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Keywords:	Rheumatoid arthritis, Foot and ankle, Psychometry, systematic review

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Abstract

Objective. To identify self-reported outcome measures specific to the foot and ankle in patients with rheumatoid arthritis and to investigate the methodological quality and psychometric properties of these measures. ***Methods.*** A systematic review focusing on patients with rheumatoid arthritis. **Setting:** The search was conducted in the PubMed, SCOPUS, CINAHL, PEDro and Google Scholar databases, based on the following inclusion criteria: population (with rheumatoid arthritis) >18 years; psychometric or clinimetric validation studies of patient-reported outcomes specific to the foot and ankle, in different languages, with no time limit. Two of the present authors independently assessed the quality of the studies located and extracted the relevant data. Terwee's criteria and the COSMIN checklist were employed to ensure adequate methodological quality. ***Results*:** Of the initial 431 studies considered, 14 met the inclusion criteria, representing 7,793 patients (56.8 years). These instruments were grouped into 3 dimensions (pain; perceived health status and quality of life and disability). The time to complete any of the PROMs varies around fifteen minutes. PROMs criterias with the worst scores by COSMIN, 92.85% and 85.71% were criterion validity, measurement error, internal consistency and responsiveness. 28.57% of PROMs were compared the measurement properties. ***Conclusion***: the Self-Reported Foot and Ankle Score achieved the highest number of positive criteria (according to Terwee and COSMIN), and is currently the most appropriate for patients with Rheumatoid Arthritis

Keywords: Rheumatoid arthritis, Foot, Ankle, Psychometrics, Methodological quality, Patient-reported outcome measures, Measure.

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Systematic review of the psychometric properties of patient-reported outcome measures for rheumatoid arthritis in the foot and ankle

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Abstract

Objective. To identify self-reported outcome measures specific to the foot and ankle in patients with rheumatoid arthritis and to investigate the methodological quality and psychometric properties of these measures. ***Methods.*** A systematic review focusing on patients with rheumatoid arthritis. **Setting:** The search was conducted in the PubMed, SCOPUS, CINAHL, PEDro and Google Scholar databases, based on the following inclusion criteria: population (with rheumatoid arthritis) >18 years; psychometric or clinimetric validation studies of patient-reported outcomes specific to the foot and ankle, in different languages, with no time limit. Two of the present authors independently assessed the quality of the studies located and extracted the relevant data. Terwee's criteria and the COSMIN checklist were employed to ensure adequate methodological quality. ***Results*:** Of the initial 431 studies considered, 14 met the inclusion criteria, representing 7,793 patients (56.8 years). These instruments were grouped into 3 dimensions (pain; perceived health status and quality of life and disability). The time to complete any of the PROMs varies around fifteen minutes. PROMs criterias with the worst scores by COSMIN, 92.85% and 85.71% were criterion validity, measurement error, internal consistency and responsiveness. 28.57% of PROMs were compared the measurement properties. ***Conclusion***: the Self-Reported Foot and Ankle Score achieved the highest number of positive criteria (according to Terwee and COSMIN), and is currently the most appropriate for patients with Rheumatoid Arthritis

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Introduction

In patients with rheumatoid arthritis, foot pain, joint stiffness, deformity and loss of foot function are the major determinants of problems in foot-health-related quality of life (1-3). The consequences of foot problems in rheumatoid arthritis can be measured in a variety of ways, including physical activity (2), clinical status (3) and patient-reported outcome measures (4). The latter have the specific advantage of being meaningful to the individual patient, reflecting the issues that affect their health and lives. Existing patient-reported outcome measures differ in the foot-health concepts measured, but generally include pain (7-10), disability (8,10), function (5), activity limitation (7), footwear and general foot health (5).

In clinical practice, patient-reported outcome measures support physicians and patients, enabling them to co-create personalised care plans, taking into account patients' preferences and values. For this purpose, robust instruments with good psychometric properties are necessary. Whilst many instruments for the foot and ankle are available (4), few are specific to rheumatoid arthritis (8,9), and their validation remains unclear. Further evidence is needed to determine how best to summarise and interpret the research data obtained and to determine the conditions that must be met in order to make well-founded recommendations. Furthermore, the evidence derived from research may be specific to the characteristics of the patients involved and rigorous methods are needed to overcome the potential bias associated with the study of human subjects.

The main aims of this review were to identify patient-reported outcome measures specific to the effects of rheumatoid arthritis in the foot and ankle, and to evaluate the methodological quality and psychometric properties of these instruments.

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Material and Methods

This systematic review was carried out to assess patient-reported outcome measures used for patients with foot and ankle pathologies associated with rheumatoid arthritis. The review protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO: CRD 42018090594) prior to the identification of articles and data extraction.

Search strategy

The following databases were searched: PubMed, Scopus, CINAHL, PEDro and Google Scholar from inception until February 2018. All databases were searched again at the first of June 2019. In pubmed, the search was conducted in accordance with the strategy described by Terwee et al. (10) to detect the corresponding psychometric properties: construct search (patient-reported outcomes specific to the foot and ankle); population search (rheumatoid arthritis); instrument search (questionnaires, scales, instrument); measurement properties (filters). (Appendix 1).

