**Measurement Properties of Instruments Assessing Psoriatic Arthritis Symptoms: A Systematic Literature Review**

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**A. Search strategy**

**Pubmed**

We conducted a MEDLINE search through Pubmed from inception to March 2018 to identify validation studies in patients with psoriasis and/or psoriatic arthritis of the instruments selected in Step 2. The search strategy was based on recommendations for performing systematic reviews of measurement properties published by Terwee et al[1]. Consequently, we combined terms for “psoriasis or psoriatic arthritis”, “instrument name” and “measurement properties”.

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| **#1: population** | "Arthritis, Psoriatic"[Mesh] OR Arthritis, Psoriatic[tiab] OR Psoriasis, Arthritic[tiab] OR Arthritic Psoriasis[tiab] OR Psoriatic Arthritis[tiab] OR Psoriasis Arthropathica[tiab] OR Psoriatic Arthropathy[tiab] OR Arthropathies, Psoriatic[tiab] OR Arthropathy, Psoriatic[tiab] OR Psoriatic Arthropathies[tiab] OR "Psoriasis"[MeSH] OR Psoriasis[tiab] OR Psoriases[tiab] OR Pustulosis of Palms and Soles[tiab] OR Pustulosis Palmaris et Plantaris[tiab] OR Palmoplantaris Pustulosis[tiab] OR Pustular Psoriasis of Palms and Soles[tiab] |
| **#2: instrument search** | Patient Global OR Patient Global Assessment[tiab] OR PGA[tiab] OR Routine Assessment Patient Index Data 3[tiab] OR RAPID3[tiab] OR Psoriatic Arthritis Impact of Disease[tiab] OR PsAID[tiab] OR PsAID9[tiab] OR PsAID12[tiab] |
| **#3: measurement properties** | **#1 and #2 and SENSITIVE FILTER for measurement properties:**  (instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR ‘‘psychometrics’’[MeSH] OR psychometr\*[tiab] OR clinimetr\*[tw] OR clinometr\*[tw] OR ‘‘outcome assessment (health care)’’[MeSH] OR outcome assessment[tiab] OR outcome measure\*[tw] OR ‘‘observer variation’’[MeSH] OR observer variation[tiab] OR ‘‘Health Status Indicators’’[Mesh] OR ‘‘reproducibility of results’’[MeSH] OR reproducib\*[tiab] OR ‘‘discriminant analysis’’[MeSH] OR reliab\*[tiab] OR unreliab\*[tiab] OR valid\*[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR ‘‘internal consistency’’[tiab] OR (cronbach\*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation\*[tiab] OR selection\*[tiab] OR reduction\*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR ‘‘precise values’’[tiab] OR test–retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab\*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intraobserver[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa’s[tiab] OR kappas[tiab] OR repeatab\*[tiab] OR ((replicab\*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results[tiab] OR test[tiab] OR tests[tiab])) OR generaliza\*[tiab] OR generalisa\*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation\*[tiab]) OR discriminative[tiab] OR ‘‘known group’’[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension\*[tiab] OR subscale\*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR interscale correlation\*[tiab] OR error[tiab] OR errors[tiab] OR ‘‘individual variability’’[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR ‘‘standard error of measurement’’[tiab] OR sensitiv\*[tiab] OR responsive\*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small\*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change[tiab] OR ‘‘ceiling effect’’[tiab] OR ‘‘floor effect’’[tiab] OR ‘‘Item response model’’[tiab] OR IRT[tiab] OR Rasch[tiab] OR ‘‘Differential item functioning’’[tiab] OR DIF[tiab] OR ‘‘computer adaptive testing’’[tiab] OR ‘‘ item bank’’[tiab] OR ‘‘cross-cultural equivalence’’[tiab]) |
| **#5** | **#3 NOT exclusion filter:**  (‘‘addresses’’[Publication Type] OR ‘‘biography’’[Publication Type] OR ‘‘case reports’’[Publication Type] OR ‘‘comment’’[Publication Type] OR ‘‘directory’’[Publication Type] OR ‘‘editorial’’[Publication Type] OR ‘‘festschrift’’[Publication Type] OR ‘‘interview’’[Publication Type] OR ‘‘lectures’’[Publication Type] OR ‘‘legal cases’’[Publication Type] OR ‘‘legislation’’[Publication Type] OR ‘‘letter’’[Publication Type] OR ‘‘news’’[Publication Type] OR ‘‘newspaper article’’[Publication Type] OR ‘‘patient education handout’’[Publication Type] OR ‘‘popular works’’[Publication Type] OR ‘‘congresses’’ [Publication Type] OR ‘‘consensus development conference’’[Publication Type] OR ‘‘consensus development conference,nih’’[Publication Type] OR ‘‘practice guideline’’[Publication Type]) NOT (‘‘animals’’[MeSH Terms] NOT ‘‘humans’’[MeSH Terms]) |

**EMBASE** (Inception-March 31, 2018)

We used the search filter used by Egerton *et. al*[2] to identify clinimetric studies.

