the HAP (good criterion validity, with poor internal consistency and
42
43 responsiveness and fair hypothesis testing); the ODSS (good responsiveness but fair inter-rater and
44
45 intra-rater reliability and construct validity); the UNEQ (excellent content validity, fair test-retest
46
47 reliability, and poor internal consistency, construct validity, and responsiveness); the TBQ (good
48
49 construct validity, fair test-retest reliability, and poor internal consistency); the UENS (excellent
50
51 criterion validity, with poor inter-rater reliability and responsiveness); and the BPI-DPN (excellent
52
53 internal consistency and discriminative validity, fair construct validity and poor criterion validity).
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55 Since study methodology may influence results for psychometric properties, it is recommended that
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3 further evaluation of these psychometric properties with studies of improved methodological quality
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5 should be carried out.
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8 Limitations 9

10
11 Firstly, it is acknowledged that 'Neuropathic Pain conditions' is an umbrella term which
12 covers a range of different conditions such as diabetic neuropathy, trigeminal neuralgia, and post
13 herpetic neuralgia.⁸¹ For the search strategy, MESH terms/ key words indexed for neuropathy,
14 neuralgia, and neurodynia were used to be as inclusive as possible. It is acknowledged that each
15 condition could have been separately searched, and that such an approach may have lessened the
16 chances of missing studies.
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25 Secondly, psychometric properties such as reliability and validity, including responsiveness,
26 are sub classified into various forms such as internal consistency, inter-rater/test retest reliability,
27 content validity, minimal important difference, and standard error of measurement etc.⁸² For the
28 current search strategy, keywords in three broader areas (reliability and/or, validity and/or, and
29 responsiveness) were used rather than individual sub classified keywords. However, since these
30 broader terms are the most commonly used to denote the various forms of psychometric properties,
31 it is anticipated that the majority of studies would have been selected.
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41 Lastly, for this systematic review, multidisciplinary, international consensus-based
42 methodological quality reporting guidelines, COSMIN, were followed for rating the quality of
43 included studies of psychometric properties. The COSMIN checklist has well developed data
44 extraction forms with detailed instructions for completion. The 4-point rating scale classifies each
45 assessment of a measurement property as 'excellent, good, fair, or poor', based on the scores of the
46 items in the corresponding COSMIN box. The methodological quality of a study is considered
47 adequate if all items in a box (A to J) are considered adequate. However, frequently not all items in a
48 box are scored adequate, and it is not feasible to provide overall definitive grade for each
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3 psychometric property; thus no decisions can be drawn for the methodological quality of the studies
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5 based purely on COSMIN findings.
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8 Conclusion

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11 In this review we evaluated the evidence for psychometric properties of 61 unique outcome
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13 measures identified to assess pain and physical functioning outcome domains in trials of NeP
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15 conditions. We have presented extensive data which demonstrate the psychometric properties of
16
17 these available outcome measures, and recommend the use of the mTCNS, the TRNSI, the ZBPI, the
18
19 NPSI, the 0 to 10 PI NRS, the QST- pain threshold, and the NPS to detect changes in pain intensity
20
21 and physical functions. We found that important information regarding the methodological quality
22
23 of the majority of studies demonstrating these psychometric properties is lacking or is of poor
24
25 quality. Since NeP is a multi-disabling condition with significant associated morbidity, usage of
26
27 quality evidenced pain and physical functional measures is a key recommendation for future
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29 research in NeP intervention studies. It appears that despite representing these measures in many
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31 studies of NeP, the methodological quality for most of the measures is not strong enough to
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33 recommend their use based on their psychometric properties. Thus, good quality future research is
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35 required to further investigate the psychometric properties of identified outcome measures used for
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37 clinical and research purposes.
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FIGURE LEGENDS

Figure I Flow diagram summarising study selection process

Table I Search Strategy

Theme 1	AND	Theme 2	AND	Theme 3
Psychometric properties		Pain and/or Physical functional Outcome measures		Neuropathic Pain
Clinometric properties OR		Visual Analog Scale OR		Pain OR
Validity OR		Numerical Pain Rating scale OR		Nerve pain OR
Reliability OR		McGill pain rating scale OR		Neuralgia OR
Sensitivity OR		Pain disability index OR		Neurodynia
Responsiveness OR		Functional component of The Western Ontario		OR
Minimal(ly) clinically important		and McMaster Universities Arthritis Index OR		Neuropathy
difference OR		Timed scored functional activity OR		
Minimal(ly) clinically important		Functional reach test OR		
change OR		Timed 9.1 metre to walk OR		
Minimum detectable change OR		Disability of the arm shoulder and hand		
Smallest detectable change		questionnaire OR		
		Ulnar Neuropathy at Elbow questionnaire OR		
		Daily activities by Verbal Rating Scale OR		
		Function interference by Numerical Rating Scale		

Table II Summary of included studies

Reference	Participant's characteristics	Outcome measures studied	Psychometric properties tested
Alderson & McGall 1999	Carpal Tunnel Syndrome n= 17 Gender = 5 M, 12 F	Alderson-McGall hand function questionnaire	Reliability- Internal consistency, test-retest reliability; Validity- Convergent validity
Amirjani et al. 2011	Carpal Tunnel Syndrome n= 162 Gender = 120 M, 42 F	Dellon-modified Moberg pick-up test	Reliability- test-retest reliability; Validity- Discriminative validity
Asad et al. 2010	Type 2 diabetics sensorimotor NeP n= 60 Gender = not mentioned	modified Neuropathy Disability Score	Validity- Criterion validity
Bastyr et al. 2005	Diabetic peripheral NeP n= 205 Gender = 122 M, 83 F	Neuropathy Total Symptom Score- 6	Reliability- Internal consistency, test-retest reliability; Validity- Construct & Convergent validity, Responsiveness
Bouhassira et al. 2004	Peripheral and Central NeP n= 176 Gender = 97 M, 79 F	Neuropathic Pain Symptom Inventory	Reliability- test-retest reliability; Validity- Face validity, Structural validity, Criterion validity, Convergent validity, Divergent validity, Responsiveness

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Bril & Perkins 2002	Type 1 and 2 diabetic	n= 89	Toronto Clinical Scoring System	Reliability- inter-rater, intra-rater reliability;
	NeP	Gender = 65 M, 24 F		Validity- Construct validity
Bril et al. 2009	Diabetic sensorimotor	n= 65	modified Toronto Clinical	Reliability- Internal consistency, inter-rater, intra-
	poly NeP	Gender = 40 M, 25 F	Neuropathy Score	rater reliability;
				Validity- Criterion validity
Collins et al. 2008	Complex regional pain	n= 27	Trauma Related Neuronal	Reliability- test-retest reliability & Measurement
	syndrome-I	Gender = 5 M, 22 F	Dysfunction Symptoms Inventory	error
Coplan et al. 2004	Herpes Zoster	n= 121	Zoster Brief Pain Inventory	Reliability- test-retest reliability;
		Gender = 45 M, 76 F	Questionnaire	Validity- Hypothesis testing
Cornblath et al.	Diabetic poly NeP	n= 30	Total Neuropathy Score	Reliability- inter-rater & intra-rater reliability;
1999		Gender = 18 M, 12 F		Validity- Construct validity
Crawford et al.	Neuropathic Pain	n= 130	Neuropathic Pain Symptom	Validity- Content validity
2008		Gender = 70 M, 60 F	Inventory questionnaire	
Davidoff et al. 1988	Reflex Sympathetic	n= 17	Visual Analog Scales	Validity- Hypothesis testing
	Dystrophy Syndrome	Gender = 5 M, 12 F		
de Andrade et al.	Neuropathic Pain	n= 94	Portuguese Neuropathic Pain	Reliability- test-retest reliability;
2011		Gender = 57 M, 37 F	Symptoms Inventory	Validity- Face validity & Construct validity,
				Responsiveness

Pain Practice

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2	Dias et al. 2008	Wrist and hand	n= 26	The Patient Evaluation Measure;	Reliability- Internal consistency, test-retest
3					
4		disorders due to nerve	Gender = not	The Michigan Hand Outcome	Reliability;
5					
6		involvement	mentioned	Questionnaire;	Validity- Construct validity
7					
8				The Disabilities of Arm, Shoulder	
9					
10				and Hand Questionnaire	
11					
12					
13	Dworkin et al. 2009	Diverse chronic pain	n= 1108	Short-form McGill Pain	Reliability- Internal consistency;
14					
15		syndrome;	Gender = 599 M, 509 F	Questionnaire- 2	Validity- Construct validity, Responsiveness
16					
17		Diabetic NeP			
18					
19	Eklund et al. 2009	Charcot-Marie-Tooth	n= 20	The Disabilities of Arm, Shoulder	Validity- Hypothesis testing
20					
21		disease	Gender = 9 M, 11 F	and Hand Questionnaire	
22					
23					
24	Erdmann et al.	Chronic idiopathic	n= 30	Berg Balance Measure;	Validity- Hypothesis testing
25					
26	2005	demyelinating	Gender = 17 M, 13 F	10 meter walk test	
27					
28		polyneuropathy;			
29					
30		Multifocal Mono			
31					
32		neuropathy			
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35	Farrar et al. 2010	Diabetic peripheral NeP;	n= 1700	0 to 10 Numeric Rating Scale	Validity- Responsiveness
36					
37		Fibromyalgia syndrome	Gender = 680 M, 1020 F		
38					
39	Farrar et al. 2001	Diabetic peripheral NeP;	n= 984	0 to 10 point Pain Intensity	Validity- Responsiveness
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		Post Herpetic Neuralgia	Gender = 567 M, 417 F	Numerical Rating Scale	
Farrell et al. 1996		Post Herpetic Neuralgia	n= 31	Human Activity Profile	Reliability- Internal consistency;
			Gender = not mentioned		Validity- Criterion validity & Hypothesis testing, Responsiveness
Felix & Widerstrom-Noga 2009		NeP related to Spinal Cord Injury	n= 22 Gender = 19 M, 3 F	Quantitative Sensory Testing (cold and heat pain thresholds)	Reliability- inter-rater & test-retest reliability; Validity- Construct validity
Galer & Jensen 1997		Post Herpetic Neuralgia; Diabetic NeP; Peripheral Nerve Injury	n= 160 (69; 24; 67) Gender = not mentioned	The Neuropathic Pain Scale	Validity- Hypothesis testing- Discriminative validity & Predictive validity
Geber et al. 2011		Peripheral Nerve lesion; Other neuropathies	n= 60 Gender = 37 M, 23 F	Quantitative Sensory Testing (heat, cold, mechanical and pressure pain threshold)	Reliability- inter-rater & test-retest reliability
Graham & Hughes 2006		Peripheral NeP	n= 65 Gender = 36 M, 29 F	12-Item Multiple Sclerosis Walking Scale	Reliability- Internal consistency & test-retest reliability; Validity- Hypothesis testing
Graham & Hughes 2006		Peripheral NeP	n= 100 Gender = 51:49	The Overall Neuropathy Limitations Scale	Reliability- Internal consistency, inter-rater, test-retest reliability;