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The criteria applied for inclusion in the analysis were:

- Participants: patients with rheumatoid arthritis, aged over 18 years. The studies should be specifically focused on the foot and ankle;
- Studies: psychometric validation studies of patient-reported outcomes, published in English or Spanish;
- Outcomes: psychometric or clinimetric properties based on criteria according to *Terwee* (content validity; internal consistency; criterion validity; construct validity; reproducibility (agreement and reliability); responsiveness; floor/ceiling effect; interpretability) or *COSMIN* (structural validity; internal consistency; reliability; measurement error; hypothesis testing for construct validity; cross cultural validity/measurement invariance; criterion validity and responsiveness).

The exclusion criteria were:

- Studies: those based on questionnaires of orthopaedic injuries

Quality appraisal

The updated COSMIN checklist (Figure 1) was used to evaluate the methodological quality of studies investigating the measurement properties of a patient-reported outcome measure (11). This standard can be used either to assess the methodological quality of a study (12) or to compare the properties of various measurement instruments in a systematic review (13). The measurement properties considered are divided into three domains: reliability, validity and responsiveness. Each property contains various items, evaluated on a 4-point Likert scale as poor, fair, good or excellent. The "worst score counts" approach was applied to derive a final rating for each patient-reported outcome measure considered (13).

With respect to the psychometric properties proposed by Terwee (14), each issue was rated as positive "+" (adequate description or value or measure or argument related to the psychometric property), negative "-" (inadequate or values below the accepted standards for the psychometric property), indeterminate "?" (doubtful methods or measures or design) or absent "0" (no information available about the psychometric property), except for responsiveness, which was rated only as present/absent.

Study selection

Two blinded reviewers (LRP and PCG) evaluated the search results. The reference lists were reviewed independently to observe fulfilment or otherwise of the inclusion criteria. Disagreements were resolved by discussion between the two evaluators, or if consensus was not possible, further opinion was sought (ABOA, GGN, CN and JMMA).

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Data extraction

Titles and abstracts were then reviewed independently by two reviewers (PCG and LRP) and relevant articles were then obtained in full text. The same reviewers undertook the second stage of screening by reading the full text of selected articles. The following data were extracted from each study, using a standardised template: full title, country, year of publication, dimensions and number of items, population used for the validation process, psychometric properties (Terwee's criteria with a positive rating), cross-cultural adaptation into the language of each questionnaire included, and methodological quality (according to COSMIN). In studies lacking any of these elements, the authors were contacted to obtain the necessary data. The studies were first grouped into broad themes (according to the items), and then narrowed down into three main categories: pain, perceived health status/quality of life and disability.

No meta-analysis was carried out due to the heterogeneity of the dimensions and outcomes included in these studies.

Results

An initial 431 studies were identified, but 63 were duplicated among the different databases. The remaining 368 were screened against our inclusion/exclusion criteria, using the titles, abstracts and key words. Fifty seven studies met the inclusion criteria. After quality appraisal, a further 43 were excluded, and so 14 studies remained in the final analysis. Figure 2 shows the PRISMA flow diagram for the studies included in the review (15).

Population. A total of 7,793 participants were included in the 14 studies (61.4% female; 38.6% male, with a mean age of 56.8 years). The classification obtained for each measurement instrument is detailed in Table 1.

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The Dimensions included in the different instruments were grouped into three areas (Table 2):

- pain (in the foot or ankle);
- perceived health status and quality of life (overall, lower limb-related or foot-related);
- disability (concerning activities of daily living, limitation of general function, limitation of sports/recreational function).

The range of dimensions were between two and seven. Four of the patient-reported outcome measures considered (the Ankle Osteoarthritis Scale, the Manchester Foot Pain and Disability Index, the Foot and Ankle Ability Measure and the Leeds Foot Impact Scale) had two dimensions, and one (the Podiatry Health Questionnaire) had seven dimensions.

Structure

The shortest patient-reported outcome measure (the Podiatry Health Questionnaire) had seven items, and the longest (the Leeds Foot Impact Scale) had 51.

Psychometric properties

The psychometric properties of each patient-reported outcome measure are summarised in Tables 1 and 2, following Terwee's criteria. The Self-reported Foot and Ankle Score, included in the pain group, presented the best overall psychometric properties, with positive evidence for content validity (clear description of measurement aim, target population, item selection and reduction), internal consistency (Cronbach's alpha 0.70-0.95), construct validity (evidence from factor analysis to confirm the study hypotheses), reproducibility/reliability (ICC>0.7), floor/ceiling effect (only described for the Self-reported Foot and Ankle Score (0%)). On the other hand, the evidence was indeterminate

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for three criteria (reproducibility:agreement, responsiveness and interpretability) and negative for one (criterion validity).

In the perceived health status/quality of life group, there was positive evidence for the Foot Health Status Questionnaire on four criteria: content validity, internal consistency, construct validity and reproducibility:reliability.

In the disability group, there was positive evidence for the Rheumatoid and Arthritis Outcome Score on three criteria: content validity, internal consistency and reproducibility/reliability.

With respect to criterion validity; reproducibility:agreement, responsiveness and interpretability, positive ratings were obtained in very few cases; most of the patient-reported outcome measures considered obtained an indeterminate or absent rating.

