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Author: Visser, Anna Willemina (Willemien)

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PART II

Identification of appropriate outcome measurements for hand OA
research

CHAPTER 7

**Instruments measuring pain, physical function or patient global assessment
in hand osteoarthritis – a systematic literature search**

A.W. Visser, P. Bøyesen, I.K. Haugen, J.W. Schoones, D.M. van der Heijde,
F.R. Rosendaal, M. Kloppenburg

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ABSTRACT

Objective

Description of use and metric properties of instruments measuring pain, physical function or patient global assessment in hand osteoarthritis (OA).

Methods

Medical literature databases up to January 2014 were systematically reviewed for studies reporting on instruments measuring pain, physical function or patient global assessment in hand OA. The frequency of the use of these instruments were described, as well as their metric properties, including discrimination (reliability, sensitivity to change), feasibility and validity.

Results

In 66 included studies, various questionnaires and performance- or assessor-based instruments were applied for evaluation of pain, physical function or patient global assessment. No major differences regarding metric properties were observed between the instruments although the amount of supporting evidence varied. The most frequently evaluated questionnaires were the Australian/Canadian Hand OA Index (AUSCAN) pain subscale and visual analogue scale (VAS) pain for pain assessment and the AUSCAN function subscale and Functional Index for Hand OA (FIHOA) for physical function assessment. Excellent reliability was shown for the AUSCAN and FIHOA and good sensitivity to change for all mentioned instruments; additionally the FIHOA had good feasibility. Good construct validity was suggested for all mentioned questionnaires. The most commonly applied performance- or assessor-based instrument were grip and pinch strength for assessment of physical function, in addition to assessment of pain by palpation. For these measures good sensitivity to change and construct validity were established.

Conclusion

The AUSCAN, FIHOA, VAS pain, grip and pinch strength and pain on palpation were most frequently tested and provided most supporting evidence for good metric properties. More research has to be performed to compare the different instruments to each other.

INTRODUCTION

Hand osteoarthritis (OA) is a highly prevalent disorder, characterized by bony enlargements and deformities.¹⁻³ Most studies on individuals with OA are based on the general population. Individuals with hand OA can experience symptoms as pain, decreased grip strength and disability, leading to a high clinical burden.⁴⁻⁶ In clinical practice, treatment for patients with hand OA (individuals with hand OA seeking health care) is administered to decrease symptoms and improve function, however the evidence to support these treatments is limited since few high-quality clinical trials have been performed in hand OA.^{7,8}

An important problem in the lack of high-quality clinical trials in hand OA is the lack of standardization of outcome measures.⁸ Therefore, the Outcome Measures in Rheumatology (OMERACT) and Osteoarthritis Research Society International Task Force on Clinical Trials Guidelines defined core domains to describe outcomes in clinical trials on symptom modification, comprising pain, physical function and patient global assessment.⁹⁻¹²

For assessment of these domains, several patient reported outcome (PRO) measures are available. Hand OA specific questionnaires as the Functional Index for Hand OA (FIHOA) and Australian/Canadian Hand OA Index (AUSCAN),^{13,14} but also hand disorder or arthritis specific questionnaires as the Michigan Hand Outcomes Questionnaire (MHQ), Arthritis Impact Measurement Scale-2 (AIMS-2) and Health Assessment Questionnaire (HAQ) have been developed to assess one or more of these domains.¹⁵⁻¹⁷ In addition, physical function can be assessed using performance-based measures such as grip or pinch strength or the Arthritis Hand Function Test (AHFT). In addition to self-report and performance-based instruments, assessor-based measures such as joint tenderness upon palpation are used for assessment of pain.^{18,19} Besides the above mentioned questionnaires and assessor- or performance-based measures, several other instruments, which will be described in this manuscript, are used for clinical assessment of hand OA. Although most available instruments have been shown to be reliable for measurement of pain, physical function or patient global assessment, a systematic comparison of the different instruments for assessment of hand OA has not been performed.

Our study was conducted in the framework of the OMERACT hand OA working group, aiming to identify instruments for measurement of pain, physical function and patient global assessment in hand OA which can be recommended for use in clinical trials on OA. Therefore, insight into available instruments and their metric properties is needed. To this end, we performed a systematic literature review aiming to describe the frequency of use of available instruments measuring pain, physical function or patient global assessment in studies on hand OA, and to describe the metric properties of these instruments.²⁰ Metric properties were described using the OMERACT filter,²¹ focusing on aspects of discrimination (reliability and sensitivity to change), feasibility and truth (validity).