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3					Validity- Content validity & Construct validity,
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5					Responsiveness
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7	Harden et al. 2010	Complex and non-	n= 155	Complex regional pain syndrome	Validity- Concurrent validity
8		complex regional pain	Gender = 68 M, 87 F	severity score	
9		syndrome			
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13	Helme et al. 1989	Chronic Neuropathic	n= 49	McGill Pain Questionnaire	Validity- Concurrent validity
14		Pain due to Post	Gender = 10 M, 39 F		
15		Herpetic Neuralgia			
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19	Jensen et al. 2005	Peripheral NeP	n= 133	The Neuropathic Pain Scale	Validity- Responsiveness
20			Gender = 63 M, 70 F		
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22					
23	Jensen et al. 2006	Diabetes related foot	n= 159	The Neuropathic Pain Scale	Validity- Responsiveness
24		pain	Gender = 83 M, 76 F		
25					
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28	Jensen et al. 2006	Carpal Tunnel Syndrome	n= 40	Pain Quality Assessment Scale	Validity- Responsiveness
29			Gender = 12 M, 2 F		
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31					
32	Jensen et al. 2010	Carpal Tunnel Syndrome	n= 100	Pain Quality Assessment Scale	Reliability- Internal consistency;
33			Gender = 75 M, 25 F		Validity- Construct validity
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37	Kilmer et al. 2000	Hereditary motor and	n= 9	Work stimulation tasks;	Reliability- test-retest reliability;
38		sensory NeP	Gender = 3 M, 6 F	Hand-held dynamometry	Validity- Construct validity
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Lee et al. 2010	Typical & atypical facial pain due to Trigeminal Neuralgia	n= 156 Gender = 58 M, 98 F	Brief Pain Inventory- Facial	Reliability- Internal consistency; Validity- Construct validity
Manor et al. 2008	Peripheral NeP	n= 20 Gender = 8 M, 12 F	Physical Performance Measures	Reliability- test-retest reliability
Maser et al. 1989	Diabetic neuropathy	n= 100 Gender = 54 M, 46 F	Quantitative sensory testing (thermal sensitivity)	Reliability- inter-rater reliability
Melchior & Velema 2011	Leprosy related Neuropathic Pain	n= 25 Gender = not mentioned	Screening of Activity Limitation and Safety Awareness Scale	Validity- Construct validity
Merkies & Schmitz 2006	Guillain Barré Syndrome; Chronic idiopathic demyelinating polyneuropathy	n= 20 Gender = 12 M, 8 F	The INCAT Overall Disability Sum Score	Validity- Concurrent validity
Merkies et al. 2002	Neuropathic Pain	n= 113 Gender = not mentioned	The Overall Disability Sum Score	Reliability- inter-rater & intra-rater reliability; Validity- construct validity, Responsiveness

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2	Merkies et al. 2000	Neuropathic Pain	n= 113	Inflammatory Sensory Score	Reliability- Internal consistency, inter-rater, intra-
3					rater reliability;
4			Gender = not		
5					
6			mentioned		Validity- Construct validity, Responsiveness
7					
8	Mondelli et al.	Ulnar Neuropathy at	n= 292	Ulnar neuropathy at the elbow	Reliability- Internal consistency & test-retest
9					
10	2006	Elbow;	Gender = 103 M, 189 F	Questionnaire	reliability;
11					
12		Carpal Tunnel Syndrome			Validity- content validity & construct validity,
13					Responsiveness
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17	Murphy et al. 2011	Charcot-Marie-Tooth	n= 34	Charcot-Marie-Tooth disease	Reliability- inter-rater & intra-rater reliability
18					
19		disease	Gender = not	neuropathy score- 2	
20					
21			mentioned		
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24	Novak et al. 2010	Peripheral Nerve injury	n= 124	The Disabilities of Arm, Shoulder	Reliability- Internal consistency;
25					
26			Gender = 83 M, 41 F	and Hand Questionnaire	Validity- Construct validity
27					
28	Novak et al. 2004	Type 2 diabetic NeP	n= 30	Foot Function Index (pain sub	Reliability- Internal consistency;
29					
30			Gender = 10 M, 20 F	scale)	Validity- Hypothesis testing
31					
32	Oerlemans et al.	Reflex Sympathetic	n= 54	The Radboud skills Questionnaire	Reliability- inter-rater & test-retest reliability;
33					
34	2000	Dystrophy Syndrome	Gender = 10 M, 44 F		Validity- Construct validity
35					
36					
37	Padua et al. 2008	Charcot-Marie-Tooth	n= 211	Barthel Index;	Validity- Construct validity
38					
39		disease	Gender = 84 M, 127 F	Deambulation Index	
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Padua et al. 2009	Peripheral Nerve disease	n= 392 Gender = 218 M, 174 F	Italian Neuropathic Pain Symptom Inventory	Reliability- test-retest reliability; Validity- Construct validity, Responsiveness
Perez et al. 2002	Complex regional pain syndrome-1	n= 21 Gender = 4 M, 17 F	Walking stairs Questionnaire; Questionnaire rising and sitting down	Reliability- test-retest reliability
Rejas et al. 2008	Neuropathic Pain	n= 603 Gender = 211 M, 392 F	Sheehan Disability Scale	Reliability- Internal consistency; Validity- Responsiveness
Schmader et al. 2007	Herpes Zoster	n= 165 Gender = 66 M, 99 F	Zoster Impact Questionnaire; Zoster Brief Pain Inventory	Validity- Hypothesis testing
Schreuders et al. 2008	Charcot-Marie-Tooth disease	n= 45 Gender = 25 M, 20 F	Sensory evaluation with Semmes-Weinstein Monofilaments	Validity- Construct validity
Sezgin et al. 2006	Idiopathic Carpal Tunnel Syndrome	n= 67 Gender = 5 M, 62 F	Turkish version of the Boston Questionnaire	Reliability- Internal consistency & test-retest reliability; Validity- Construct validity
Shy et al. 2005	Charcot-Marie-Tooth disease	n= 60 Gender = not mentioned	Charcot-Marie-Tooth disease neuropathy score	Reliability- Inter-rater & intra-rater reliability; Validity- Construct validity
Shy et al. 2008	Charcot-Marie-Tooth	n= 72	Charcot-Marie-Tooth disease	Validity- Responsiveness

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2		disease	Gender = 48 M, 24 F	Neuropathy Score;	
3					
4				Neuropathy Impairment Score	
5					
6	Singleton et al.	Diabetic peripheral NeP	n= 129	The Utah Early Neuropathy Scale	Reliability- inter-rater reliability;
7					
8	2008		Gender = not		Validity- Criterion validity, Responsiveness
9			mentioned		
10					
11	Smith et al. 2004	Diabetic peripheral NeP	n= 57	Step Activity Monitor	Validity- Hypothesis testing
12					
13			Gender = 57 M, 0 F		
14					
15	Solari et al. 2008	Charcot-Marie-Tooth	n= 40	The Overall Neuropathy Limitations	Reliability- inter-rater & intra-rater reliability
16					
17		disease	Gender = 21 M, 19 F	Scale;	
18				10 m walk;	
19				9 hole peg test	
20					
21	The SALSA Group	Leprosy &Diabetes	n= 568	Screening of Activity Limitation and	Reliability- Internal consistency;
22					
23	2007	related NeP	Gender = 37.6%; 47% F	Safety Awareness Scale	Validity- Content validity
24					
25	Valk et al. 2000	Type I and II Diabetes	n= 78	The Diabetes symptom checklist-	Reliability- test-retest reliability;
26					
27		NeP	Gender = 43 M, 35 F	Type 2	Validity- Construct validity
28					
29	van Schie et al.	Diabetic peripheral	n= 24	Step Activity Monitor (4 minute	Validity- Construct validity & Criterion validity
30					
31	2011	neuropathy	Gender = 17 M, 7 F	walking test)	
32					
33	VanSwearingen &	Facial paralysis	n= 46	Facial Disability Index	Reliability- Internal Consistency;
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Brach 1996		Gender = 16 M, 30 F		Validity- Construct Validity
Videler et al. 2008	Hereditary motor and sensory type 1a neuropathy	n= 49 Gender = 21 M, 28 F	Sollerman Hand function test; Functional dexterity test	Reliability- Internal Consistency & test-retest reliability
Villoria et al. 2011	Chronic Neuropathic Pain	n= 548 Gender = 209 M, 339 F	Spanish Neuropathic Pain Symptom Inventory	Reliability- Internal Consistency, test-retest reliability; Validity- Construct validity
Zelman et al. 2005	Diabetic Peripheral NeP	n= 255 Gender = 114 M, 131 F	Brief Pain Inventory- Diabetic Peripheral Neuropathy scale	Reliability- Internal Consistency; Validity- Construct validity, Discriminative & Criterion validity
Zimmerman et al. 2009	Ulnar nerve injury	n= 48 Gender = not mentioned	The Disabilities of the Arm Shoulder and Hand Questionnaire; Levine-Katz Questionnaire	Validity- Criterion validity & Construct validity