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| --- | --- |
| **1: population** | 'psoriasis'/exp OR 'psoriasis':ab,ti OR 'erythrodermic psoriasis':ab,ti OR 'guttate psoriasis':ab,ti OR 'psoriasis guttata':ab,ti OR 'nail psoriasis':ab,ti OR 'nummular psoriasis':ab,ti OR 'palmoplantar psoriasis':ab,ti OR 'psoriasis pustulosa':ab,ti OR 'pustular psoriasis':ab,ti OR 'pustulosis palmoplantaris':ab,ti OR 'pustulous psoriasis':ab,ti OR 'psoriasis vulgaris':ab,ti OR 'psoriasis, palmoplantar':ab,ti OR 'scalp psoriasis':ab,ti |
| **2: instruments** | 'patient global':ab,ti OR 'PGA':ab,ti OR 'Routine Assessment Patient Index Data 3':ab,ti OR 'RAPID3':ab,ti OR 'Psoriatic Arthritis Impact of Disease':ab,ti OR 'PsAID':ab,ti OR 'PsAID9':ab,ti OR 'PsAID12':ab,ti |
| **3: measurement properties** | 'clinical assessment tool'/exp OR 'scoring system'/exp OR 'psychometry'/exp OR 'measurement'/exp OR 'rating scale'/exp OR 'reliability'/exp OR 'validity'/exp OR 'validity' OR 'validation study'/exp OR valid\*.ti |
| **4** | 1 AND 2 AND 3 |

**B. Ten criteria for good content validity**

Relevance

1 Are the included items relevant for the construct of interest?

2 Are the included items relevant for the target population of interest?

3 Are the included items relevant for the context of use of interest?

4 Are the response options appropriate?

5 Is the recall period appropriate?

Comprehensiveness

6 Are no key concepts missing?

Comprehensibility

7 Are the PROM instructions understood by the population of interest as intended?

8 Are the PROM items and response options understood by the population of interest as intended?

9 Are the PROM items appropriately worded?

1. o the response options match the question?

**C. Hypotheses generated for hypothesis testing for construct validity and responsiveness**

For the PGA-arthritis, PGA-Psoriatic arthritis, RAPID3, PSAID9 and PSAID12, correlations were expected to be:

>0.7 with measures of pain

>0.5 with measures of discomfort, physical functional, fatigue, and disease activity scores

>0.3 with tender and swollen joint counts, enthesitis, dactylitis, mental health, emotional wellbeing

< 0.5 with instruments measuring skin disease severity (e.g. PASI, BSA), skin-related quality of life (e.g. DLQI, PQoL-12)