METHODS

Study design and identification of studies

The study design and performance followed the PRISMA guidelines.²⁰ In cooperation with a medical librarian (JWS), a systematic literature search was performed to obtain all man-

uscripts reporting on instruments measuring pain, physical function or patient global assessment in hand OA. Medical literature databases (PubMed, Embase, Web of Science, COCHRANE, CINAHL, Academic Search Premier and ScienceDirect) were searched from the date of their inception up to January 2014, using all variations of the following key words 'hand', 'osteoarthritis', 'outcome assessment', 'reliability', 'sensitive', 'feasibility' and 'validity' (see supplementary file for exact search strings).

Inclusion and exclusion criteria

First all retrieved titles were screened, subsequently selected abstracts were reviewed and finally full text articles of the remaining references were read by one reviewer (AWV). A random sample of 200 titles (9% of the titles identified by literature search) was also reviewed by a second reviewer (MK). Because of the similar selection of titles further extraction was done by a single reviewer but in case of uncertainties, these were discussed and solved by consensus.

Studies reporting on metric properties of instruments assessing pain, physical function and patient global assessment in hand OA were included. The metric properties of the studied instruments were described according to four items: reliability, sensitivity to change, feasibility and validity, inclusion criteria differed per item:

- Reliability was described based on studies evaluating the reliability of one or more instruments performed more than once in the same group of patients, either by the same performer over time or by different performers during one study visit. Both cross-sectional and longitudinal studies were included.
- Sensitivity to change was described based on longitudinal studies evaluating change of pain, physical function or patient global assessment in hand OA measured by one or more instruments.
- Feasibility was described based on studies evaluating this item of one or more instruments.
- Validity was described based on studies comparing different instruments assessing pain, physical function or patient global assessment in the same patients. Again, both cross-sectional and longitudinal studies were included.

Studies that fulfilled the requirements for at least one of these four items were included in this review. In order to be able to generalize the description of metric properties of the applied instruments to different populations, evaluation by only one study was considered as insufficient evidence to draw conclusions. Therefore, only instruments that were assessed by at least two studies were included in the description of metric properties.

Studies reporting on surgical interventions, less than 25 patients having hand OA or on diseases other than hand OA were excluded, as well as animal studies, reviews, abstracts, letters to the editor and studies in languages other than English. Because of the recently published systematic literature review on outcome measures in trapeziometacarpal OA by Marks et al.,²² studies reporting only on trapeziometacarpal OA were also excluded.

Data extraction

A self-made standardized form was used to extract information on the following data: (1) Study population (population size, setting, age, sex), (2) Instruments and assessed domains, (3) Study design and follow-up duration, (4) Results concerning: measures of

reliability (intraclass correlation coefficient (ICC), kappa-value, percentage of agreement, smallest detectable difference (SDD)), sensitivity to change (percentage of change, amount of change, standardized response mean (SRM)), feasibility (time needed to perform outcome measure), validity (correlation, association and measures of agreement between different instruments assessing the same domain). From 6 random studies data were also extracted by MK, resulting in similar extracted data. All extracted results were discussed by both reviewers to avoid missing information.

Statistical analyses

Because of the heterogeneity of the studies with respect to the evaluated instruments it was not possible to perform a meta-analysis. Therefore, we performed a descriptive review.

RESULTS

Literature flow

In total 4,351 titles were identified, 2,244 unique references were left for screening after removing duplicate references (Figure 1). During the screening, 2,008 references could be removed based on title. After reviewing 236 abstracts and 92 full-text articles, 66 studies satisfied the inclusion criteria (Table 1).