Table III The COSMIN checklist with 4-point scale [Terwee 2012]

Step 1	Evaluated measurement properties in the article: Internal consistency, Reliability; relative measures (including test-retest reliability, inter-rater reliability and intra-rater reliability), Measurement error; absolute measures Content validity (including face validity), Structural validity, Hypothesis testing, Cross-cultural validity, Criterion validity, Responsiveness and Interpretability
Step 2	Determining if the statistical method used in the article are based on Classical Test Theory (CTT) or Item Response Theory (IRT): Box General requirements for studies that applied IRT models: excellent/ good/ fair/ poor
Step 3	Determining if a study meets the standards for good methodological quality: excellent/ good/ fair/ poor
Step 4	Determining the Generalizability of the results

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Table IV Summary of identified pain Intensity outcome measures with their published psychometric properties and COSMIN grading

OMs	Reliability	COSMIN	Validity:	COSMIN	Responsiveness	COSMIN
BPI-	Internal consistency:	excellent	Construct validity:	fair	xx	xx
DPN	<i>Zelman (2005):</i> BPI-DPN showed satisfactory unidimensionality both for the severity and the interference scales (Excellent, $\alpha = 0.94$)		<i>Zelman (2005):</i> BPI-DPN showed satisfactory construct validity for both the severity and the interference scales Discriminant validity: <i>Zelman (2005):</i> Subcomponents of BPI-DPN: the severity and the interference scale showed satisfactory discriminant validity as both are correlated to a different extent with other measures- SF-12, and HADS ($p < 0.001$) Criterion validity: <i>Zelman (2005):</i> BPI-DPN severity scale showed high and significant correlations with SF-12v2, and VRS, $r's > 0.66$ at $p < 0.001$	excellent		poor

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5	CRPS	xx	xx	Concurrent validity:	fair	xx
6						xx
7	score			<i>Harden (2010):</i> Higher CRPS scores were significantly		
8				associated with higher Rand 36 scores (pain intensity,		
9				worse physical and social functioning, greater role		
10				limitations due to physical and emotional problems,		
11				and lower energy and emotional well-being)		
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18	dSCT2	test-retest reliability:	fair	Construct validity:	fair	xx
19						xx
20		<i>Valk (2000):</i> Satisfactory test-retest		<i>Valk (2000):</i> dSCT2 showed appropriate correlation		
21		correlation coefficient: severity of		with almost all nerve function tests		
22		sensory alteration (0.89), and				
23		neuropathic pain (0.85)				
24						
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28						
29	FFI	Internal consistency:	poor	Hypothesis testing:	fair	xx
30						xx
31		<i>Novak (2004):</i> FFI pain subscale showed		<i>Novak (2004):</i> FFI pain subscale showed moderate		
32		high unidimensionality (Excellent α =		correlation with 6 meter walk test ($r = -0.449$, $p <$		
33		0.9752)		0.001)		
34						
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37						
38	Italian	test-retest reliability:	poor	Construct validity:	fair	Responsiveness:
39						fair
40	NPSI	<i>Padua (2009):</i> Results showed high		<i>Padua (2009):</i> I-NPSI scores showed significant		<i>Padua (2009):</i> I-NPSI scores
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agreement between I-NPSI scores at two different visits

correlation with DN4, VAS and ID pain changes ($p=0.001$)

represent reliable measurements to assess NeP symptoms and effectiveness of treatment on them

MPQ xx xx **Concurrent validity:** poor xx xx

Helme (1989): MPQ showed a significant correlation with VAS ($r=0.67$), Word descriptor scale ($r=0.67$), and ADL measures ($r=0.53$, $p<0.001$)

mTCNS **Internal consistency:** good **Criterion validity:** excellent xx xx

Bril (2009): mTCNS showed satisfactory unidimensionality (Moderate, $\alpha=0.78$)

Bril (2009): Low but acceptable correlation with TCNS ($\gamma=0.58$)

inter-rater reliability: good

Bril (2009): Satisfactory ICC scores with good reliability (ICC= 0.83, 95% CI)

intra-rater reliability: good

Bril (2009): Satisfactory correlation with

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symptom and sensory test ($\kappa= 0.55-0.73$)

NPS	xx	xx	Hypothesis testing: Descriptive validity-	poor	Responsiveness:	excellen
			<i>Galer (1997):</i> 10 NPS pain descriptors showed minimal overlap between most items ($\gamma < 0.50$)		<i>Jensen (2005):</i> NPS was significantly able to detect changes from pre-treatment to post-treatment scores	t
			Predictive validity:	poor	<i>Jensen (2006):</i> From 10 NPS pain descriptors, seven descriptors (intense, sharp, hot, dull, sensitive, unpleasant, and deep pain) were significantly able to pick up changes in score after treatment	poor
NPSI	test-retest reliability:	fair	Face validity:	fair	Responsiveness:	poor

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Bouhassira (2004): Satisfactory ICC scores with excellent test retest reliability (ICC> 0.90)

Bouhassira (2004): The NPSI was completed accurately and appeared to be fully understood, notably by elderly subjects

Bouhassira (2004): Poor but acceptable correlations with PGIC and CGIC scores

Content validity:

excellent

($\rho= 0.67$; and $\rho= 0.58$)

Crawford (2008): Majority of subjects did not raise any concerns with NPSI. Thus no changes to NPSI were consistently suggested

Structural validity:

fair

Bouhassira (2004): Each of five factors of NPSI corresponded to a relevant clinical component of NeP

Convergent validity:

fair

Bouhassira (2004): Poor but low correlation with global pain intensity measured by a numerical scale ($\rho= 0.60$, $p< 0.001$)

Divergent validity:

fair

Bouhassira (2004): No correlation with anxiety and depression scores measured by HADS ($\rho= 0.27$; and $\rho=$

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For Peer Review

0.32)

Criterion validity:

fair

Bouhassira (2004): Lower but acceptable correlations:

pain with brushing ($\rho= 0.70$), pain due to pressure ($\rho=$

0.73); and pain due to cold ($\rho= 0.66$)

0-10 xx

xx

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Responsiveness:

fair

NRS

Farrar (2010): On ROC

analysis a raw change of -

1.74 and a % change of -

27.9% were associated

with clinically meaningful

change

NTSS-6 **Internal consistency:**

poor

Construct validity:

fair

Responsiveness: MCIDs

fair

Bastyr (2005): NTSS-6 showed

Bastyr (2005): NTSS-6 and NSC scores showed

Bastyr (2005): A change of

satisfactory unidimensionality

moderately positive and significant correlation. ($\Upsilon=$

0.97 points showed a

(Moderate, $\alpha= 0.7$)

0.773-0.885, $p< 0.001$)

reasonable change for

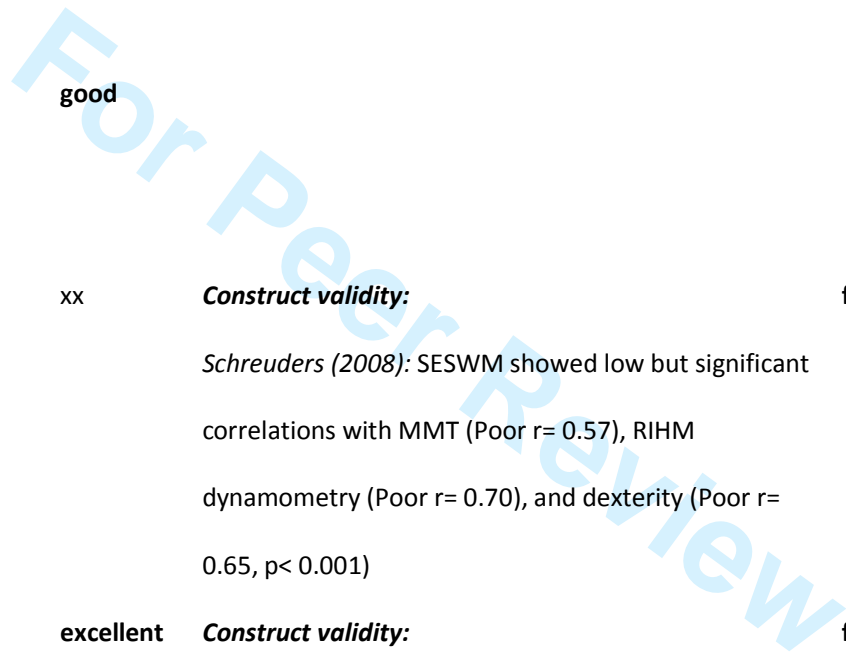
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For Peer Review

	test-retest reliability:	fair	Convergent validity:	fair	minimal improvement.
	<i>Bastyr (2005):</i> Satisfactory ICC scores with lower but acceptable test retest reliability (Baseline ICC= 0.900, End point ICC= 0.903)		<i>Bastyr (2005):</i> NTSS-6 and NSC scores showed poorly positive and significant correlation with changes from baseline ($Y= 0.519-0.708, p< 0.001$)		
0-10 point PI-NRS	xx	xx	xx	xx	Responsiveness: good <i>Farrar (2001):</i> On ROC analysis a raw change of -2, -2.5, and -3 were associated with least, average, and worst pains
PQAS	Internal consistency: <i>Jensen (2010):</i> PQAS showed satisfactory unidimensionality: Deep scale (Moderate $\alpha= 0.75$), surface scale (Poor $\alpha= 0.69$), and paroxysmal scale (Good $\alpha= 0.87$)	fair	Construct validity: <i>Jensen (2010):</i> Three of the PQAS items and scale scores showed significant correlation with concurrent pain interference on BPI ($p< .01$)	fair	Responsiveness: poor <i>Jensen (2006):</i> Ten of the PQAS descriptor items significantly picked up the changes in scores after treatment ($p< .0025$)