**D. Characteristics of the included study populations**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PROM** | **Ref** | **Population** | | | **Disease characteristics** | | | **Instrumental Administration** | | |
| **N** | **Age, yr**  **mean (SD) / median (range)** | **Gender (% females)** | **Disease** | **Disease Duration Mean (SD) or yr** | **Disease Severity/ Activity**  **mean (SD) / median (range)** | **Setting** | **Country** | **Language** |
| **PGA-arthritis VAS** | Cauli et al. 2011[3] | 319 | 52 (13) | 42 | Psoriatic arthritis | 10 | TJC: 5 (1–13)  SJC: 1 (0–5)  PASI score: 2.80 (0.75–6.57).  Dactylitis 7%  Enthesitis 21% | 17 rheumatology clinics and 1 dermatology clinic | Italy, United States, Canada, The Netherlands, Hungary, New Zealand, Germany, Brazil, Spain, United Kingdom | English; for non-English countries, the questionnaires was translated |
| **PGA-arthritis NRS** | Eder et al. 2015[4] | 565 | 51.7 (13.2) | 41.4 | Psoriatic arthritis | 14.3 (19.4) | TJC: 8.5 (10.1)  SJC: 4.9 (6.5)  Clinically damaged joint count:12.5 (14.1)  Axial disease 51.1%  Dactylitis 11%  Enthesitis 13.8%  ESR 14.3 (19.4)  Mean PASI score: 3.4 (5.3) | University of Toronto PsA  cohort | Canada | English |
|  | Talli et al. 2016[5] | 223 | 51.0 (13.3) | 51.1 | Psoriatic arthritis | 9.9 (10.1) | TJC: 8.5 (9.2)  SJC: 4.1 (5.1)  DAS28-ESR 3.5 (1.3)  BSA< 6%: 56.1%  BSA 6-20%: 22.6%  No psoriasis: 15.8% | Secondary or tertiary care centers | Austria, Belgium, Estonia, Germany,  France, Hungary, Ireland, Italy, Norway, Romania, Spain, Turkey, the United Kingdom | English, Estonian,  Flemish, French, German, Hungarian, Italian, Norwegian,  Romanian, Russian, Spanish, Turkish |
| **PGA-Psoriatic Arthritis VAS** | Lubrano et al. 2015[6] | 124 | 3.3 (25th–75th percentile: 3.5–5) | 53 | Psoriatic arthritis | 7 (25th–75th percentile: 4–13) | TJC: 4.5 (1–10)  SJC: 1 (0–5)  DAPSA 20 (14.2-28.5)  DAS28-CRP 3.72 (2.7-4.8)  Dactylitis 33%  Enthesitis 29.8%  ESR 22 (12-29)  CRP 0.7 (0.36-1.2)  PASI score: 0.9 (0-2.5). | Outpatient clinic of the Academic Rheumatology Unit in Campobasso | Italy | Not specified |
|  | Cauli et al. 2011[3] | 319 | 52 (13) | 42 | Psoriatic arthritis | 10 | TJC: 5 (1–13)  SJC: 1 (0–5)  PASI score: 2.80 (0.75–6.57).  Dactylitis 7%  Enthesitis 21% | 17 rheumatology clinics and 1 dermatology clinic | Italy, USA, Canada, The Netherlands, Hungary, New Zealand, Germany, Brazil, Spain, United Kingdom | English; for non-English countries, the questionnaires was translated |
| **PGA-Psoriatic Arthritis NRS** | Leung et al. 2011[7] | 125 | 47.5 (12.4) | 48 | Psoriatic arthritis | 8.2 (6.8) | TJC: 3.98 (5.22)  SJC: 1.84 (2.67)  DAS28 3.8 (1.5)  Damaged joint count 3.07 (4.49)  PASI 5.48 (7.33) | Outpatient specialist clinic in a tertiary rheumatology center | Hong Kong | Han Chinese |
|  | Talli et al. 2016[5] | 223 | 51.0 (13.3) | 51.1 | Psoriatic arthritis | 9.9 (10.1) | TJC: 8.5 (9.2)  SJC: 4.1 (5.1)  DAS28-ESR 3.5 (1.3)  BSA< 6%: 56.1%  BSA 6-20%: 22.6%  No psoriasis: 15.8% | Secondary or tertiary care centers | Austria, Belgium, Estonia, Germany,  France, Hungary, Ireland, Italy, Norway, Romania, Spain, Turkey, the United Kingdom | English, Estonian,  Flemish, French, German, Hungarian, Italian, Norwegian,  Romanian, Russian, Spanish, Turkish |