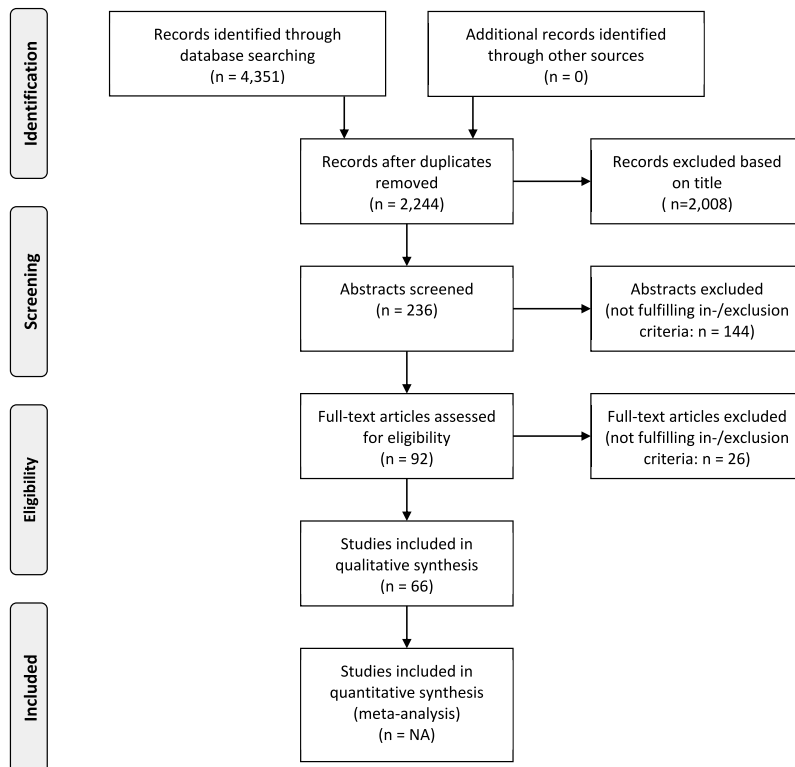


Figure 1. Overview of literature research

Table 1. Overview of included studies (n = 66)

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Allen, 2006 ²³	GOGO study (familial OA), 531 (80), 68	Bony enlargement, KL \geq 2 in \geq 1 DIP	Observational, mean FU 4 years	- AUSCAN (Likert) - Grip/pinch strength
Allen, 2006 ²⁴	GOGO study, 878 (80), 69	Bony enlargement, KL \geq 2 in \geq 1 DIP	Observational, cross-sectional	- AUSCAN (Likert) - Self-reported pain (0-3) - Grip/pinch strength
Altman, 2009 ⁴⁵	Secondary care, 385 (77), 64	ACR criteria	RCT (intervention > control)* duration 8 weeks	- AUSCAN (VAS) - VAS pain, global
Backman, 1997 ¹⁸	Secondary care, 26 (88), 67	OA \geq 2 joints, rheumatologist confirmed	Observational, test-retest after 2 weeks	- OMFAQ - AHFT
Barthel, 2010 ⁴⁶	Secondary care, 783 (80), 64	ACR criteria, KL \geq 1, symptoms \geq 1 year	RCT (intervention > control), duration 8 weeks	- AUSCAN (VAS) - VAS pain, global
Bellamy, 2002 ²⁵	Study 1: secondary care, 50 (80), 60 Study 2: secondary care, 44 (86), 60	ACR criteria	Study 1: Observational, test-retest after 1 week Study 2: Intervention, duration 6 weeks	Study 1 and 2: - AUSCAN (Likert, VAS) - FIHOA (original, Likert, VAS) Study 1 only: - HAQ, HAQ pain scale - Global pain/function(0-4) - Modified Doyle Index - Grip/pinch strength
Bijsterbosch, 2010 ¹⁹	GARP study (familial polyarticular OA), 260 (84), 65	ACR criteria	Observational, cross-sectional	- AUSCAN (Likert) - Doyle index
Bijsterbosch, 2011 ⁸²	GARP study, 289 (83), 60	ACR criteria	Observational, FU 6 years	- AUSCAN (Likert)
Botha-Scheepers, 2008 ⁸³	GARP study, 289 (83), 60	ACR criteria	Observational, FU 2 years	- AUSCAN (Likert) - Pain intensity score (pain on pressure, 0-60)
Brosseau, 2005 ⁴⁷	Secondary care, 88 (78), 65	ACR criteria, radiographic OA	RCT (intervention=control)# duration 6 weeks	- AUSCAN (Likert) - VAS pain - Grip/pinch strength
Dilek, 2013 ⁴⁸	Secondary care, 56 (89), 59	ACR criteria, bilateral	RCT (intervention > control), duration 3 weeks	- AUSCAN (not specified) - FIHOA - VAS pain rest/during ADL - Grip/pinch strength - No. painful/tender joints
Dreiser, 1993 ⁴⁹	Secondary care, 60 (85), 59	Radiographic OA	RCT (intervention > control), duration 2 weeks	- FIHOA - VAS pain - Pain movement/pressure (1-5)
Dreiser, 1995 ¹³	Secondary care, 200 (84), 66	Radiographic OA	Observational, cross-sectional	- FIHOA - VAS pain