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5	P-NPSI	test-retest reliability:	fair	Face validity:	poor	Responsiveness:
6						fair
7		<i>de Andrade (2011):</i> Satisfactory ICC		<i>de Andrade (2011):</i> P-NPSI was filled in less than 8		<i>de Andrade (2011):</i> PV-
8		scores with moderate test retest		minutes by 85% of participants. Prevalence rate= 65%		NPSI change scores show
9		reliability (ICC= 0.7678)		Construct validity:	fair	significant correlation with
10				<i>de Andrade (2011):</i> PV-NSSI showed low but		P-GIC (Good $\rho= 0.727$), and
11				acceptable correlation with NRS: at first visit (Poor $\rho=$		C-GIC scores (Poor $\rho=$
12				0.40, $p < 0.0001$), at second visit (Poor $\rho= 0.53$, $p <$		0.645)
13				0.0001), and change score (Poor $\rho= 0.22$, $p < 0.0001$)		
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22	QST	inter-rater reliability:	good	Construct validity:	poor	xx
23						xx
24		<i>Geber (2011):</i> QST showed significant		<i>Felix (2009):</i> QST showed significant correlation with		
25		inter-rater reliability, $r= 0.83$ (range=		average thermal pain threshold ($r= 0.58$ at $p < 0.02$)		
26		0.56- 0.89, $p < 0.01$)				
27						
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29		<i>Maser (1989):</i> 81% of inter-observer	fair			
30		agreement that QST can be used				
31		adjacent to clinical examination for NeP				
32		assessment				
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test-retest reliability: poor

Felix (2009): Low but acceptable ICC scores: cold, and hot pain (Poor ICCs= 0.50)

Geber (2011): QST showed significant test-retest reliability, r= 0.86 (range= 0.67- 0.93, p< 0.01) good

SESWM xx xx **Construct validity:** fair xx xx

Schreuders (2008): SESWM showed low but significant correlations with MMT (Poor r= 0.57), RIHM dynamometry (Poor r= 0.70), and dexterity (Poor r= 0.65, p< 0.001)

SF- **Internal consistency:** excellent **Construct validity:** fair **Responsiveness:** fair

Dworkin (2009): SF-MPQ-2 showed satisfactory unidimensionality: Web survey data (Excellent, $\alpha = 0.91$), and clinical trial data (Excellent, $\alpha = 0.95$)
Dworkin (2009): SF-MPQ-2 scores showed significant correlation with rating of pain and sleep interference, BPI interference scale scores, the SF- 36 PCS, MCS scores, the HADS anxiety and depression subscale
Dworkin (2009): Both total and sub-scale scores were responsive to changes that were meaningful to

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scores patients

Spanish **Internal consistency:** excellent **Construct validity:** fair xx xx

NPSI *Villoria (2011):* S-NPSI showed satisfactory unidimensionality: total NPSI score ($\alpha > 0.80$), and NPSI sub scores ($\alpha > 0.70$)

Villoria (2011): S-NPSI showed acceptable accuracy to detect responses of pain as defined by either the clinical or the discriminant criteria

test-retest reliability: good

Villoria (2011): Moderate test-retest reliability with satisfactory ICC scores (0.680- 0.810)

TCSS **Inter-rater reliability:** poor **Construct validity:** good xx xx

Bril (2002): Low but acceptable inter-rater reliability (6.3%)

Bril (2002): TCSS showed poor and inverse correlation with SUMAMP and SUMCV ($\Upsilon = 0.424$; $\Upsilon = 0.302$ at $p < 0.0001$; and $p = 0.0044$)

Intra-rater reliability: poor

Bril (2002): Moderate and satisfactory intra-rater reliability (7.3%)

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TNS	inter-rater reliability:	fair		Construct validity:	fair	xx		xx
	<i>Cornblath (1999):</i> Satisfactory ICC			<i>Cornblath (1999):</i> TNS showed significantly high and				
	scores with excellent inter-rater			positive correlation with NIS (Good, $\rho= 0.89$, 95 % CIs)				
	reliability (ICC= 0.938, 95% CIs, $p\geq$			& NSS (Good, $\rho= 0.86$, 95% CIs)				
	0.836)							
	intra-rater reliability:	fair						
	<i>Cornblath (1999):</i> Satisfactory ICC							
	scores with excellent intra-rater							
	reliability (ICC= 0.973, 95% CIs, $p\geq$							
	0.950)							
TRNSDI	test-retest reliability:	good	xx		xx	xx		xx
	<i>Collins (2008):</i> Satisfactory test-retest							
	reliability for CRPS-I and Fibromyalgia							
	(Excellent and Good, ICC= 0.93; and							
	0.83)							
	Measurement error:	good						
	<i>Collins (2008):</i> SEM values were small							

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compared with domain sum scores

(3.5%- 8.3%)

UENS

inter-rater reliability:

poor

Criterion validity:

excellent

Responsiveness:

poor

Singleton (2008): UENS showed a satisfactory high inter-rater reliability (94%)

Singleton (2008): UENS (baseline and changeover scores) showed a close correlation with Michigan Diabetic Neuropathic scale and Neuropathy Impairment Score- Lower Leg ($p < 0.001$)

Singleton (2008): UENS showed a Good diagnostic sensitivity at baseline without sacrificing specificity

VAS

xx

xx

Hypothesis testing:

poor

xx

xx

Davidoff (1988): The VAS had significant correlations with limb volume ($r^2 = 0.160$), active ROM (upper extremity: $r^2 = 0.167$; lower extremity: $r^2 = 0.508$) and joint pain ($r^2 = 0.341$)

ZBPI

test-retest reliability:

good

Hypothesis testing:

good

xx

xx

Coplan (2004): ZBPI showed low but acceptable test-retest reliability (Poor, ICC= 0.63 b/w 5-7 days; Moderate, ICC=

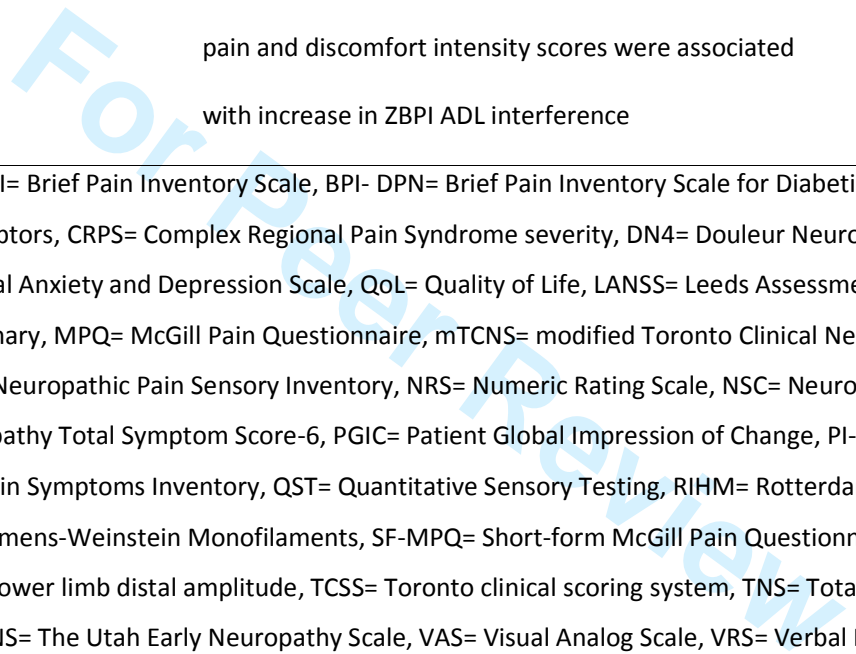
Coplan (2004): ZBPI showed satisfactory and acceptable correlations with MPQ (24 hours: $\gamma > 0.79$ and for 14-35 days $\gamma > 0.65$), ADL (for 14-35 days: γ

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0.78 b/w 8-10 days and 11-14 days after >0.52), and QoL ($\gamma = 0.78$)

rash onset)

Schmader (2007): ZBPI showed a significant **fair** correlation with other domains. Increased composite pain and discomfort intensity scores were associated with increase in ZBPI ADL interference



