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

Index

|  |  |
| --- | --- |
| **Section** | **Page #** |
| A. Search strategy | 1 |
| * Pubmed
 | 1 |
| * Embase
 | 3 |
| B. Ten criteria for good content validity | 4 |
| C. Hypotheses generated for hypothesis testing for construct validity and responsiveness | 5 |
| D. Characteristics of the included study populations | 6 |
| E. Information on feasibility of PROMs | 11 |
| F. Information on interpretability of PROMs | 14 |
| G. Evaluation of content validity of PsAID9 and PsAID12 | 19 |
| References | 21 |

**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”.

|  |  |
| --- | --- |
| **#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.

|  |  |
| --- | --- |
| **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**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 PsAcohort | 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 | Centerof Excellence in psoriasis and psoriatic arthritis clinic at Oregon Health & ScienceUniversity | 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 secondaryor 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 secondaryor 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 of2 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**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 pain1 item for PGA10 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 theformula 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/orleisure 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) NRSvalue (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) NRSvalue (range 0–10) x 2) + (PsAID5 (function) NRS value (range 0–10) x 2) + (PsAID6 (discomfort) NRSvalue (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) NRSvalue (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 settingCharges 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: 0.72-0.73Sensitivity, 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 -1.06Standard care group:-mean score at baseline 3.59-mean score change: -1.01-SRM -0.47-Effect size -0.52t-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 weeksRAPID3 remission (score < 3) was in exact agreement with RAPID3SJC1 in 86.2% of patients at 48 weeksRAPID3 remission (score < 3) was in exact agreement with VLDA in 73.6%% of patients at 48 weeksRAPID3 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: 1.41Using 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=0.67Changes 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)

**References**

1. Terwee CB, Jansma EP, Riphagen, II, et al. Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2009 Oct;18(8):1115-23.

2. Egerton T, Riphagen, II, Nygard AJ, et al. Systematic content evaluation and review of measurement properties of questionnaires for measuring self-reported fatigue among older people. Qual Life Res. 2015 Sep;24(9):2239-55.

3. Cauli A, Gladman DD, Mathieu A, et al. Patient global assessment in psoriatic arthritis: a multicenter GRAPPA and OMERACT study. The Journal of rheumatology. 2011 May;38(5):898-903.

4. Eder L, Thavaneswaran A, Chandran V, et al. Factors explaining the discrepancy between physician and patient global assessment of joint and skin disease activity in psoriatic arthritis patients. Arthritis care & research. 2015 Feb;67(2):264-72.

5. Talli S, Etcheto A, Fautrel B, et al. Patient global assessment in psoriatic arthritis - what does it mean? An analysis of 223 patients from the Psoriatic arthritis impact of disease (PsAID) study. Joint, bone, spine : revue du rhumatisme. 2016 May;83(3):335-40.

6. Lubrano E, Perrotta FM, Parsons WJ, et al. Patient's Global Assessment as an Outcome Measure for Psoriatic Arthritis in Clinical Practice: A Surrogate for Measuring Low Disease Activity? The Journal of rheumatology. 2015 Dec;42(12):2332-8.

7. Leung YY, Ho KW, Zhu TY, et al. Construct validity of the modified numeric rating scale of patient global assessment in psoriatic arthritis. The Journal of rheumatology. 2012 Apr;39(4):844-8.

8. Coates LC, Tillett W, Shaddick G, et al. Value of RAPID3 in patients with PsA: results from the TICOPA and LOPAS II databases. Arthritis care & research. 2017 Nov 7.

9. Vakil-Gilani KM, Dinno A, Rich-Garg N, et al. Routine Assessment of Patient Index Data 3 Score and Psoriasis Quality of Life Assess Complementary Yet Different Aspects of Patient-Reported Outcomes in Psoriasis and Psoriatic Arthritis. Journal of clinical rheumatology: practical reports on rheumatic & musculoskeletal diseases. 2018.

10. Gossec L, de Wit M, Kiltz U, et al. A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative. Annals of the rheumatic diseases. 2014 Jun;73(6):1012-9.

11. Holland R, Tillett W, Korendowych E, et al. Validation of the Psoriatic Arthritis Impact of Disease (PsAID) Questionnaire and its potential as a single-item outcome measure in clinical practice. Annals of the rheumatic diseases. 2017 Nov 16.

12. Salaffi F, Di Carlo M, Carotti M, et al. The Psoriatic Arthritis Impact of Disease 12-item questionnaire: equivalence, reliability, validity, and feasibility of the touch-screen administration versus the paper-and-pencil version. Therapeutics and clinical risk management. 2016;12:631-42.

13. Di Carlo M, Becciolini A, Lato V, et al. The 12-item Psoriatic Arthritis Impact of Disease Questionnaire: Construct Validity, Reliability, and Interpretability in a Clinical Setting. The Journal of rheumatology. 2017 Mar;44(3):279-285.

14. Kalyoncu U, Kiraz S, Bilgen SA, et al. Change in PsAID-12 scores in patients continuing or discontinuing anti-TNF treatments in psoriatic arthritis: results from the HUR-BIO biologic registry. Clinical rheumatology. 2019 Apr;38(4):1187-1192.

15. Pincus T, Bergman MJ, Yazici Y. RAPID3-an index of physical function, pain, and global status as "vital signs" to improve care for people with chronic rheumatic diseases. Bulletin of the NYU hospital for joint diseases. 2009;67(2):211-25.