Table 1. Continued

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Dreiser, 2000 ²⁶	Not specified, 261 (92), 61	ACR criteria, radio-graphic OA \geq 2 joints bilateral, symptoms	RCT (effect not specified), duration 6 months	- FIHOA - VAS pain - Grip strength
Dziedzic, 2007 ²⁷	Primary care, 55 (60), 67	Hand problems (symptoms, nodes)	Observational, test-retest after 1 month	- AUSCAN (Likert) - Grip/pinch strength, GAT
Dziedzic, 2013 ⁵⁰	Primary care, 257 (66), 66	ACR criteria	RCT (intervention > control), duration 6 months	- AUSCAN (not specified) - ASES pain - Average pain severity (0-10) - Satisfaction hand function (0-10) - Severity functional problem (0-10) - Grip/pinch strength, GAT
Fernandes, 2012 ²⁸	Secondary care, 211 (95), 63	ACR criteria	Observational, FU 3 months	- AUSCAN (Likert) - ASES pain - COPM - MAP-hand - Modified HAQ - Grip strength, GAT
Fioravanti, 2014 ⁵¹	Primary care, 60 (87), 71	ACR criteria, symptomatic	RCT (intervention > control), duration 2 weeks	- FIHOA - HAQ - VAS pain
Flynn, 1994 ⁵²	Secondary care, 26 (88), range 52-82	ACR criteria	RCT (intervention > control), duration 2 months	- Disease severity (1-10) - Global assessment (1-6) - Grip strength - No. painful/tender joints
Gabay, 2011 ⁵³	Secondary care, 162 (74), 63	ACR criteria, radio-graphic OA \geq 2 joints \geq 2 flares finger OA	RCT (intervention > control), duration 6 months	- FIHOA - VAS pain - Grip strength
Garfinkel, 1994 ⁵⁴	Not specified, 25 (56), range 52-79	ACR criteria	RCT (intervention > control), duration 10 weeks	- Pain rest/activity (not specified) - Hand function (not specified) - Grip strength - Tenderness
Grifka, 2004 ⁵⁵	Secondary care, 594 (83), 62	ACR criteria, symptomatic \geq 3 months	RCT (intervention > control), duration 4 weeks	- AUSCAN (Likert) - HAQ - VAS pain, global - Grip strength
Haugen, 2009 ²⁹	Secondary care, 83 (93), 60	ACR criteria, KL \geq 2, \geq 1 swollen/tender joint, VAS pain \geq 30	RCT (intervention > control), duration 42 days	- AUSCAN (not specified) - VAS pain, global - No. tender joints
Haugen, 2011 ³⁰	Secondary care (Oslo hand OA cohort), 209 (91), 62	ACR criteria	Observational, FU 7 years	- AIMS-2 - FIHOA - AUSCAN (Likert)