Abbreviations: ADL= Activities of Daily Living, BPI= Brief Pain Inventory Scale, BPI- DPN= Brief Pain Inventory Scale for Diabetic Peripheral Neuropathy, CGIC= Clinical Global Impression of Change, CPD= Chronic pain descriptors, CRPS= Complex Regional Pain Syndrome severity, DN4= Douleur Neuropathique 4, dSCT-2= diabetes Symptom Checklist Type-2, FFI= Foot Function Index, HADS= Hospital Anxiety and Depression Scale, QoL= Quality of Life, LANSS= Leeds Assessment of Neuropathic pain Symptoms and signs Screening Tool, MCS= Mental Component Summary, MPQ= McGill Pain Questionnaire, mTCNS= modified Toronto Clinical Neuropathy Score, NIS= Neuropathy Impairment Score, NPS= The Neuropathic Pain Scale, NPSI= Neuropathic Pain Sensory Inventory, NRS= Numeric Rating Scale, NSC= Neuropathy Symptom and Change score, NSS= neuropathy sensory symptoms, NTSS-6= Neuropathy Total Symptom Score-6, PGIC= Patient Global Impression of Change, PI-NRS= Pain Intensity Numeric Rating Scale, P-NPSI= Portuguese version of the Neuropathic Pain Symptoms Inventory, QST= Quantitative Sensory Testing, RIHM= Rotterdam Intrinsic Hand Myometer, SEM= Standard Error of Mean, SESWM= Sensory evaluation with Semmens-Weinstein Monofilaments, SF-MPQ= Short-form McGill Pain Questionnaire, SF-12= The Medical Outcomes Study Short Form Health Survey (SF-12), SUMAMP= Sum of lower limb distal amplitude, TCSS= Toronto clinical scoring system, TNS= Total Neuropathy Score, TRNSDI= The Trauma Related Neuronal Dysfunction Symptoms Inventory, UENS= The Utah Early Neuropathy Scale, VAS= Visual Analog Scale, VRS= Verbal Rating Scale, xx= not determined, ZBPI= Zoster Brief Pain Inventory

Table V Summary of identified physical functioning outcome measures with their published psychometric properties and COSMIN grading

OMs	Reliability	COSMIN	Validity	COSMIN	Responsiveness	COSMIN
AMHF	Internal consistency:	poor	Convergent validity:	poor	xx	xx
Q	Alderson (1999): AMHFQ showed satisfactory unidimensionality (Excellent, $\alpha = 0.97$)		Alderson (1999): Poor correlation with dynamic two-point discrimination ($\gamma = -0.32$), static two-point discrimination ($\gamma = -0.127$), the Valpar upper extremity range of motion ($\gamma = -0.2388$), Pain VAS ($\gamma = 0.36$), functional VAS ($\gamma = 0.3688$), grip strength ($\gamma = 0.3867$), three point pinch strength ($\gamma = 0.295$), and lateral pinch strength ($\gamma = 0.151$)			
	test-retest reliability:	poor				
	Alderson (1999): All the items showed consistent results with in 95th percentile confidence limits (Poor – Moderate ICCs)					
BI	xx	xx	Construct validity:	fair	xx	xx
			Padua (2008): Significant relationship b/w ability to walk on toes, strength of lower limbs muscles, abnormal stand-up, abnormal Romberg test, tactile sensory tests; medium relationship with ability to stand up and strength forearm and intrinsic hand			

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			muscles; and lowest relationship with strength of			
			hand intrinsic muscles			
BBM	xx	xx	Hypothesis testing:	fair	xx	xx
			<i>Erdmann (2005):</i> High BBS showed low correlation			
			with 10 MWT and SIP68 scores ($\rho = -0.76$, and $\rho = -$			
			0.62)			
BPI-Facial	Internal consistency:	fair	Construct validity:	fair	xx	xx
	<i>Lee (2010):</i> BPI-Facial showed		<i>Lee (2010):</i> BPI-Facial showed borderline significant			
	satisfactory unidimensionality: entire		correlation with NRS: At least amount of pain (1.01, $p =$			
	instrument (Excellent $\alpha = 0.94$),		0.111), and during the week (0.95, $p = 0.101$)			
	intensity of pain (Good $\alpha = 0.86$),					
	interference with general activities					
	(Good $\alpha = 0.89$), and interference of					
	facial- specific items (Excellent $\alpha =$					
	0.95)					
CMTN	inter-rater reliability:	fair	Construct validity:	fair	Responsiveness:	poor
S	<i>Shy (2005):</i> Satisfactory ICC scores		<i>Shy (2005):</i> CMTNS showed strong and satisfactory		<i>Shy (2008):</i> CMTNS can be	
	with excellent inter-rater reliability		correlations with Ambulation Index ($r = 0.81$), Self-		used satisfactorily to detect	

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(ICC= 0.98, p<0.01)

Assessment Questionnaire (r= 0.76), Hand Function

progression of CMT disease

(r= 0.66), 9 Hole Peg test (r= 0.65), CMTNS ulnar and

intra-rater reliability:

fair

median CMAP amplitudes (r= 0.76, 0.72) and

Neuropathy Impairment Score (r= 0.96)

Shy (2005): The scores from intra-

scoring examination did not

significantly vary on sensory

evaluation

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CMTN **inter-rater reliability:**

poor

xx

xx

xx

xx

S-2 *Murphy (2011):* Satisfactory ICC scores

with excellent inter-rater reliability:

CMTSS2 (ICC= 0.97), and CMTES2

(ICC= 0.96)

intra-rater reliability:

poor

Murphy (2011): Satisfactory ICC scores

with excellent intra-rater reliability:

CMTSS2 (ICC= 0.96), and CMTES2

(ICC= 0.97)

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DASH	Internal consistency:	poor	Construct validity:	poor	xx	xx
	<i>Dias (2008):</i> DASH showed satisfactory unidimensionality (Excellent, $\alpha= 0.98$)		<i>Dias (2008):</i> DASH showed no significant correlations with Gartland and Worley scores ($\Upsilon= -0.33$, 5% level)			
	<i>Novak (2010):</i> DASH showed satisfactory unidimensionality (Excellent, $\alpha= 0.96$)	poor	<i>Zimmerman (2009):</i> DASH showed a significant correlation with grip strength ($r= -0.53$), and pinch strength ($r= -0.49$)	fair		
	test-retest reliability:	poor	<i>Novak (2010):</i> DASH showed a positive correlation with VAS for pain (Poor, $r= 0.51$, $p< 0.001$)	fair		
	<i>Dias (2008):</i> Lower test retest reliability (test-retest differences= -4.7 to 4.9, 95% CIs, $p= 0.02$)		Criterion validity:	fair		
			<i>Zimmerman (2009):</i> DASH scores corresponded strongly with clinical staging ($p< 0.001$)			
			Hypothesis testing:	poor		
			<i>Eklund (2009):</i> DASH showed strong relationship b/w reduced hand function and upper-limb disability: manual dexterity ($r= -0.64$), finger dexterity ($r= 0.83$), grip strength ($r= -0.72$), tactile gnosis ($r= -0.79$), and hand function index ($r= -0.71$)			
DI	xx	xx	Construct validity:	fair	xx	xx

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Padua (2008): DI showed a significant relationship b/w ability to walk on toes, strength of lower limbs muscles, abnormal stand-up, abnormal Romberg test, tactile sensory tests; medium relationship with ability to stand up and strength forearm and intrinsic hand muscles; and lowest relationship with strength of hand intrinsic muscles

DMM	test-retest reliability:	fair	Hypothesis testing: Discriminative validity-	fair	xx	xx
PUT	<i>Amirjani (2011)</i> : Satisfactory ICC scores with excellent test retest reliability (ICC= 0.91 at 95% CI, p< 0.001)		<i>Amirjani (2011)</i> : DMMPUT was significantly able to differentiate between impaired hand functions with mild, moderate and severe CTS			
FDI	Internal consistency:	fair	Construct validity:	fair	xx	xx
	<i>VanSwearingen (1996)</i> : FDI showed a satisfactory unidimensionality (Theta reliability= 0.88)		<i>VanSwearingen (1996)</i> : FDI physical function subscale showed a good correlation with clinician’s physical examination of facial movements			
FDT	test-retest reliability:	fair	xx	xx	xx	xx
	<i>Videler (2008)</i> : Satisfactory ICC scores					

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with good test retest reliability (ICC=

0.83-0.95, 95% CIs)

HAP

Internal consistency:

poor

Hypothesis testing:

fair

Responsiveness:

poor

Farrell (1996): HAP showed

Farrell (1996): HAP showed strong relationship with

Farrell (1996): HAP was

satisfactory unidimensionality

both maximum activity score and adjusted activity

sensitive enough to pick up

(Excellent to Moderate $\alpha = 0.73 - 0.97$)

score (Excellent, $r = 0.97, p < 0.000$)

changes in initial scores at the

Criterion validity:

good

time of discharge

Farrell (1996): HAP showed strong correlation with

maximum activity score (Good $r = 0.78, p < .000$),

adjusted activity score (Good $r = 0.83, p < 0.000$), and

Barthel Index: Self-care (Moderate $r = 0.75, p < 0.000$),

mobilising (Poor $r = 0.61, p < 0.000$)

INCAT

xx

xx

Concurrent validity:

poor

xx

xx

ODSS

Merkies (2006): INCAT ODSS showed low but

significant association with changes in ODSS (Poor $r =$

$0.66, p = 0.007$), Rankin changes (Poor $r = 0.60, p = 0.02$),

and GBS Disability Scale changes (Poor $r = 0.56, p =$

0.04)