Cross-Cultural Adaptation

Neither the Rowan Foot Pain Assessment Questionnaire nor the Salford Rheumatoid Arthritis Foot Evaluation considered the question of cross-cultural adaptation. The other patient-reported outcome measures had been translated or culturally adapted into diverse languages, including Arabic, Somali, Thai, Danish, Spanish, Hungarian, Polish and Greek. In this respect, the Foot and Ankle Ability Measure was the most widely adapted, being translated into eleven languages (French, Japanese, Persian, German, Italian, Turkish, Brazilian, Spanish, Chinese, Thai and Dutch).

Methodological Quality

The Self-reported Foot and Ankle Score and the Foot and Ankle Ability Measure were assessed by the COSMIN criteria for methodological quality (Table 3). The first of these patient-reported outcome measures had a positive rating for reliability, hypothesis testing for construct validity and responsiveness, a negative one for structural validity and criterion validity, and indeterminate ratings for internal consistency, measurement error

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and cross-cultural validity/measurement invariance. The second had a positive rating for reliability, measurement error and responsiveness, a negative one for structural validity, hypothesis testing for construct validity and criterion validity, and indeterminate ratings for internal consistency and cross-cultural validity/measurement invariance. Overall, both presented poor methodological quality.

For the following properties, the other patient-reported outcome measures had few positive ratings, often presenting missing or unknown data: internal consistency (Cronbach's alpha not determined or dimensionality unknown), measurement error (patient-reported outcome measures not defined by minimally-important change), hypothesis testing (hypothesis not defined or results conflicting with the hypothesis), cross-cultural/measurement invariance (no important differences found between group factor or differential item functioning), criterion validity or responsiveness (no hypothesis defined, results conflicting with the hypothesis or area under the curve <0.70)

- *Methodological quality according to measurement properties*

In addition to the above, we evaluated the methodological quality of the best-rated patient-reported outcome measures, using COSMIN boxes to classify their quality as poor, fair, good or excellent. These details are shown in Table 4. In this respect, only the Foot Health Status Questionnaire, the Foot and Ankle Ability Measure, Salford Rheumatoid Arthritis Foot Evaluation and the Self-reported Foot and Ankle Score achieved a positive score according to COSMIN. In the context of the low overall score, the Foot and Ankle Ability Measure was rated highest, with excellent ratings for content validity, structural validity and criterion validity. None of these patient-reported outcome measures were evaluated for cross-cultural validity as the inclusion criteria limited the studies considered to those focusing on rheumatoid arthritis.

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Discussion

The objective of this systematic review was to identify patient-reported outcome measures concerning the effects of rheumatoid arthritis on the foot and ankle, and to evaluate the methodological quality and psychometric properties of these measures. The Self-reported Foot and Ankle Score presented the best overall psychometric properties and methodological quality. With respect to psychometric properties, the Self-reported Foot and Ankle Score (16) obtained the highest number of positive criteria, although it presented deficiencies in criterion validity, agreement, responsiveness and interpretability. This patient-reported outcome measure is relatively new and to date only one cross-cultural adaptation (into German) has been made

The patient-reported outcome measures analysed in this review had 2-7 dimensions and were further categorised into three areas: pain, perceived health status and quality of life and disability, according to their main components. Similar categorisations have been performed by Van der Leeden et al. (4) and Oude Voshaar et al. (2), both of whom combined patient-reported outcome measures with scales and other instruments measuring foot function, pain or foot-related disability.

Most of the patient-reported outcome measures analysed have been culturally adapted for use in other languages. Such transcultural adaptations are important, enabling health professionals in different societies and countries to have the same perspective and to obtain comparable data for patients with rheumatoid arthritis. On the other hand, if it is to be valid, any such cross-cultural adaptation must be performed with scientific rigour.

Most of the patient-reported outcome measures considered presented deficiencies regarding construct validity, responsiveness, floor/ceiling effect and interpretability. It is important to highlight these shortcomings, as they may have significant consequences in clinical and research contexts. Construct validation is an on-going process of learning,

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prediction and testing (17). If it is not performed appropriately, the resulting conclusions on assisting patients in the development of self-management skills will be unreliable and discounted.

Another important question is that of the floor/ceiling effect. This parameter helps identify any redundant items it may include. Obviously, if a patient-reported outcome measure did not provide information about what (change in) score would be clinically meaningful, it would have little practical or theoretical value.

The study presents certain limitations. Importantly, some instruments were excluded from our analysis, namely the Oxford Ankle Foot Questionnaire for Children (18) and the Juvenile Arthritis Foot Disability Index (19), due to our focus on patients aged over 18 years, therefore, our findings could only be related to adult RA population. Another limitation was the fact that some data were incomplete, despite our efforts to contact the original authors. Among its strengths, this study was based on a literature search of five medical databases, with a well-defined search strategy and no limitation on time. Moreover, all the studies included had been clinimetrically validated. The review we describe was based on a blinded quality appraisal following a well-established method, the COSMIN checklist.