Table 1. Continued

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Haugen, 2013 ³⁴	Oslo hand OA cohort, 209 (91), 62	ACR criteria	Observational, FU 7 years	- AUSCAN - Grip strength - No. tender joints
Hirsch, 1999 ³¹	Women's Health and Aging Study, 919 (100), age \geq 65	ACR criteria	Observational, cross-sectional	- Pain/tenderness (no./intensity (0-3)) - Grip/pinch strength
Horvath, 2011 ⁵⁶	Secondary care, 63 (81), 63	ACR criteria, radiographic OA, pain \geq 3 months	RCT (intervention > control), duration 3 weeks	- HAQ - VAS pain (rest/exertion), global - Grip/pinch strength - No. tender joints
Kanat, 2013 ⁵⁷	Not specified, 50 (100), 63	ACR criteria	RCT (intervention > control), duration 10 days	- AUSCAN (not specified) - Cochin scale - Pain rest/motion (0-10) - Grip/pinch strength
Keen, 2010 ⁵⁸	Secondary care, 36 (86), 58	ACR criteria or radiographic OA	Intervention, FU 4 weeks (after injection)	- AUSCAN (VAS) - VAS pain (most painful/all), global
Kjeken, 2011 ⁵⁹	Secondary care, 70 (97), 61	ACR criteria	RCT (intervention = control), duration 3 months	- AUSCAN (Likert) - COPM (0-10) - Modified HAQ - VAS pain, global
Kovacs, 2012 ⁶⁰	Secondary care, 45 (93), 59	ACR criteria, KL \geq 2 in \geq 2 joints, VAS pain \geq 30	RCT (intervention > control), duration 3 weeks	- AUSCAN (Likert) - HAQ - VAS pain - Grip strength
Kvien, 2007 ⁶¹	Secondary care, 83 (93), 60	ACR criteria, KL \geq 2, \geq 1 swollen/tender joint, VAS pain \geq 30	RCT (intervention > control), duration 42 days	- AUSCAN (not specified) - VAS pain, global - No. tender joints
Kwok, 2011 ⁶²	Secondary care, 195 (87), 59	Diagnosed by rheumatologist	Observational, FU 3 months	- AUSCAN (Likert)
MacIntyre, 2009 ³²	Community-dwelling, 99 (80), 67	ACR criteria (dominant hand)	Observational, cross-sectional	- AIMS-2 - Dexterity - Grip strength
MacIntyre, 2010 ³³	Community-dwelling, 104 (81), 68	ACR criteria (dominant hand)	Observational, cross-sectional	- PRWHE - Dexterity - Grip/pinch strength
Marshall, 2013 ³⁵	Primary care, 1076 (60), 65	Hand symptoms	Observational, FU 3 years	- AUSCAN (Likert)
Moe, 2010 ³⁴	Secondary care (Oslo hand OA cohort), 128 (91), 69	ACR criteria	Observational, test-retest after 1 week	- AIMS-2 - AUSCAN (not specified) - FIHOA - HAQ - VAS pain - Grip strength - MPUT
Moratz, 1986 ⁶³	Population/secondary care, 77 (73), 69	Not specified	Intervention, duration 12 weeks	- Disability (0-3) - Grip/pinch strength

Table 1. Continued

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Myers, 2011 ³⁵	Primary care, 55 (60), 66	Hand pain/problems	Observational, test-retest after 1 month	- Interview on hand problems - Pain (0-10) - Grip/pinch strength, GAT - Pain/tenderness palpation
Myrer, 2011 ⁶⁴	Volunteers, 35 (77), 64	ACR criteria, FIHOA >5	RCT (intervention > control), duration 4 weeks	- FIHOA - VAS pain (rest/movement)
Pastinen, 1988 ⁶⁵	Secondary care, 29 (79), 58	Clinical/radio-graphic finger OA	RCT (intervention > control), duration 14 weeks	- VAS pain (during grip/pinch) - Grip/pinch strength
Poiraudeau, 2001 ³⁶	Secondary care, 89 (91), 63	ACR criteria	Observational, FU 6 months	- Cochin scale - FIHOA - Revel functional index - Ritchie articular index - VAS pain, handicap
Poole, 2010 ³⁷	Population based (senior centres), 40 (60), 63	Diagnosis of OA (not specified), symptoms	Observational, test-retest 1 week	- Cochin scale - FIHOA - MHQ - AHFT - HFI, HAMIS
Reeves, 2000 ⁶⁶	Not specified, 27 (59), 64	Radiographic OA, pain	RCT (intervention > control), FU 6 months (after injection)	- VAS pain (rest/movement/grip) - Flexion motion
Rintelen, 2009 ³⁸	Secondary care, 71 (91), 60	ACR criteria	Observational, cross-sectional	- Short Form-SACRAH - Modified-SACRAH
Rogers, 2007 ⁶⁷	Secondary care, 55 (80), 72	KL \geq 2	Intervention, duration 2 years	- AIMS-2 - Pain (0-10) - Grip strength
Rogers, 2009 ⁶⁸	Community-based, 46 (87), 75	KL \geq 2	RCT (intervention = control), duration 6 weeks	- AUSCAN (VAS) - Dexterity - Grip/pinch strength
Romero-Cerecero, 2013 ⁶⁹	Not specified, 113 (95), 62	ACR criteria, radio-graphic OA \geq 2, joints VAS \geq 40, FIHOA \geq 5	RCT (intervention = control), duration 4 weeks	- FIHOA - VAS pain
Rothacker, 1994 ⁷⁰	Not specified, 49 (84), 66	Physician/radio-graphic confirmed OA, symptoms	RCT (intervention > control), FU 45 minutes (after cream)	- Pain 0-5
Rothacker, 1998 ⁷¹	Secondary care, 81 (74), 61	Physician confir-med OA, symptoms	RCT (intervention > control), FU 45 minutes (after cream)	- Pain 0-5