| **RAPID3** | Coates et al. 2018 (TICOPA study)[8] | 206 | 45 (38-53) | 47.6 | Psoriatic arthritis | 0.8 (0.4, 2.0) | TJC: 9 (4-18)  SJC (5 (2-9)  PASI 2.6 (1.2-4.8) | 8 secondary care rheumatology centers | United Kingdom | Not specified |
| **RAPID3** | Coates et al. 2018 (LOPAS II study)[8] | 318a | 51 | Not reported | Psoriatic arthritis | 5.8 (7.77) | Not reported | 24 centers across United Kingdom | United Kingdom | Not specified |
| **RAPID3** | Vakil-Gilani et. 2018[9] | 165 | 45.9 (12.8) | 50.3 | Psoriatic arthritis | Not reported | Not reported | Center  of Excellence in psoriasis and psoriatic arthritis clinic at Oregon Health & Science  University | United States | Not specified |
| **PsAID-9** | Gossec et al. 2014[10] | 474 (validation study)  12 (focus group), 140 (priority exercise) | 50.4 (12.6) | 50.2 | Psoriatic arthritis receiving TNF-alpha blockers | 9.6 (9.4) | TJC: 5.4 (8)  SJC: 2.4 (4.1)  DAS28-ESR 2.8 (1.4) | Rheumatology outpatient clinics in secondary  or tertiary care centers | Austria, Belgium, Estonia, Germany,  France, Hungary, Ireland, Italy, Norway, Romania, Spain, Turkey, the UK | English, Estonian,  Flemish, French, German, Hungarian, Italian, Norwegian,  Romanian, Russian, Spanish, Turkish |
|  | Holland et al. 2017[11] | 129 | 52.1 (13.3) | 57.4 | Psoriatic arthritis | 10.2 (7.8) | TJC: 6 (0-54)  SJC: 1 (0-15)  PASI 0.2 (0-7.9)  mCPDAI 3 (0-10)  LEI 0 (0-6)  Dactylitis 0 (0-7)  Erosive Disease 38.8% | Royal National Hospital for Rheumatic Diseases, Bath, UK | The UK | Not specified |
| **PsAID-12** | Gossec et al. 2014[10] | 474 (validation study)  12 (focus group), 140 (priority exercise) | 50.4 (12.6) | 50.2 | Psoriatic arthritis receiving TNF-alpha blockers | 9.6 (9.4) | TJC: 5.4 (8)  SJC: 2.4 (4.1)  DAS28-ESR 2.8 (1.4) | Rheumatology outpatient clinics in secondary  or tertiary care centers | Austria, Belgium, Estonia, Germany,  France, Hungary, Ireland, Italy, Norway, Romania, Spain, Turkey, the United Kingdom | English, Estonian,  Flemish, French, German, Hungarian, Italian, Norwegian,  Romanian, Russian, Spanish, Turkish |
|  | Holland et al. 2017[11] | 129 | 52.1 (13.3) | 57.4 | Psoriatic arthritis | 10.2 (7.8) | TJC: 6 (0-54)  SJC: 1 (0-15)  PASI 0.2 (0-7.9)  mCPDAI 3 (0-10)  LEI 0 (0-6)  Dactylitis 0 (0-7)  Erosive Disease 38.8% | Royal National Hospital for Rheumatic Diseases, Bath, United Kingdom | United Kingdom | Not specified |
|  | Salaffi et al. 2016[12] | 159 | 56.49 (11.65) | 61 | Psoriatic arthritis | 8.40 (5.21) | TJC: 5.99 (5.96)  SJC: 3.78 (4.05)  PASDAS 4.44 (1.77)  DAPSA 21.76 (14.44)  ESR 25.15 (17.99)  CRP 3.56 (3.37)  Dactylitis 2.01 (2.28)  LEI 1.39 (3.36)  PhGA 3.98 (2.7)  PASI 5.36 (5.08) | Outpatient and inpatient clinics of the Rheumatology Department of the Polytechnic University of Marche, Ancona, Italy | Italy | Italian |
|  | Di Carlo et al. 2017[13] | 144 | 51.4 (12.8) | 43.8 | Psoriatic arthritis | 10.3 (8.0) | TJC or SJC > 1: 26.4%  Dactylitis10.4%  LEI>1 26.4%  Axial disease: 16% | Outpatient clinics of  2 Italian tertiary rheumatology centers | Italy | Italian |
|  | Kalyoncu et al. 2019[14] | 70 | 45.5 (12.0) | 78.5 | Psoriatic arthritis | 5.3 (4.4) | DAS28 4.07 (1.22)  BASDAI 6.5 (1.7)  BASFI 4.9 (2.4)  ESR 22(17)  CRP 2.3 (2.8) | Hacettepe University biological database | Turkey | Turkish |