The clinical implications of these results point out the gap regarding the dimension of self-care, prevention or treatment adherence specifically with respect to the foot and ankle. This issue is of major importance to patients with rheumatoid arthritis, as its impact on the foot and ankle often limits or prevents the activities of daily life. Instruments with these dimensions should be available for patients and clinicians.

On the other hand, the scarcity of responsiveness evaluation for most of the instruments implies a major shortfall for clinical practice. The criterion of responsiveness is of crucial importance, revealing the clinically important changes that must be observed and helping

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clinicians and patients monitor the condition. Moreover, this issue may jeopardize the outcome evaluation in longitudinal research.

Future research should address the structure of the questionnaires considered; the number of items varied widely among the patient-reported outcome measures, and response options were also heterogeneous, with some offering a simple yes/no choice, while others measured outcomes on a Likert scale. In future research, it would be useful to examine whether the number of items and the response options provided correctly discriminate the interventions performed, the health status of the patients and the follow up procedures employed.

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Clinical messages

1. On available evidence, the **Self-reported foot and ankle score** is currently the most appropriate patient-reported outcome measure available for patients with Rheumatoid Arthritis.
2. The most of patient-reported outcome measures have poor evidence of their psychometric properties and should be used with caution for patients with Rheumatoid Arthritis
3. Robust methods should be designed and implemented to get higher-quality instruments for patients with Rheumatoid Arthritis.

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Tables and Figure

Figure 1. Instruction for completing the COSMIN checklist

Figure 2. PRISMA. Flow diagram

Table 1. Instruments included in the study

Table 2. Assessment of the measurement properties of the questionnaires

Table 3. Detailed COSMIN ratings

Table 4. Methodological quality per PROM property (COSMIN)

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Table 1. Instruments included in the study

	Author/Year	Data of Psychometric properties	Dimensions and items	Population used for validation	Psychometric properties	Cross-cultural adaptation
FFI (7) **Foot function Index (original)**	E. Budiman-Mak et al. 1991		3 dimensions: pain, disability and activity restriction 23 items	87 patients with RA 77 male (89%) 10 female (11%) Mean age: 61 years (24-79)	Internal consistency: Cronbach´s alpha 0.96-0.73 (total: 0.95) Test-retest reliability: (0.87 – 0.69). ICC= 0.87 4 factors: foot pain (1-9) disability (10-18) activity limitation (19-21) social issues (22-23)	8 Brazilian/Portuguese(20), Polish (20), Korean(21), Italian(22), Taiwan Chinese(23), French(24), Spanish (25), German(26)
FFI-R(27) **Foot function Index(revised)**	E. Budiman-Mak et al. 2006	Internal consistency: Cronbach´s alpha 0.88-0.94 Test-retest reliability: (0.64-0.79) 2factors: ICC (0.70-0.83) – ICC (0.63-0.71)				
AOS(28) **Ankle Osteoarthritis Scale**	R T. Domsic and C L. Saitzman 1998		2 dimensions: pain and disability 18 items	562 patients 264 male (47%) 298 female (53%) Age 20-85 years	Test - retest analysis ICC of 0.97 (0.94-0.99)	1 French(29)
FHSQ(5)	P J. Bennett et al. 1998		4 dimensions: foot pain, foot function, footwear, and general foot health	111 patients 25 male (22.5%)	Internal consistency: Cronbach's α between 0.85 and 0.88	2 Spanish(30),Brazilian(31)

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Foot Health Status Questionnaire			13 items	Mean age 45 years 85 female (77.5%) Mean age 57 years	Construct validity: 4 factors from 0.0 to 1.0 Reliability: ICC between 0.74 and 0.91	
MFPDI(6) **Manchester Foot Pain Disability Index**	A P. Garrow et al. 1999		2 dimensions: foot pain and disability 19 items	1078 patients 604 male (56%) 474 female (44%) Group 1 (RA) 45 Mean age 53 years (42-65) Group 2 (foot-related problem) 33 Mean age 61 years (41-76) Group 3 (survivor of foot disorders) 1000 Mean age 50 years (37-63)	Internal consistency: Cronbach's α= 0.99 Construct validity: 6.42 - 34.9 % Reliability: kappa values of 0.48, 0.50, and 0.17	3 Danish(32), Spanish(33), Greek(34), Chinese(35)
ROFPAQ(36) **Rowan Foot Pain Assessment Questionnaire**	K. Rowan 2001		3 dimensions: multi-dimensional pain (sensory-discriminative, motivational-affective and cognitive-evaluative). 39 items	17 patients 5 male (29%) 12 female (71%) Mean age 65 years (46-73)	Internal consistency: Cronbach's α between 0.80 and 0.90 Criterion validity: Spearman correlations with Headache scale from 0.15 to 0.48 Test-retest reliability: from 0.81 to 0.92	0