Table 1. Continued

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Sautner, 2004 ³⁹	Secondary care, 60 (73), 62	ACR criteria	Observational, cross-sectional	- SACRAH, modified-SACRAH - VAS global
Sautner, 2008 ⁴⁰	Secondary care, 66 (77), 58	ACR criteria	Observational, cross-sectional	- AUSCAN (VAS) - SACRAH, modified-SACRAH - VAS global
Saviola, 2012 ²²	Secondary care, 38 (95), 61	Radiographic erosive OA ≥ 2 joints, VAS ≥ 40	RCT (intervention 1 > intervention 2), duration 2 years (intervention 2 only 1y)	- FIHOA - VAS pain, global - Grip strength - No. tender joints
Schnitzer, 1994 ⁷³	Not specified, 59 (68), 68	Radiographic/physical OA findings	RCT (intervention > control), duration 9 weeks	- HAQ - VAS pain - Grip strength - Joint tenderness (by dolorimeter)
Seiler, 1983 ⁷⁴	Secondary care, 41 (90), median 63	Radiographic OA, ≥ 3 painful/tender joints, ≥ 1 inflamed Heberden node	RCT (intervention > control), duration 4 weeks	- No. painful joints - Grip strength - Pain index (no./intensity (0-3))
Shin, 2013 ⁷⁵	Secondary care, 86 (97), 58	ACR criteria	RCT (intervention = control), duration 12 weeks	- AUSCAN (not specified) - HAQ - VAS global - No. tender joints
Stamm, 2007 ⁴¹	Secondary care, 100 (87), 61	Bony swelling ≥ 1 DIP/PIP, pain/bony swelling ≥ 1 CMC1	Observational, cross-sectional	- AIMS-2 - AUSCAN (not specified) - Cochin scale - FIHOA - HAQ - SACRAH, modified-SACRAH - Grip strength - JTHFT, MPUT, button Test
Stamm, 2002 ⁷⁶	Secondary care, 40 (88), 60	ACR criteria	RCT (intervention > control), duration 3 months	- HAQ - VAS pain, global - Grip strength
Stange-Rezende, 2006 ⁷⁷	Secondary care, 45 (93), 60	ACR criteria	RCT (intervention = control), duration 3 weeks	- AUSCAN (Likert) - VAS pain (general/hands), global - Grip strength - MPUT
Stukstette, 2013 ⁷⁸	Secondary care, 151 (83), 59	ACR criteria	RCT (intervention = control), duration 3 months	- AUSCAN (Likert) - COPM - Grip/pinch strength
Tubach, 2012 ⁴²	Secondary care, 249 (88), 64	ACR criteria	Intervention, FU 4 weeks	- VAS pain, global, functional disability

Table 1. Continued

First author, year of publication	Source population, no. of patients (% women), mean age (years)	Definition of hand OA	Study design	Applied instruments
Verbruggen, 2011 ⁷⁹	Secondary care, 60 (85), 61	ACR criteria	RCT (intervention = control), duration 1 year	- AUSCAN (not specified) - Grip strength - No. tender joints
Wenham, 2012 ⁸⁰	Not specified, 70 (81), 61	ACR criteria	RCT (intervention = control), duration 4 weeks	- AUSCAN (VAS) - VAS pain (average/worst joint), global - No. tender joints
Widrig, 2007 ⁸¹	Primary and secondary care, 204 (74), 64	ACR criteria, radio-graphic OA \geq 2 joints VAS \geq 40, FIHOA \geq 5	RCT (intervention = control), duration 3 weeks	- FIHOA - VAS pain - No. tender joints
Wittoek, 2009 ⁴³	Secondary care, 72 (89), 62	ACR criteria	Observational, cross-sectional	- AUSCAN (Likert) - FIHOA - VAS pain
Ziv, 2008 ⁴⁴	Not specified, 32 (100), 70	ACR criteria	Observational, test-retest after 1 week	- Gip/pinch strength

*Intervention group performed better than control group, according to primary outcome measure.