aSample size was extracted from reference provided in the manuscript

PGA, Patient Global Assessment; RAPID3, Routine Assessment Patient Index Data 3; PsAID, Psoriatic Arthritis Impact of Disease; VAS, Visual Analogue Scale; NRS, Numeric Rating Scale; SD, Standard Deviation; TJC, Tender Joint Count; SJC, Swollen Joint; PASI, Psoriasis Area and Severity Index; ESR, erythrocyte sedimentation rate; DAS28, Disease Activity Score 28; BSA, Body Surface Area; DAPSA, Disease Activity Index for Psoriatic Arthritis; CRP, C-reactive protein; mCPDAI, Modified Composite Psoriatic Disease Activity Index; TNF, Tumor Necrosis Factor; LEI, Leeds Enthesitis Index; PASDAS, Psoriatic Arthritis Disease Activity Score; PhGA, Physician Assessment of disease activity; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index.

**E. Information on feasibility of PROMs**

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| **Feasibility aspects** | **PGA-arthritis VAS** | **PGA-arthritis NRS** | **PGA-Psoriatic Arthritis VAS** | **PGA-Psoriatic Arthritis NRS** | **RAPID3** | **PsAID-9** | **PsAID-12** |
| **Patient’s comprehensibility** | Not assessed | Not assessed | Not assessed | Not assessed | Not assessed | Assessed but data not shown | Assessed but data not shown |
| **Type and ease of administration** | Paper-and-pencil or digital form | Paper-and-pencil or digital form | Paper-and-pencil or digital form | Paper-and-pencil or digital form | Paper-and-pencil or digital form | Paper-and-pencil or digital form | Paper-and-pencil or digital form  PsAID-12 touch-screen:  95% of patients reported it was “easy to use”  97% considered the interface “friendly”  92% “liked using the touch-screen to complete the questionnaire.  84% preferred the touch-screen over the paper-and-pencil format |
| **Length of the instrument** | 1 item | 1 item | 1 item | 1 item | 1 item for pain  1 item for PGA  10 items for physical function  (3 additional informative questions about sleep, anxiety and depression) | 9 items | 12 items |
| **Completion time** | Not reported | Not reported | ‘Very quick test’ | Not reported | Not reported | Not reported | Mean time 2.7 (95% CI 2.25-2.88) minutes (paper version), 2.0 (95% CI 1.71 to 2.21) minutes (touch screen version) |
| **Patient’s required mental and physical ability level** | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported |
| **Ease of standardization** | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported | Not reported |
| **Ease of score calculation** | Raw score entered by patient | Raw score entered by patient | Raw score entered by patient | Raw score entered by patient | 5 to 10 seconds to calculate[9,15]. Formula:  1. Add up the scores in questions 1-10 on physical function. Use the  formula provided to calculate the formal score (0-10).  2. Enter the patient’s pain raw score (0-10)  3. Enter the patient’s global assessment raw score (0-10)  4. Add the total score (0-30) from questions 1, 2, and 3 and enter them as the patient’s RAPID3 cumulative score.  5. Use a conversion table provided to simplify the patient’s weighed RAPID3 score | Calculation time not reported. Formula:  PsAID final value= (PsAID1 (pain) NRS value (range 0- 10) x 0.174) + (PsAID2 (fatigue) NRS value (range 0–10) x 0.131) + (PsAID3 (skin) NRS value (range 0–10) x 0.121) + (PsAID4 (work and/or  leisure activities) NRS value (range 0–10) x 0.110) + (PsAID5 (function) NRS value (range 0–10) x 0.107) + (PsAID6 (discomfort) NRS value (range 0–10) x 0.098) + (PsAID7 (sleep) NRS value  (range 0–10) x 0.089) + (PsAID8 (coping) NRS value (range 0–10) x 0.087) + (PsAID9 (anxiety) NRS  value (range 0–10) x 0.085) | Calculation time not reported. Formula:  PsAID final value = (PsAID1 (pain) NRS value (range 0–10) x 3) + (PsAID2 (fatigue) NRS value (range 0–10) x 2) + (PsAID3 (skin) NRS value (range 0–10) x 2) + (PsAID4 (Work and/or leisure activities) NRS  value (range 0–10) x 2) + (PsAID5 (function) NRS value (range 0–10) x 2) + (PsAID6 (discomfort) NRS  value (range 0–10) x 2) + (PsAID7 (sleep) NRS value (range 0–10) x 2) + (PsAID8 (coping) NRS value (range 0–10) x 1) + (PsAID9 (anxiety) NRS value (range 0–10) x 1) + (PsAID10 (embarrassment) NRS  value (range 0–10) x 1) + (PsAID11 (social life) NRS value (range 0–10) x 1) + (PsAID12 (depression)  NRS value (range 0–10) x 1). The total is divided by 20. |
| **Cost of an instrument** | No (free of charge) | No (free of charge) | No (free of charge) | No (free of charge) | Free of charge for use in academic setting  Charges apply for pharmaceutical companies | No (free of charge) | No (free of charge) |
| **Required equipment** | Paper and pencil or digital device | Paper and pencil or digital device | Paper and pencil or digital device | Paper and pencil or digital device | Paper and pencil or digital device | Paper and pencil or digital device | Paper and pencil or digital device |
| **Availability in different settings** | Used in clinical practice and clinical trials | Used in clinical practice and clinical trials | Used in clinical practice and clinical trials | Used in clinical practice and clinical trials | Initially developed for Rheumatoid Arthritis. Later used across multiple rheumatologic conditions. Used in clinical practice and clinical trials. | Intended for clinical trials | Intended for clinical practice |