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PHQ(37) **Podiatry Health Questionnaire**	S. Macran et al. 2003		7 dimensions: walking, hygiene, nail care, foot pain, worry/concern, quality of life and PHQ_{vas} 7 items	2073 patients 684 male (33%) 1389 female (67%) Mean age 72 years (18-96)	Criterion validity: Kendal correlation from -0.35 to 0.58 Floor effect: 86% in the nail care dimension	1 Spanish(38)
RAOS(37) **Rheumatoid and Arthritis Outcome Score**	A BI. Bremander et al. 2003		5 dimensions: Pain; other symptoms like stiffness, swelling, and range of motion; activities of Daily Living (ADL); sport and Recreational activities (Sport/Rec); and lower limb-related Quality of Life (QOL). 42 items	119 patients with inflammatory joint disease (51% RA) 32 male (27%) 87 female (73%) Mean age 56 years	Cronbach's alpha: from 0.78 to 0.95 ICC = 0.76 – 0.92 Floor effect: 37%	3 Turkish(39) French (40) Persian(41)
FAM-AAOS(42) **Foot and Ankle Module of American Academy of Orthopaedic Surgeons**	N A. Johanson et al. 2004		5 dimensions: function, pain, stiffness and swelling, giving way and shoe comfort 25 items	205 patients 111 male (54%) 94 female (46%) Mean age 48 years (21-85) Group 1 (sport/knee diagnosis) n:59 Group 2 (hip and knee diagnosis) 43 Group 3 (foot and ankle diagnosis) n:70	Internal consistency: Cronbach's α between 0.7 and 0.95 Criterion validity: r between 0.49 and 0.95 Reliability: between 0.68 and0.99	1 Spanish(43)

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FAAM(44) **Foot and Ankle Ability Measure**	R L. Martin et al. 2005		2 dimensions: activities of daily living (ADL) and sports. 21 items	1027 patients 391 male (38.1%) 629 female (61.2%) Gender not reported (0.7%) Mean age 42 years (8-83) Group 1 (Expected to change) 97 male (59.15%) 67 female (40.85%) Mean age 41.2 years Group 2 (Expected to remain stable) 47 male (59.5%) 32 female (40.5%) Mean age 45.2 years	Criterion validity: with SF-36 function subscale (r = 0.84, 0.78), physical component summary score (r = 0.78, 0.80), mental function subscale (r = 0.18, 0.11) and mental component summary score (r = 0.05, −0.02). Construct validity: one factor in Group 1 (80.46% of the variance and an eigenvalue of 16.90). Two factors in Group 2 (first factor 78.37% of the variance and an eigenvalue of 16.46; second factor 12.28% of the variance and an eigenvalue of 2.58) Agreement: minimal detectable change for the ADL subscale ±5.7. For the Sports subscale ±−12.3 points. Minimal clinically important diference for ADL 8 and for Sports subscale 9 points. Test-retest reliability: 4 weeks apart. 0.89 and 0.87 for the ADL and Sports subscales, respectively.	11 French(45), Japanese(46), Persian (47), German (48), Italian (49), Turkish (50), Brazilian (51), Spanish(52), Chinese (53), Thai (54) and Dutch(55)
BFS(56)	S. Barnett et al. 2005		5 dimensions: mobility, pain, footwear, foot health and disability,	400 patients Pilot study 10	Internal consistency: Cronbach's α= 0.90	1 Spanish(57)

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Bristol Foot Score			and perception of self as a result of foot problems 15 items	3 male (30%) 7 female (70%) Age 24 to 89 years Version 4 71 23 male (32%) 48 female (68%) Mean age 58 years (13-90)	3 factors: feet pain (50%), footwear and general foot health (10%) and mobility (9%).	
LFIS(58) **Leeds Foot Impact Scale**	P. Helliwell et al. 2005		2 dimensions: impairment/shoe and activities/participation 51 items	192 patients with RA (yielded 148) 34 male (23%) 114 female (77%) Mean age 61.7 years (28-89)	Content validity: qualitative pilot study with 30 subjects Reliability: Impairment / shoes subscale ICC of 0.84 (95% CI 0.75–0.90); Activities / participation subscale ICC of 0.96 (95% CI 0.93–0.98).	3 Dutch(59) German Hungarian(60)
SAFE(61) **Salford Rheumatoid Arthritis Foot Evaluation**	S. Walmsley 2012		3 dimensions: impairment, disability and foot wear 19 items	28 patients 7 male (25%) 21 female (75%) Mean age 58,5	Content validity: qualitative study Criterion validity: MFPDI 0.83 and LFIS 0.79	0

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FAOS(62) **Foot and Ankle Outcome Score**	Y M. Golightly et al. 2014		4 dimensions: pain, activities of daily living (ADL), sport and recreational function (sport/recreation), quality of life (QOL), other symptoms 42 items	1670 patients 541 male (32.4%) 1129 female (67.6%) Mean age 69 years (50-95) Group 1(pain) 1641 Group 2 (ADL) 1609 Group 3 (sport /recreation) 1454 Group 4 (QOL) 1632 Group 5 (other symptoms) 1670	Internal consistency: group 1 Cronbach's α= 0.95 – 0.97; group 2 Cronbach's α= 0.97-0.98; group 3 Cronbach's α= 0.94 – 0.96; group 4 Cronbach's α= 0.89 – 0.92; group 5 Cronbach's α= 0.72 – 0.82 Reliability: ICC=0.63 – 0.81	6 Persian(63) Korean(64) Dutch(65) German(66) Thai(67) Turkish(68) Chinese(69)