Intervention group did not perform better than control group, according to primary outcome measure.

ADL, activities of daily living; AHFT, Arthritis hand function test; AIMS-2, Arthritis Impact Measurement Scale; ASES, Arthritis Self Efficacy Scale; AUSCAN, Australian/Canadian Hand OA Index; ACR, American College of Rheumatology; CMC1, 1st carpometacarpal joint; COPM, Canadian Occupational Performance Measure; DIP, distal interphalangeal joint; FIHOA, Functional Index for Hand Osteoarthritis; FU, follow-up; GARP, Genetics osteoArthritis and Progression; GAT, grip ability test; GOGO, Genetics of Generalized Osteoarthritis; HAQ, Health Assessment Questionnaire; JTHFT, Jepsen-Taylor Hand Function Test; KL, Kellgren-Lawrence; MAP-hand, Measure of Activity Performance; MHQ, Michigan Hand Outcomes Questionnaire; MPUT, Moberg Picking Up Test; no., number; OA, osteoarthritis; OMFAQ, OARS (Older Americans' Resources and Services) Multidimensional Functional Assessment Questionnaire; PIP, proximal interphalangeal joint; PRWHE, Patient-Rated Wrist/Hand Evaluation; RCT, randomized controlled trial; SACRAH, Score for Assessment and Quantification of Chronic Rheumatoid Affections of the Hands; VAS, visual analogue scale.

Clinical outcome measures

The instruments that were used for assessment of the OMERACT core domains pain, physical function and patient global assessment in the 66 identified studies are specified in Table 2. Different instruments were applied, comprising twelve questionnaires, one interview and a number of rating scales (visual analogue scale (VAS), numeric rating scale (NRS) or Likert). Furthermore, nine different performance- or assessor-based measures were applied for assessment of physical function; pain was assessed by palpation, using the number of painful or tender joints, the Doyle index or Ritchie articular index.

The AUSCAN was most frequently applied (n = 34), followed by the VAS pain (n = 30), VAS global (n = 16), FIHOA (n = 14) and HAQ (n = 12). The AIMS-2 was applied in five studies, the Cochin scale and Score for Assessment and Quantification of Chronic Rheumatoid Affections of the Hands (SACRAH) in four studies, the Canadian Occupational Performance Measure (COPM) in three studies and the Arthritis Self Efficacy Scale (ASES) in two studies. The Measure of Activity Performance (MAP-hand), MHQ, Older Americans' Resources and Services Multidimensional Functional Assessment Questionnaire (OMFAQ), Patient-Rated Wrist/Hand Evaluation (PRWHE) and Revel functional index were all used in only one study each.

Of the performance- or assessor-based measures, grip strength was applied most frequently (n = 35), followed by pain or tenderness on palpation (n = 21). Other applied performance- or assessor-based measures were pinch strength (n = 17), the grip ability test (GAT) (n = 4), Moberg Pickup Test (MPUT) (n = 3), Arthritis Hand Function Test (AHFT) (n = 2), evaluation of dexterity (n = 3), button test (n = 1), Hand Mobility in Scleroderma Test (HAMIS) (n = 1), Hand Functional Index (HFI) (n = 1) and the Jebsen-Taylor Hand Function Test (JTHFT) (n = 1).

Table 2. Instruments measuring pain, physical function or patient global assessment applied in the included studies