PGA, Patient Global Assessment; RAPID3, Routine Assessment Patient Index Data 3; PsAID, Psoriatic Arthritis Impact of Disease; VAS, Visual Analogue Scale; NRS, Numeric Rating Scale; CI, Confidence Interval

**F. Information on interpretability of PROMs**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **PROM** | **Ref.** | **Distribution of scores in the study population** | **% of missing items and % of missing total scores** | **Floor and ceiling effects** | **Scores and change scores available for relevant (sub)groups** | **Minimal Important Change (MIC) or Minimal Important Difference (MID)** | **Cut-off values for Disease Activity [Remission (REM)/Minimal Disease Activity (MDA)]** |
| **PGA-arthritis VAS** | Cauli et al. 2011[3] | Median 47 (range 22–69) | Not reported | Not reported | Mean (range) scores:  Polyarticular PsA: 47 (22–71)  Oligoarticular PsA:  50 (20–71)  Axial PsA: 45 (21–60)  Distal PsA: 58  (29–77)  Mutilans PsA :54 (32–73)  More than one subset: 36 (20–60) | Not reported | Not reported |
| **PGA-arthritis NRS** | Eder et al. 2015[4] | Mean (SD) 3.97 (2.67)[4]  Median (IQR) 4 (2–6)[4]  Mean (SD) 5.6 (2.5)[5] | Not reported | Not reported | Not reported | Not reported | Not reported |
| Talli et al. 2016[5] | Mean (SD) 5.6 (2.5) | Not reported | Not reported | Not reported | Not reported | Not reported |
| **PGA-Psoriatic Arthritis VAS** | Cauli et al. 2011[3] | Median 49 (range 25-66)[3] | Not reported | Not reported | Mean (range) scores:  Polyarticular PsA: 30 (14–62)  Oligoarticular PsA:  20 (9–51)  Axial PsA: 30 (14–68)  Distal PsA: 58  (25–77)  Mutilans PsA: 34 (4–74)  More than one subset: 30 (15–50) | Not reported | Not reported |
| Lubrano et al. 2015[6] | Median  (25th–75th percentile) 59 (45–70) | Not reported | Not reported | Not reported | Not reported | Concordance expressed as Cohen K coefficient between PGA<20 mm and MDA: 0.72-0.73  Sensitivity, specificity and likelihood ratio of PGA for the MDA were 0.76-0.91; 0.81-0.94; 4.9-14.8, respectively |
| **PGA-Psoriatic Arthritis NRS** | Leung et al. 2011[7] | Mean (SD)  4.56 (2.32) | Not reported | Not reported | Patients with DAS28 <2.6: PGA 3.17 (2.25)  Patients with DAS28 >2.6: PGA 4.98 (2.18)  Patients with MDA: PGA 2.06 (2.02)  Patients without MDA: PGA 4.95 (2.14) | Not reported | Not reported |
| Talli et al. 2016[5] | Mean (SD) 4.8 (2.7)[5] | Not reported | Not reported | Not reported | Not reported | Not reported |
| **RAPID3** | Coates et al. 2018 (TICOPA study)[8] | Baseline 4.18 (tight control group), 3.59 (standard care group) | Not reported | Not reported | Tight control group: -mean score at baseline 4.18  -mean score change: -2.16  -SRM -1.07  -Effect size -1.06  Standard care group:  -mean score at baseline 3.59  -mean score change: -1.01  -SRM -0.47  -Effect size -0.52  t-value -3.43, p < 0.01 | Not reported | RAPID3 remission (score < 3) was in exact agreement with MDA in 85.2% of patients at 48 weeks  RAPID3 remission (score < 3) was in exact agreement with RAPID3SJC1 in 86.2% of patients at 48 weeks  RAPID3 remission (score < 3) was in exact agreement with VLDA in 73.6%% of patients at 48 weeks  RAPID3 disease activity cutoff lies between MDA and VLDA |
|  | Coates et al. 2018 (LOPAS II study)[8] | Mean (SD) of change: -6.2 (9.9) | Not reported | Not reported | Not reported | Minimal important difference using anchor-based method was -8.1 (+ 5.9)  Minimal important difference using the ROC curve: -5.1 [AUC 0.84] | Not reported |
|  | Vakil-Gilani et. 2018[9] | Mean (SD) at baseline 3.7 (2.4) | Not reported | Not reported | Psoriasis patients: Mean (SD) at baseline 2.4 (2.01) | Not reported | RAPID3 cut-offs for PQoL-12 scores in patients with psoriasis:  Mild PQoL (score = 48): RAPID3 cutoff: 1.55 (SE 0.3); Sensitivity 70.3% (SE, 4.85); Specificity 74.3% (SE, 5.14)  Moderate PQoL (score = 96): RAPID3 cutoff: 5.72 (SE, 0.45); Sensitivity 28.6% (SE, 7.2); Specificity 95.8% (SE, 1.27)  RAPID3 cut-offs for PQoL-12 scores in patients with PsA:  Mild PQoL (score = 48): RAPID3 cutoff: 1.89 (SE, 0.209); Sensitivity 81.3% (SE, 8.33); Specificity 62.9% (SE, 8.77)  Moderate PQoL (score = 96): RAPID3 cutoff: 6.34 (SE, 0.300); Sensitivity 40.3% (SE, 1.03); Specificity 94.5% (SE, 1.93) |
| **PsAID-9** | Gossec et al. 2014[10] | Baseline 4.11 (2.40) | <0.5%  1% | Floor effects 1%, ceiling effects 0% | Not reported | Minimal Important Change (MIC) was estimated using ROC curves: 3.6 points of change. Proposed MIC: 3 points. | The cut-off value of Patient-Acceptable Symptom State (PASS) was estimated as the 75 % of patients considering themselves in an “acceptable” state at baseline.  PASS cut-off for PsAid-9: < 4.1. Proposed cut-off value: 4. |
| **PsAID-12** | Gossec et al. 2014[10] |  | <0.5%  1% | Floor effects 1%, ceiling effects 0% | Not reported | Minimal Important Change (MIC) was estimated using ROC curves: PsAid-12: 3 points. Proposed MCI: 3 points. | The cut-off value of Patient-Acceptable Symptom State (PASS) was estimated as the 75 % of patients considering themselves in an “acceptable” state at baseline.  PASS cut-off: PsAid-12: <3.95. Proposed cut-off value: 4. |
|  | Holland et al. 2017[11] | Baseline 3.92 (2.26) | <0.5% | Not reported | Not reported | Minimal Detectable Change: 1.41  Using the anchor-based method [improved (overall, my condition has improved) versus not improved (overall, my condition has not improved)], authors constructed an ROC curve; the area under the curve was 0.821.  Minimal Clinical Important Improvement (MCII) = 1.25 (Sensitivity 61%; Specificity of 80%). Previous reported MCII defined by a cutoff of 3 had a sensitivity of 29% and Specificity of 100% in this cohort. | Not reported |
|  | Salaffi et al. 2016[12] | Median (IQR)  Paper-and-pencil: 3.6 (1.96-4.78)  Touch-screen: 3.17 (1.93-4.54) | Not reported | Not reported | Not reported | Not reported | PsAID-12 touch-screen:  Sensitivity and specificity for the possible threshold values were obtained from data on discriminant validity (AUC 0.937 (95% CI, 0,090 0,975), selecting the highest diagnostic accuracy (minimal false-negative and false-positive results). The resulting cutoff value for was 2.5 (sensitivity 86.2%, specificity 91.7%) with a positive likelihood ratio of 10.3, when MDA-OMERACT were used. |
|  | Di Carlo et al. 2017[13] | Not reported | Not reported | Not reported | Not reported | Not reported | According to the Clinical DAPSA values, patients were classified into 4 disease activity states: Remission (REM) <4; Low Disease Activity (LDA) >4 and <13; Moderate Disease Activity (MDA >13 and <27; High Disease Activity (HDA)>27. Cut-off values of the PSAID were obtained considering the 75th and 25th percentile mean values of adjacent categories:   * REM < 1.4 * LDA >1.4 and <4.1 * MDA >4.1 and <6.7 * HDA >6.7 |
|  | Kalyoncu et al. 2019[14] | Baseline 6.6 (1.5)[14] | Not reported | Not reported | Anti TNF continued: 6.6 (1.7)  Anti TNF stopped/switched: 6.7 (1.3)  P=0.67  Changes in PsAID12 among patients that reached a favorable response rate according to pain (VAS) PGA of disease activity, BASDAI, DAS28 and HAQ-DI are reported in the manuscript. | Not reported | Not reported |