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SEFAS(16) **Self-reported Foot and Ankle Score**	M. Cöster et al. 2014		3 dimensions: pain, function, and limitation of function 12 items	224 patients Group 1 (Forefoot disorders): 118 22 male (19%) 96 female (81%) Mean age 57 years (16–87) Group 2 (midfoot, hindfoot or ankle disorders): 106 47 male (44%) 59 female (56%) Mean age 55 years (18–81)	Internal consistency: group 1 Cronbach's α = 0.84; group 2 Cronbach's α= 0.86, Criterion validity: Spearman rho with FAOS, SF-36, EQ-5D (0.6 – 0.8) Construct validity: 80% of predefined hypotheses confirmed Reliability: group 1 ICC = 0.92; group 2 ICC = 0.93 Floor/ceiling effect: group 1= 0%; group 2= 0%	1 German(70)

RA Rheumatoid Arthritis; *N* number of patients; *ICC* Intraclass correlation coefficient; *ADL* Activities of Daily Living; *SF-36* Short Form-36 health survey; *EQ-5D* EuroQol-5D

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Table 2. Assessment of the measurement properties of the questionnaires

		Content validity	Internal consistency	Criterion validity	Construct validity	Reproductibility Agreement	Reproductibility Reliability	Responsiveness	Floor/ceiling effect	Interpretability	Final assessment
PAIN	AOS	+	0	-	?	0	+	0	0	0	
	MFPDI	+	-	?	-	?	-	0	0	0	
	ROFP AQ	+	+	+	-	0	+	0	0	0	
	SEFAS	+	+	-	+	?	+	?	+	?	V
Perceived Health Status and Quality of Life	FHSQ	+	+	?	+	0	+	0	0	?	V
	PHQ	+	0	-	0	0	0	0	-	?	
	BFS	+	+	?	-	?	?	?	0	?	
	FAOS	+	-	?	?	?	-	0	0	?	
Disal	FFI	+	+	0	?	0	-	?	0	?	
	RAOS	+	+	?	0	0	+	0	-	?	V
	FAAM	+	?	-	-	-	+	+	0	0	

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	FAM AAOS	+	+	-	0	0	-	0	0	?
	LFIS	+	0	?	0	0	+	0	?	?
	SAFE	+	0	+	0	?	+	0	?	?

Group:

- Pain: AOS **Ankle Osteoarthritis Scale**; MFPDI **Manchester Foot Pain Disability Index**; ROFPAQ **Rowan Foot Pain Assessment Questionnaire**; SEFAS **Self-reported Foot and Ankle Score**
- Perceived Health Status and Quality of Life: FHSQ **Foot Health Status Questionnaire;** PHQ **Podiatry Health Questionnaire;** BFS **Bristol Foot Score;** FAOS **Foot and Ankle Outcome Score**
- Disability: FFI **Foot Function Index;** RAOS **Rheumatoid and Arthritis Outcome Score;** FAAM **Foot and Ankle Ability Measure;** FAM-AAOS **Foot and Ankle Module of American Academy of Orthopaedic Surgeons;** LFIS **Leeds Foot Impact Scale;** SAFE **Salford Rheumatoid Arthritis Foot Evaluation**

Rating: + Positive; ? Indeterminate; - Negative; 0 No information available.

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Table 3. COSMIN ratings

	Structural Validity	Internal Consistency	Reliability	Measurement Error	Hypothesis testing for construct validity	Cross Cultural Validity/Measurement Invariance	Criterion Validity	Responsiveness
FFI	+	+	-	?	?	?	?	?
AOS	-	?	+	?	?	?	-	?
FHSQ	-	?	+	?	-	-	?	-
MFPDI	-	?	-	?	?	-	?	?
ROFPAQ	-	?	+	?	?	?	-	?
PHQ	-	?	?	?	?	?	-	?
RAOS	-	?	+	?	?	?	-	?
FAM AAOS	-	?	-	?	?	?	-	?
FAAM	-	?	+	+	-	?	-	+
BFS	+	+	-	?	?	?	?	?
LFIS	-	?	+	?	?	-	?	?
SAFE	-	?	+	?	-	?	+	-
SEFAS	-	?	+	?	+	?	-	+
FAOS	-	?	-	?	?	-	?	?

Rating: "+": Positive; "?": Indeterminate; "-": Negative

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FFI **Foot Function Index;** AOS **Ankle Osteoarthritis Scale;** FHSQ **Foot Health Status Questionnaire;** MFPDI **Manchester Foot Pain Disability Index;** ROFPAQ **Rowan Foot Pain Assessment Questionnaire;** PHQ **Podiatry Health Questionnaire;** RAOS **Rheumatoid and Arthritis Outcome Score;** FAM-AAOS **Foot and Ankle Module of American Academy of Orthopaedic Surgeons;** FAAM **Foot and Ankle Ability Measures;** BFS **Bristol Foot Score;** LFIS **Leeds Foot Impact Scale;** SAFE **Salford Rheumatoid Arthritis Foot Evaluation;** SEFAS **Self-reported Foot and Ankle Score;** FAOS **Foot and Ankle Outcome Score**

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Table 4. Methodological quality per PROM property (COSMIN)*