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3	ISS	Internal consistency:	poor	Construct validity:	fair	Responsiveness:
4						poor
5		<i>Merkies (2000):</i> ISS showed		<i>Merkies (2000):</i> ISS showed moderate correlations		<i>Merkies (2000):</i> ISS showed
6		satisfactory unidimensionality: First		with the additional scales in the stable group (Poor, r=		significant association of
7		visit (Poor $\alpha= 0.68$), second visit		0.38- 0.56, $p< 0.006$)		patient's grading with the
8		(Moderate $\alpha=0.73$), third visit				clinical judgment scores
9		(Moderate $\alpha= 0.71$), and longitudinal				during follow up ($p< 0.0001$)
10		(Good $\alpha= 0.87$)				
11		inter-rater reliability:	fair			
12		<i>Merkies (2000):</i> Satisfactory ICC scores				
13		with good inter-rater reliability (ICC=				
14		0.85 to 0.89, $p< 0.0001$)				
15		intra-rater reliability:	fair			
16		<i>Merkies (2000):</i> Satisfactory ICC scores				
17		with good intra-rater reliability (ICC=				
18		0.85 to 0.89, $p< 0.0001$)				
19	LKQ	xx	xx	Criterion validity:	poor	xx
20				<i>Zimmerman (2009):</i> LKQ showed a significant		xx
21				correlation with DASH: symptom score ($r= 0.79$), and		

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			function score ($r= 0.87, p< 0.001$)			
			Construct validity:		poor	
			<i>Zimmerman (2009):</i> LKQ function and symptom scores corresponded strongly with clinical staging ($p< 0.001$)			
MHQ	Internal consistency:	poor	Construct validity:	poor	xx	xx
	<i>Dias (2008):</i> MHQ showed satisfactory unidimensionality (Excellent, $\alpha= 0.93$)		<i>Dias (2008):</i> MHQ showed no significant correlations with Gartland and Worley scores ($\gamma= -0.30, 5\%$ level)			
	test-retest reliability:	poor				
	<i>Dias (2008):</i> Lower test retest reliability (test-retest differences= -4.3 to 2.2, 95% CIs, $p= 0.02$)					
mNDS	xx	xx	Criterion validity:	good	xx	xx
			<i>Asad (2010):</i> mNDS proved 92.31% sensitivity and 47% specificity in assessing the sensorimotor neuropathy			
10-	inter-rater reliability:	fair	Hypothesis testing:	poor	xx	xx
MWT	<i>Solari (2008):</i> Satisfactory inter-rater reliability with ICC= 0.97 (CI= 0.88-0.99)		<i>Erdmann (2005):</i> High 10 MWT scores correlated significantly with high SIP68 scores ($\rho= 0.59, p= 0.036$)			

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intra-rater reliability: fair

Solari (2008): Satisfactory intra-rater reliability with ICC= 0.96 (CI= 0.87-0.99)

NHPT **inter-rater reliability:** fair xx xx xx xx

Solari (2008): Satisfactory inter-rater reliability with ICC= 0.95 (CI= 0.89-0.97)

intra-rater reliability: fair

Solari (2008): Satisfactory intra-rater reliability with ICC= 0.95 (CI= 0.89-0.97)

NIS xx xx xx **Responsiveness:** poor

Shy (2008): NIS can be used satisfactorily to detect progression of CMT disease

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ODSS	inter-rater reliability:	fair	Construct validity:	fair	Responsiveness:	good
	<i>Merkies (2002):</i> Satisfactory ICC scores with excellent inter-rater reliability: Experienced examiners (ICC= 0.95), Variable examiners (ICC= 0.90)		<i>Merkies (2002):</i> ODSS showed low correlation with MRC (Poor r= 0.45), INCAT sensory sum score (Poor r= 0.41), and Right & left hand grip strengths (Poor r= 0.54 & 0.53)		<i>Merkies (2002):</i> Scores showed significant association with clinical changes during follow ups (Poor r= 0.66, p= 0.008)	
	intra-rater reliability:	fair				
	<i>Merkies (2002):</i> Satisfactory ICC scores with excellent intra-rater reliability: Experienced examiners (ICC= 0.95), Variable examiners (ICC= 0.93)					
ONLS	Internal consistency:	fair	Content validity:	fair	Responsiveness:	poor
	<i>Graham (2006):</i> ONLS showed satisfactory unidimensionality (Poor, $\alpha= 0.6$)		<i>Graham (2006):</i> The results showed that ONLS is appropriate to use in clinical practice		<i>Graham (2006):</i> ONLS was capable enough to capture a change in activity measures to a similar extent as that of ODSS (SRM= 0.76, 95% CIs)	
	inter-rater reliability:	poor	Construct validity:	fair		
	<i>Graham (2006):</i> Satisfactory ICC scores with excellent test retest reliability (ICC= 0.97)		<i>Graham (2006):</i> ONLS showed a variable correlation with ODSS (Excellent, r= 0.97, p<0.001), 10-meter walk time (Poor, r= 0.58), and MRC score (Poor, r= -0.62)			

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Solari (2008) Satisfactory inter-rater **fair**

reliability with weighted kappa for
arm score= 0.65 (95% CI= 0.44-0.86),
and weighted kappa for leg score=
0.63 (95% CI= 0.41- 0.85)

intra-rater reliability: **fair**

Solari (2008): Satisfactory intra-rater
reliability with weighted kappa for
arm score= 0.75 (95% CI= 0.54-0.96),
and weighted kappa for leg score=
0.68 (95% CI= 0.47- 0.90)

test-retest reliability: **poor**

Graham (2006): ONLS showed
acceptable test-retest reliability as 15
neurologists independently preferred
ONLS

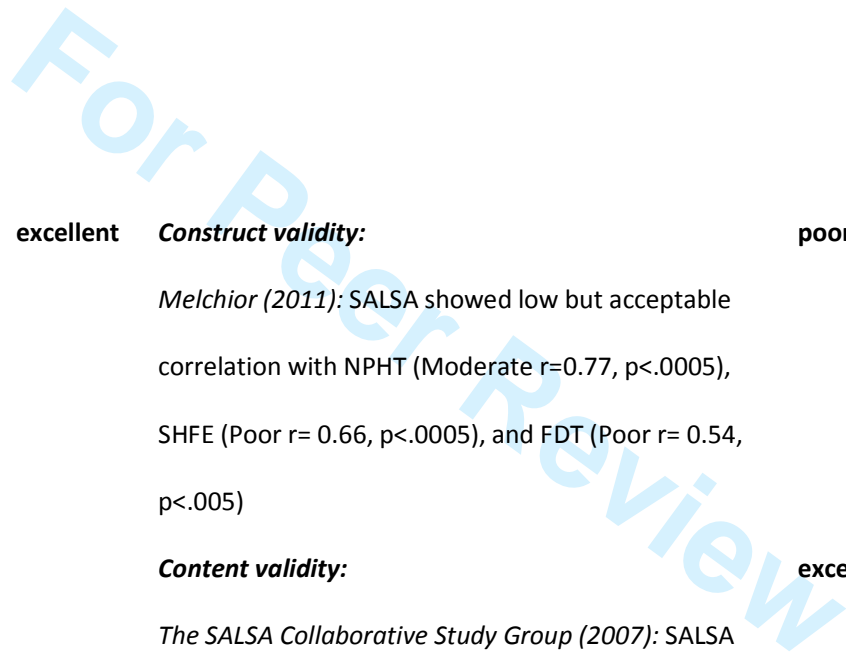
PEM ***Internal consistency:*** **poor** ***Construct validity:*** **poor** xx xx

Dias (2008): PEM showed satisfactory *Dias (2008):* PEM showed no significant correlations

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	unidimensionality (Excellent, $\alpha = 0.94$)		with Gartland and Worley scores ($\Upsilon = -0.37$, 5% level)			
	test-retest reliability:	poor				
	<i>Dias (2008)</i> : Lower test retest					
	reliability (test-retest differences= -9.3					
	to 2.3, 95% CIs, $p = 0.02$)					
PPMs	test-retest reliability:	poor	xx	xx	xx	xx
	<i>Manor (2008)</i> : Both 6 minute walk					
	test and Timed up and go test showed					
	significant reliability (Excellent ICC=					
	0.93- 0.99, 95% CIs)					
QRS	test-retest reliability:	poor	xx	xx	xx	xx
	<i>Perez (2002)</i> : QRS showed satisfactory					
	ICC scores with good test-retest					
	reliability (range= 0.84- 0.87, $p < 0.001$)					
RSQ	inter-rater reliability:	poor	Construct validity:	poor	xx	xx
	<i>Oerlemans (2000)</i> : For inter-rater		<i>Oerlemans (2000)</i> : For observer A, 11 test categories			
	reliability the limits of agreement		were highly correlated (> 0.80), however for observer			
	between two observers was -0.26 and		B, the correlations were lower (but mostly > 0.60)			

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0.22

test-retest reliability: poor

Oerlemans (2000): For test-retest reliability the limits of agreement between observer A (-0.10 and 0.14) and observer B (-0.26 and 0.22) was very close

SALSA **Internal consistency:** excellent **Construct validity:** poor xx xx

The SALSA Collaborative Study Group (2007): SALSA showed satisfactory unidimensionality: Leprosy group (Good, $\alpha = 0.897$), and diabetes group (Good, $\alpha = 0.814$)

Melchior (2011): SALSA showed low but acceptable correlation with NPHT (Moderate $r = 0.77$, $p < .0005$), SHFE (Poor $r = 0.66$, $p < .0005$), and FDT (Poor $r = 0.54$, $p < .005$)

Content validity: excellent

The SALSA Collaborative Study Group (2007): SALSA showed strong relationship to the scores assigned by independent experts: Overall ($\rho = 0.67$), leprosy group ($\rho = 0.65$), and diabetes group ($\rho = 0.70$)

SAM xx xx **Hypothesis testing:** poor xx xx

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Smith (2004): SAM showed a strong correlation with physical Function scale, Physical Component Summary score, and Vitality scale ($p= 0.01$); and a weak correlation with Bodily Pain and Role Limitation ($p= 0.05$)

SAM xx
(4
mWT)

xx

Construct validity:

poor

xx

xx

van Schie (2011): SAM (4mWT) showed a significant correlation with Dutch version of International Physical Activity Questionnaire: min/ week ($p= 0.49$), and activity/ week ($p= 0.43$, $p< 0.05$)