PGA, Patient Global Assessment; RAPID3, Routine Assessment Patient Index Data 3; PsAID, Psoriatic Arthritis Impact of Disease; VAS, Visual Analogue Scale; NRS, Numeric Rating Scale; SD, Standard Deviation; IQR, Inter Quartile Range; MDA, Minimal Disease Activity; DAS28, Disease Activity Score 28; SRM, Standardized Response Mean; VLDA, Very Low Disease Activity; PQoL12, Psoriasis Quality of Life 12; SE, Standard Error; ROC, Receiving Operating Curve; AUC, Area Under the Curve; DAPSA, Disease Activity Index for Psoriatic Arthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; HAQ-DI, Health Assessment Questionnaire-Disability Index.

**G. Evaluation of content validity of PROMs**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PGA-arthritis** | | **PROM development study** | **Content Validity**  **study** | **Rating of reviewers** | **OVERALL RATINGS PER PROM3** | **QUALITY OF EVIDENCE** |
|  | | **+ / - / ?** | **+ / - / ?** | **+ / - / ?** | **+ / - / ± / ?** | **High, moderate, low, very low** |
| **Relevance** | |  |  |  |  |  |
| 1 | Are the included items relevant for the construct of interest? | N/A | N/A | + |  |  |
| 2 | Are the included items relevant for the target population of interest? | N/A | N/A | + |  |  |
| 3 | Are the included items relevant for the context of use of interest? | N/A | N/A | + |  |  |
| 4 | Are the response options appropriate? | N/A | N/A | + |  |  |
| 5 | Is the recall period appropriate? | N/A | N/A | + |  |  |
|  | **RELEVANCE RATING (+ / - / ± / ?)** | N/A | N/A | **+** | **+** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensiveness** | |  |  |  |  |  |  |
| 6 | Are all key concepts included? | N/A | N/A | - |  |  |
|  | **COMPREHENSIVENESS RATING (+ / - / ± / ?)** | N/A | N/A | **-** | **-** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensibility** | |  |  |  |  |  |  |
| 7 | Are the PROM instructions understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 8 | Are the PROM items and response options understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 9 | Are the PROM items appropriately worded? |  | N/A | + |  |  |
| 10 | Do the response options match the question? |  | N/A | + |  |  |
|  | **COMPREHENSIBILITY RATING (+ / - / ± / ?)** | N/A | N/A | + | **+** | **Very Low** |
|  |  |  |  |  |  |  |
|  | **CONTENT VALIDITY RATING (+ / - / ± / ?)** | **N/A** | **N/A** | **+** | **+** | **Very Low** |

N/A: not available

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PGA-Psoriatic Arthritis** | | **PROM development study** | **Content Validity**  **study** | **Rating of reviewers** | **OVERALL RATINGS PER PROM3** | **QUALITY OF EVIDENCE** |
|  | | **+ / - / ?** | **+ / - / ?** | **+ / - / ?** | **+ / - / ± / ?** | **High, moderate, low, very low** |
| **Relevance** | |  |  |  |  |  |
| 1 | Are the included items relevant for the construct of interest? | N/A | N/A | + |  |  |
| 2 | Are the included items relevant for the target population of interest? | N/A | N/A | + |  |  |
| 3 | Are the included items relevant for the context of use of interest? | N/A | N/A | + |  |  |
| 4 | Are the response options appropriate? | N/A | N/A | + |  |  |
| 5 | Is the recall period appropriate? | N/A | N/A | + |  |  |
|  | **RELEVANCE RATING (+ / - / ± / ?)** | N/A | N/A | **+** | **+** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensiveness** | |  |  |  |  |  |  |
| 6 | Are all key concepts included? | N/A | N/A | - |  |  |
|  | **COMPREHENSIVENESS RATING (+ / - / ± / ?)** | N/A | N/A | **-** | **-** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensibility** | |  |  |  |  |  |  |
| 7 | Are the PROM instructions understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 8 | Are the PROM items and response options understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 9 | Are the PROM items appropriately worded? |  | N/A | + |  |  |
| 10 | Do the response options match the question? |  | N/A | + |  |  |
|  | **COMPREHENSIBILITY RATING (+ / - / ± / ?)** | N/A | N/A | + | **+** | **Very Low** |
|  |  |  |  |  |  |  |
|  | **CONTENT VALIDITY RATING (+ / - / ± / ?)** | **N/A** | **N/A** | **+** | **+** | **Very Low** |