	BOX A Internal Consistency	**BOX B Reliability**	**BOX C Measurement error**	**BOX D Content Validity**	**BOX E Structural Validity**	**BOX F Hypothesis testing**	**BOX G Cross-cultural validity**	**BOX H Criterion Validity**	**BOX I Responsiveness**
FHSQ	Fair	Poor	Fair	Poor	Poor	Poor	-	Poor	Poor
FAAM	Poor	Poor	Good	Excellent	Excellent	Good	-	Excellent	Fair
SAFE	Poor	Poor	Poor	Excellent	Poor	Poor	-	Poor	Poor
SEFAS	Poor	Poor	Poor	Excellent	Poor	Fair	-	Poor	Poor

* COSMIN checklist can be used to assess the quality of a study on one measurement instrument or to compare the measurement properties of a number of measurement instruments in a systematic review

FHSQ**: Foot Health Status Questionnaire;** FAAM **Foot and Ankle Ability Measures**; SAFE **Salford Rheumatoid Arthritis Foot Evaluation;** SEFAS **Self-reported Foot and Ankle Score**

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Figure 1. Instructions for completing the COSMIN checklist

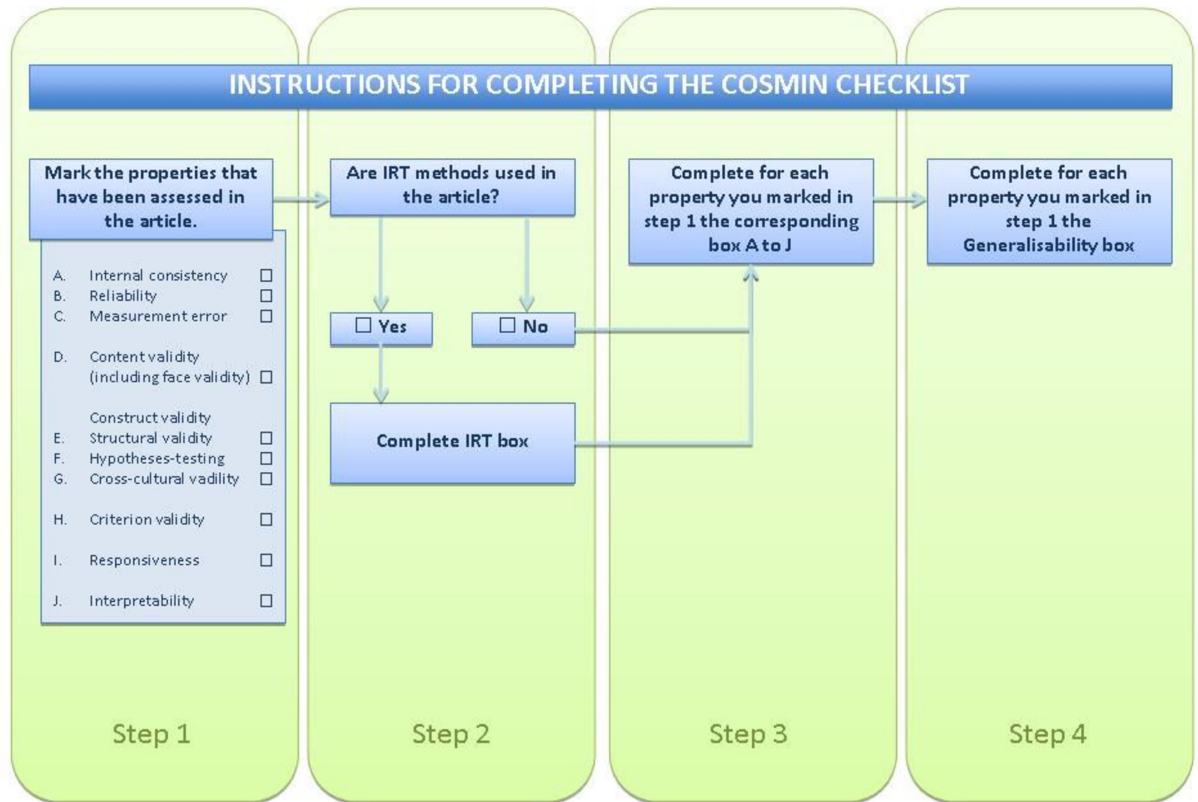

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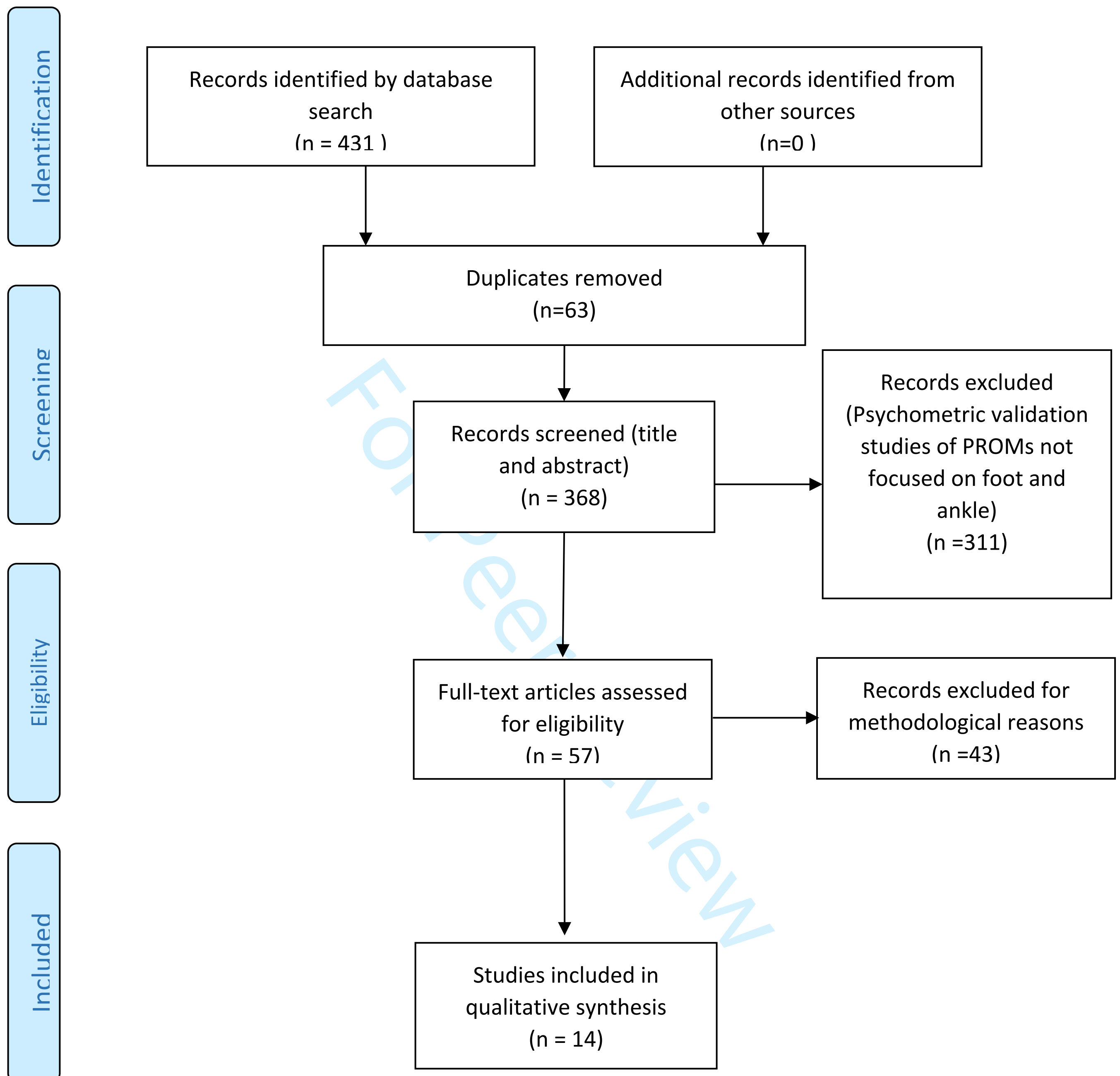
Figure 2. PRISMA Flow Diagram



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Appendix 1. Searching Strategy (Pubmed)

1	Rheumatoid Arthritis
2	Foot
3	Feet
4	Ankle
5	2 OR 3 OR 4
6	1 AND (2 OR 3 OR 4)
7	“Patient Reported Outcome Measures”
8	Questionnaire
9	Instrument
10	Scale