Criterion validity:

poor

van Schie (2011): SAM recorded an accuracy of 98.6% compared with observer- counted strides

SDS

Internal consistency:

poor

xx

xx

Responsiveness:

fair

Rejas (2008): SDS showed satisfactory unidimensionality (Excellent, $\alpha= 0.904$)

Rejas (2008): SDS was significantly able to differentiate between responders and non-

responders

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5	SHFT	Internal consistency:	fair	xx	xx	xx	xx
6							
7		<i>Videler (2008):</i> SHFT showed excellent					
8		homogeneity for both dominant					
9		hands ($\alpha= 0.96$), and non-dominant					
10		hands ($\alpha= 0.95$)					
11		test-retest reliability:	fair				
12		<i>Videler (2008):</i> SHFT showed					
13		satisfactory test-retest reliability with					
14		good ICC (83- 0.95, 95% CIs)					
15							
16	TBQ	Internal consistency:	poor	Construct validity:	good	xx	xx
17							
18		<i>Sezgin (2006):</i> TBQ showed		<i>Sezgin (2006):</i> TBQ showed satisfactory correlations			
19		satisfactory unidimensionality:		with symptoms severity scale ($r= 0.73, p< 0.00001$);			
20		symptom severity scale (Good $\alpha=$		moderate and good correlations with subscales of SF-			
21		0.82), and function status scale (Good		36- physical functioning ($r= 70.55$), physical role ($r=$			
22		$\alpha= 0.88$)		70.54), bodily pain ($r= 70.63, p< 0.0001$), and			
23		test-retest reliability:	fair	emotional role ($r= 70.40, p< 0.001$)			
24		<i>Sezgin (2006):</i> TBQ showed					

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satisfactory correlation scores with acceptable test-retest reliability: symptom severity scale (Poor, r= 0.60), and function status scale (Moderate r= 0.77, p= 0.0001)

UNEQ **Internal consistency:** **poor**
Mondelli (2006): UNEQ showed satisfactory unidimensionality (Good, $\alpha= 0.87$)
test-retest reliability: **fair**
Mondelli (2006): Satisfactory ICC scores with excellent test retest reliability (ICC= 0.97)

Content validity: **excellent**
Mondelli (2006): UNEQ showed a satisfactory content validity as all the questions were equally distributed between the symptoms numbness/tingling and elbow pain
Construct validity: **poor**
Mondelli (2006): UNEQ showed satisfactory correlations with scores of the clinical (Poor, $\rho=0.65$) and electrophysiological (Poor, $\rho=0.35$) severity scales

Responsiveness: **poor**
Mondelli (2006): UNEQ showed significant responsiveness in picking up difference in scores at follow ups (Good, $r=0.85$, $p<0.001$)

Walk-12 **Internal consistency:** **poor**
Graham (2006): Walk-12 showed satisfactory unidimensionality (Excellent, $\alpha= 0.97$)

Hypothesis testing: **poor**
Graham (2006): Walk-12 showed strong correlation with the SF-36 Physical Function Subscale ($r= 20.82$), the Social Function Component ($r= 20.86$), Physical

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	test-retest reliability:	poor	Component Summary Score (r= 20.72) and the lower limb section of the ONLS (r= 0.77)		
	<i>Graham (2006):</i> Satisfactory ICC scores with excellent test retest reliability (ICC= 0.96)				
WSQ	test-retest reliability:	poor	xx		xx
	<i>Perez (2002):</i> WSQ showed satisfactory ICC scores with moderate test-retest reliability (range= 0.78-0.87, p< 0.001)				
WST	test-retest reliability:	poor	Construct validity:	poor	xx
	<i>Kilmer (2000):</i> WST showed acceptable test-retest reliability: Pronation (Good ICC= 0.88), supination (Good ICC= 0.85), push (Excellent ICC= 0.96), pull (Excellent ICC= 0.93), and lever arm push (Poor ICC= 0.67)		<i>Kilmer (2000):</i> WST showed strong and positive correlations with Hand Held Dynamometry- measured peak torque for both dominant and non-dominant hands (p< 0.05)		

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ZIQ xx

xx

Hypothesis testing:

fair

xx

Schmader (2007): ZIQ showed a significant correlation with other domains. Increased composite pain and discomfort intensity scores were associated with increase in ZIQ ADL interference scores

Abbreviations: ADL= Activities of Daily Living, AMHFQ= The Alderson-McGall hand function questionnaire, BBM/S= Berg Balance Measure/ Score, BI= Barthel Index, BPI= Brief Pain Inventory, CMAP= compound muscle action potential, CMTNS= Charcot-Marie-Tooth disease Neuropathy score, DASH= The Disabilities of Arm, Shoulder and Hand Questionnaire, DI= Deambulation Index, DMMPUT= Dellon-modified Moberg pick-up test, FDI= Facial disability Index, FDT= Functional dexterity test, GBS= Guillain Barré Syndrome, HADS= Hospital Anxiety and Depression Scale, HAP= Human Activity Profile, ISS= Inflammatory neuropathy Sensory Score, LKQ= Levine-Katz Questionnaire, MHQ= The Michigan Hand Outcome Questionnaire, 10-MWT= 10-Meter walking test, mNDS= modified Neuropathy Disability Score, NHPT= Nine-Hole Peg test, NIS= Neuropathy Impairment Score, NRS= Numeric Rating Scale, ODSS= The Overall Disability Sum Score, ONLS= The Overall Neuropathy Limitations Scale, PEM= The Patient Evaluation Measure, PPMs= Physical Performance Measures (6 minute walk test, Timed up and go test), QRS= Questionnaire rising and sitting down, R36HS= Rand-36 Health Survey, RSQ= The Radboud skills Questionnaire, SALSA= Screening of Activity Limitation and Safety Awareness Scale, SAM= Step Activity Monitor, 4mWT= 4 min walk test, SDS= Sheehan Disability Scale, SHFT= Sollerman Hand function test, SIP68= Sickness impact profile 68, TBQ= Turkish version of the Boston Questionnaire, UNEQ= Ulnar neuropathy at the elbow Questionnaire, VAS= Visual Analog Scale, Walk-12= 12-Item Multiple Sclerosis Walking Scale, WSQ= Walking stairs Questionnaire, WST= Work stimulation tasks (knob turn, Linear motion, and Lever arm), xx= not determined, ZIQ= Zoster Impact Questionnaire

Table VI Definition of domains, measurement properties, aspects of measurement properties and accepted statistical analyses by COSMIN

Domain	Measurement property	Aspect of a measurement property	Definition	Accepted statistical analyses	Interpretation	Inappropriate statistical analyses
Reliability	Internal consistency		The degree of the interrelatedness among the items	Cronbach's alpha (α)	$\alpha > 0.90$: Excellent	Pearson's correlation coefficient Spearman's correlation coefficient
				Internal consistency coefficient	$\alpha = 0.81-0.90$: Good	
					$\alpha > 0.71-0.80$: Moderate	
					$\alpha < 0.70$: Poor	
Reliability	<i>Intra-rater reliability;</i> <i>Inter-rater reliability;</i> <i>test-retest reliability</i>		The proportion of the total variance in the measurements which is due to 'true' differences among patients	Continuous scores: ICC	ICC or K > 0.90 : Excellent	
				Dichotomous/nominal scores: Cohen's kappa (K)	ICC or K = $0.81-0.90$: Good	
				Ordinal scores: Weighted kappa	ICC or K $> 0.71-0.80$: Moderate	
					ICC or K < 0.70 : Poor	
Validity	Measurement error		The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured	SEM, SDC or LoA		
Validity	Content validity		The degree to which the content of a HR-PRO is an adequate reflection of the construct to be measured			
				<i>Face validity</i>	The degree to which (the items	Requires a subjective

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Construct validity

of) an instrument indeed looks as judgement, thus no
though they are an adequate analytical standards
reflection of the construct to be are developed
measured

The degree to which the scores of
a HR-PRO are consistent with
hypotheses (*for instance with
regard to internal relationships,
relationships to scores of other
instruments, or differences
between relevant groups*) based
on the assumption that the HR-
PRO instrument validly measures
the construct to be measured

Structural validity

The degree to which the scores of
a HR-PRO are an adequate
reflection of the dimensionality of
the construct to be measured

Factor analysis

Hypotheses testing-
Discriminant validity;
Convergent validity;
Divergent

Idem construct validity

Correlation coefficient

Positive correlation:
 $\gamma > 0.90$: Excellent
 $\gamma = 0.81 - 0.90$: Good
 $\gamma > 0.71 - 0.80$:
Moderate
 $\gamma < 0.70$: Poor
Inverse correlation:

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2 validity; $\gamma < -0.90$: Excellent
3
4 Sensitivity & $\gamma = -0.81$ to -0.90 :
5
6 specificity Good
7
8 $\gamma = -0.71$ to -0.80 :
9 Moderate
10
11 $\gamma > -0.70$: Poor

12 Cross-cultural The degree to which the Confirmatory factor
13 validity performance of the items on a analyses
14 translated or culturally adapted Differential item
15 HR-PRO instrument are an functioning analyses
16 adequate reflection of the
17 performance of the items of the
18 original version of the HR-PRO
19 instrument

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25 Criterion Concurrent The degree to which the scores of When both scores are
26 validity validity an HR-PRO instrument are an continuous:
27 adequate reflection of a 'gold Correlation co-
28 standard' efficient
29
30 When one is
31 continuous score and
32 other is dichotomous:
33 Area under the ROC
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35 When both scores are
36 dichotomous:
37 sensitivity & specificity
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Responsiveness