N/A: not available

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **RAPID3** | | **PROM development study** | **Content Validity**  **study** | **Rating of reviewers** | **OVERALL RATINGS PER PROM3** | **QUALITY OF EVIDENCE** |
|  | | **+ / - / ?** | **+ / - / ?** | **+ / - / ?** | **+ / - / ± / ?** | **High, moderate, low, very low** |
| **Relevance** | |  |  |  |  |  |
| 1 | Are the included items relevant for the construct of interest? | N/A | N/A | + |  |  |
| 2 | Are the included items relevant for the target population of interest? | N/A | N/A | + |  |  |
| 3 | Are the included items relevant for the context of use of interest? | N/A | N/A | + |  |  |
| 4 | Are the response options appropriate? | N/A | N/A | + |  |  |
| 5 | Is the recall period appropriate? | N/A | N/A | + |  |  |
|  | **RELEVANCE RATING (+ / - / ± / ?)** | N/A | N/A | **+** | **+** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensiveness** | |  |  |  |  |  |  |
| 6 | Are all key concepts included? | N/A | N/A | + |  |  |
|  | **COMPREHENSIVENESS RATING (+ / - / ± / ?)** | N/A | N/A | **+** | **-** | **Very Low** |
|  |  |  |  |  |  |  |
| **Comprehensibility** | |  |  |  |  |  |  |
| 7 | Are the PROM instructions understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 8 | Are the PROM items and response options understood by the population of interest as intended? | N/A | N/A |  |  |  |
| 9 | Are the PROM items appropriately worded? |  | N/A | + |  |  |
| 10 | Do the response options match the question? |  | N/A | + |  |  |
|  | **COMPREHENSIBILITY RATING (+ / - / ± / ?)** | N/A | N/A | + | **+** | **Very Low** |
|  |  |  |  |  |  |  |
|  | **CONTENT VALIDITY RATING (+ / - / ± / ?)** | **N/A** | **N/A** | **+** | **+** | **Very Low** |

N/A: not available

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PsAID9** | | **PROM development study** | **Content Validity**  **study** | **Rating of reviewers** | **OVERALL RATINGS PER PROM3** | **QUALITY OF EVIDENCE** |
|  | | **+ / - / ?** | **+ / - / ?** | **+ / - / ?** | **+ / - / ± / ?** | **High, moderate, low, very low** |
| **Relevance** | |  |  |  |  |  |
| 1 | Are the included items relevant for the construct of interest? | + | N/A | + |  |  |
| 2 | Are the included items relevant for the target population of interest? | + | N/A | + |  |  |
| 3 | Are the included items relevant for the context of use of interest? | + | N/A | + |  |  |
| 4 | Are the response options appropriate? | + | N/A | + |  |  |
| 5 | Is the recall period appropriate? | + | N/A | + |  |  |
|  | **RELEVANCE RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
| **Comprehensiveness** | |  |  |  |  |  |
| 6 | Are all key concepts included? | + | N/A | + |  |  |
|  | **COMPREHENSIVENESS RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
| **Comprehensibility** | |  |  |  |  |  |
| 7 | Are the PROM instructions understood by the population of interest as intended? | + | N/A |  |  |  |
| 8 | Are the PROM items and response options understood by the population of interest as intended? | + | N/A |  |  |  |
| 9 | Are the PROM items appropriately worded? |  | N/A | + |  |  |
| 10 | Do the response options match the question? |  | N/A | + |  |  |
|  | **COMPREHENSIBILITY RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
|  | **CONTENT VALIDITY RATING (+ / - / ± / ?)** | **+** | **N/A** | **+** | **+** | **Low1** |

N/A: not available

1Quality was downgraded 2 levels (very serious risk of bias) because data derived only from 1 development study of doubtful quality (cognitive interviews were not recorded and transcribed verbatim)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PsAID12** | | **PROM development study** | **Content Validity**  **study** | **Rating of reviewers** | **OVERALL RATINGS PER PROM3** | **QUALITY OF EVIDENCE** |
|  | | **+ / - / ?** | **+ / - / ?** | **+ / - / ?** | **+ / - / ± / ?** | **High, moderate, low, very low** |
| **Relevance** | |  |  |  |  |  |
| 1 | Are the included items relevant for the construct of interest? | + | N/A | + |  |  |
| 2 | Are the included items relevant for the target population of interest? | + | N/A | + |  |  |
| 3 | Are the included items relevant for the context of use of interest? | + | N/A | + |  |  |
| 4 | Are the response options appropriate? | + | N/A | + |  |  |
| 5 | Is the recall period appropriate? | + | N/A | + |  |  |
|  | **RELEVANCE RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
| **Comprehensiveness** | |  |  |  |  |  |
| 6 | Are all key concepts included? | + | N/A | + |  |  |
|  | **COMPREHENSIVENESS RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
| **Comprehensibility** | |  |  |  |  |  |
| 7 | Are the PROM instructions understood by the population of interest as intended? | + | N/A |  |  |  |
| 8 | Are the PROM items and response options understood by the population of interest as intended? | + | N/A |  |  |  |
| 9 | Are the PROM items appropriately worded? |  | N/A | + |  |  |
| 10 | Do the response options match the question? |  | N/A | + |  |  |
|  | **COMPREHENSIBILITY RATING (+ / - / ± / ?)** | **+** | N/A | **+** | **+** | **Low1** |
|  |  |  |  |  |  |  |
|  | **CONTENT VALIDITY RATING (+ / - / ± / ?)** | **+** | **N/A** | **+** | **+** | **Low1** |

N/A: not available

1Quality was downgraded 2 levels (very serious risk of bias) because data derived only from 1 development study of doubtful quality (cognitive interviews were not recorded and transcribed verbatim)

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