11	Index
12	7 OR 8 OR 9 OR 10 OR 11
13	6 AND 12
14	“Pain”
15	Disab*
16	Funct*
17	14 OR 15 OR 16
18	13 AND 17

#1 Rheumatoid Arthritis [tiab] 100484

#2Foot [tiab] 90109

#3 Feet [tiab] 27300

#4 Ankle [tiab] 54011

#5 ((foot [tiab]) OR feet [tiab]) OR ankle [tiab]) 147500

#6 (rheumatoid arthritis[tiab]) AND (((foot [tiab]) OR feet [tiab]) OR ankle [tiab]) 2387

#7 "Patient Reported Outcome Measures"[Mesh] 3291

#8 questionnaire[tiab] 373536

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#9 instrument [tiab] 110243

#10 scale [tiab] 652290

#11 index [tiab] 713203

#12 (((("Patient Reported Outcome Measures"[Mesh]) OR questionnaire[tiab]) OR instrument [tiab]) OR scale [tiab]) OR index [tiab] 1663798

#13 (((rheumatoid arthritis[tiab]) AND (((foot [tiab]) OR feet [tiab]) OR ankle [tiab]))) AND ((((("Patient Reported Outcome Measures"[Mesh]) OR questionnaire[tiab]) OR instrument [tiab]) OR scale [tiab]) OR index [tiab]) 524

#14 "Pain"[Mesh] 375794

#15 disab* 328598

#16 funct* 3700202

#17 ((pain[Mesh]) OR funct*) OR disab* 4265399

#18 (((((rheumatoid arthritis[tiab]) AND (((foot [tiab]) OR feet [tiab]) OR ankle [tiab]))) AND ((((("Patient Reported Outcome Measures"[Mesh]) OR questionnaire[tiab]) OR instrument [tiab]) OR scale [tiab]) OR index [tiab]))) AND (((pain[Mesh]) OR funct*) OR disab*) 262

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