Interpretability

Responsiveness

The ability of an HR-PRO instrument to detect change over time in the construct to be measured

When both scores are continuous:
Correlation coefficient
When one is continuous score and other is dichotomous:
Area under the ROC
When both scores are dichotomous:
sensitivity & specificity

Effect size
Standardised response mean
Norman's responsiveness coefficient
Relative efficacy statistic
Guyyatt's responsiveness ratio
MIC
Paired t-test

The degree to which one can assign qualitative meaning- i.e., clinical or commonly understood connotations- to an instrument's quantitative scores or change in scores
MIC and MID

Abbreviations: α = Cronbach's alpha, HR-PRO= Health related- patient reported outcome, ICC= Intra class correlation coefficient, K= Cohen's Kappa, LoA= Limits of Agreement, MIC= Minimal important change, MID= Minimal important difference, γ = Correlation coefficient, ROC= Receiver operating curve, SDC= Smallest Detectable Change, SEM= Standard Error of Measurement

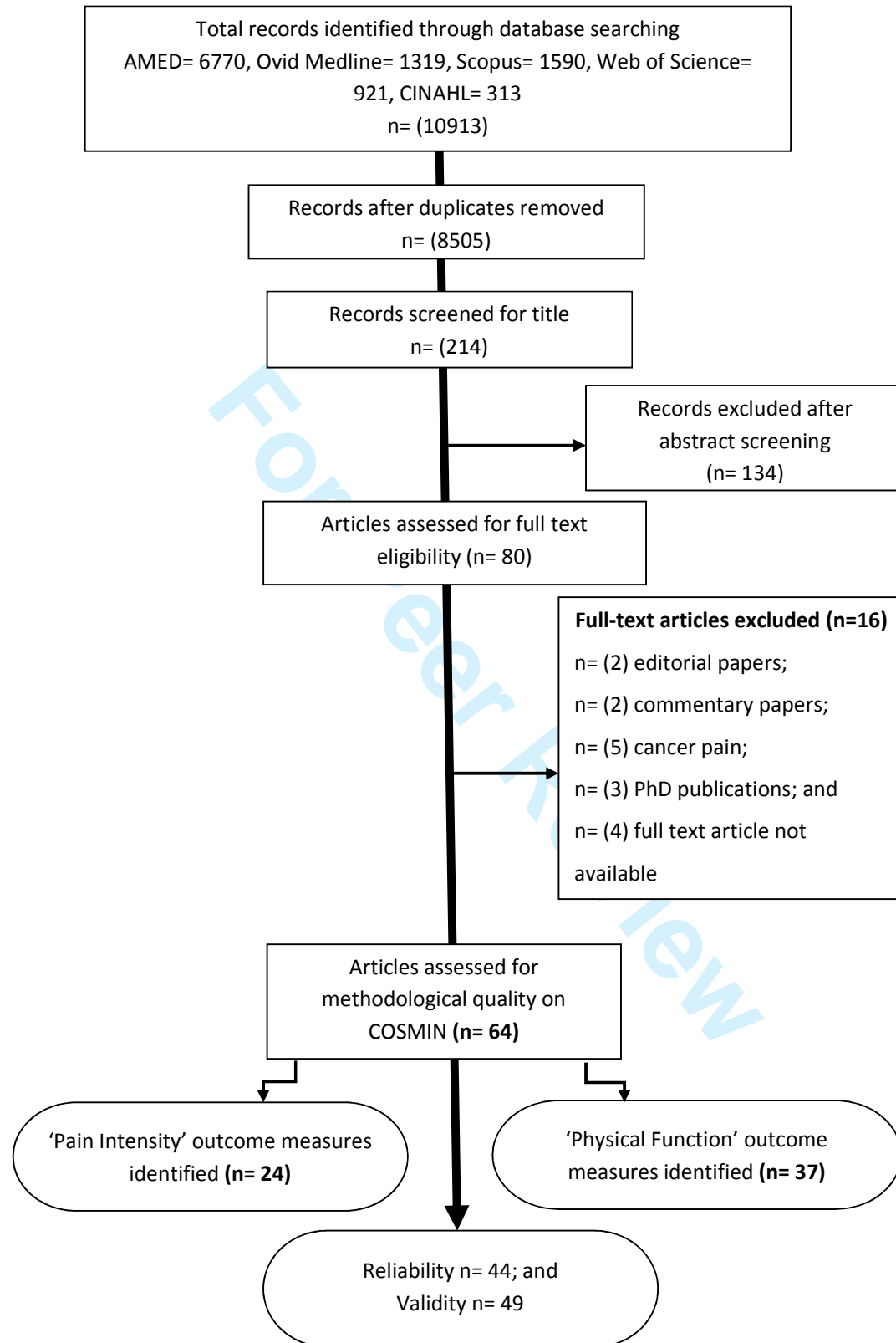


Figure I Flow diagram summarising study selection process

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Reviewer 1		
COMMENT	EXPLANATION	MODIFICATIONS (Highlighted text)
<u>Introduction</u>		
I think it is preferable to avoid using too many abbreviations e.g. PMP and OM.	We note the potential for confusion, thanks for this suggestion.	Necessary amendments on the specified pages have been made.
It would be helpful in the introduction to separate out the two concepts of 1) the need to test the psychometric properties of outcome measures-e.g. if reliability has been completed did the results indicate that the test is actually reliable and therefore could be recommended for use;[in methods would be good if you assessed this also i.e. quality of the results of measurement properties] from 2) the methods used to test the psychometric properties (e.g. with COSMIN). The objective gets lost within the final paragraph-can I suggest you rephrase as an aim and move the detail on COSMIN to your methods section.	Thank you for your comment. We note the reviewer’s concern here. And hence the required explanation has been added as indicated.	Sentences explaining the aims and objectives of the study have been rephrased.
<u>Method</u>		
Page 4: Line 41 replace ‘has also been activated’ to ‘was activated’; consider rephrasing this sentence as it is not very clear.	Agreed.	Corrections have been made in the text.
Check end search date-differs between abstract and methods.	Agreed.	Corrections have been made in the text.
Please clarify line 56 ‘OMs used in intervention trials....’ with the statement on page 5-eligibility criteria which states that cross sectional clinical trials	We note the potential for confusion. The inclusion criteria for this study was the	The term unnecessary words have been deleted to avoid the confusion.

<p>(what is this??. can you have a cross sectional intervention trial) and cohort studies (so do you mean an uncontrolled intervention study)?</p>	<p>cross sectional studies and the longitudinal cohort studies.</p>	
<p>Page 6: You seem to only describe a method to explore the methodological quality of the individual studies; there is no section on how you made a judgement on ‘the evidence for the psychometric properties’ as indicated in your objective on page 4; and there is no method section to describe how the results will be synthesised (so how can you temper the findings on reliability with the quality of the study-e.g. the study reports that the measure is very reliability but the methodological quality is very low).</p>	<p>Thanks for this comment. We concur with the reviewer’s statement here.</p>	<p>The required explanation has been added under the section of data extraction and synthesis. A new table- Table VI has been added explaining the information of the criteria used for synthesizing the results of the study.</p>
<p>Results</p>		
<p>Page 8: It would be very helpful if you were able to add some description in the text to summarise the physical function outcomes measures-so were they self-report, physical performance, measuring ability e.g. steps versus disability. A similar overview of pain (if possible) would be helpful.</p>	<p>Agreed.</p>	<p>Please see manuscript for suggested overview.</p>
<p>Page 9: It would be important for the reader to know the results of the reliability tests as well as the methodological quality of the study which reported on these results (this would help inform some of the statements in your discussion e.g. page 10, line 53-many OMs seem promising’-on what basis?). So which tests were reliable (need to indicate in your methods how you made that judgement).</p>	<p>Thanks for this suggestion. We concur with reviewer’s concern here.</p>	<p>Table VI has been added to the manuscript, explaining about the judgement criteria used for the studies.</p>
<p>Line 31-35-can you provide evidence to support your statement that ‘these measures have been proven for their PMPs’.</p>	<p>We note the reviewer’s concern here.</p>	<p>Reference has been provided in the text along with Table VI.</p>

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<p>Page 9: It would be helpful to describe in a separate section the results for each of COSMIN boxes that you used.</p>	<p>Considering the magnitude of the COSMIN (9 boxes of definitions and explanation for each psychometric property for each outcome measure) and the word limit, explaining about the results of the studies in the form of paragraph seemed to a mere replication of the tables and thus was avoided.</p>	<p>No modifications made.</p>
<p>Discussion</p>		
<p>I found the discussion challenging to read as the text of the results did not present the results of the psychometric property under test e.g. if reliability was being tested was many of the tests were reliable-and then tempering these findings by only using results from the higher quality studies-you may have done this but it is not explicit to me in your reporting. I think the discussion would become more focused if the methods and results were expanded as I have suggested.</p>	<p>We concur with the reviewer’s statement here. But considering the word count, explaining about the results of the studies in discussion seemed to a mere replication of the tables and thus was avoided. However the important facts which lead to the results and needs to be highlighted are well explained.</p>	<p>Necessary modifications have been made. The suggestion under the methods and results sections have also been accepted.</p>
<p>Reviewer 2</p>		
<p>COMMENT</p>	<p>EXPLANATION</p>	<p>MODIFICATIONS (Highlighted text)</p>
<p>Well done. I have annotated the PDF with some minor grammatical errors; otherwise, the manuscript is well done.</p>	<p>Thanks for your feedback. The potential grammatical mistakes have been</p>	<p>Necessary modifications have been made in the sections of Abstract,</p>

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	corrected as per your advice.	Introduction, Methodology, Results, and Discussion.
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