	Domain	Specifications	No. studies applied
<i>Questionnaires</i>			
AIMS-2 ¹⁶	Physical function	78 items, rated on 5 point scale. Transformed into 12 scales, score range 0 - 10 (worst possible). 1 scale for hand/finger function.	5
ASES ⁸⁹	Pain, physical function	20 items, scored 10 (very uncertain) – 100 (very certain to can do). 3 subscales: pain/function /other symptoms, scored by taking mean of subscale items (range 10-100).	2
AUSCAN ¹⁴	Pain, physical function, global assessment	15 items, Likert (0, none – 4, extreme) / VAS version. Summed into 3 subscales: pain (Likert range 0-20 / VAS range 0-100), stiffness (0-4 / 0-100), function (0-36 / 0-100).	34
Cochin scale ⁹⁰	Physical function	18 items, rated on Likert scale (0, without difficulty – 5, impossible). Summed to final score, range 0-90.	4
COPM ⁹¹	Physical function	Interview on most important activities. Five most important activities scored for performance /satisfaction (1-10). Subscale scores range 0 (not able to do/satisfied) – 10 (extremely able to do/satisfied).	3
FIHOA ¹³	Physical function	10 items, range 0 (no difficulty) – 3(impossible). Total score range 0-30. Original, VAS, Likert version.	15
HAQ ¹⁷	Physical function	20 items. Total score range 0 to 3 (higher score indicates poorer functioning).	12
MAP-hand ⁹²	Physical function	18 items, range 0 (no difficulty) – 4 (not able to do). Total mean score calculated.	1
MHQ ¹⁵	Pain, physical function,	37 items, rated on 5 point Likert (1,very good – 5, very poor). Scores normalized to 0-100 scale.	1
OMFAQ ⁹³	Physical function	5 domains of functioning, scored 1 (excellent) – 6 (total impaired). Total score range 5-30. Physical / instrumental ADL scale.	1
PRWHE ⁹⁴	Physical function	15 item scale, rated on 0-10 NRS. Summed to subscales: pain (0-50), disability (0- 60).	1
Revel functional index ⁹⁵	Physical function	10 questions, rated 0 (without difficulty) – 2 (impossible). Total score range 0-20.	1
SACRAH ⁹⁶	Pain, physical function	23 questions, rated on VAS scale. 3 domains: functional status, stiffness, pain. Original, Short-Form, Modified version.	4
VAS ⁹⁷ / NRS / Likert	Pain, physical function, global assessment	Used for assessment of pain, patient global assessment, functioning, perceived strength, etcetera.	43

Table 2. Continued

	Domain	Specifications	No. studies applied
<i>Performance- or assessor-based instruments</i>			
AHFT ¹⁸	Physical function	11-item test, 4 subscales: grip/pinch strength, dexterity, applied dexterity, applied strength. Score per subscale.	2
Button Test ⁹⁸	Physical function	Unbutton and button 5 buttons, using a standard board. Score recorded in seconds.	1
Dexterity	Physical function	Assessed using dexterity/purdue pegboard	2
GAT ⁹⁹	Physical function	Modification of Grip Function Test. 3 items, timed (sec) and summed to total GAT score. GAT score <20 sec = normal.	4
Grip strength	Physical function	Measured in mmHg or in kg.	35
HAMIS ¹⁰⁰	Physical function	9 items rated 0 (no problems performing the motion) – 3 (unable). Total score range 0-27	1
HFI ¹⁰¹	Physical function	9 wrist/hand items from Keitel Function Test, measuring motion patterns. Items ranged 0 (no difficulties) – 3 (much difficulties). Total score 0-52 (0-26 for each upper extremity)	1
JTHFT ¹⁰²	Physical function	7 items, timed in seconds. Summed to total score.	1
MPUT ¹⁰³	Physical function	Picking up 10 items and placing in container, timed in seconds.	3
Pinch strength	Physical function	Measured in mmHg or in kg.	17
Tenderness/ Pain on palpation, Doyle ¹⁰⁴ / Ritchie articular index ¹⁰⁵	Pain	Tenderness on palpation. Score range Doyle total 0-144, Doyle hand 0-72 Score range Ritchie articular index 0-60	21

AHFT, Arthritis hand function test; AIMS-2, Arthritis Impact Measurement Scale; ADL, activities of daily living; OARS, Older Americans' Resources and Services; ASES, Arthritis Self Efficacy Scale; AUSCAN, Australian/Canadian Hand OA Index; COPM, Canadian Occupational Performance Measure; FIHOA, Functional Index for Hand OA; GAT, Grip ability test; HAQ, Health Assessment Questionnaire; HAMIS, Hand Mobility in Scleroderma Test; HFI, hand functional index; JTHFT, Jebsen-Taylor Hand Function Test; MAP-hand, Measure of Activity Performance; MHQ, Michigan Hand Outcomes Questionnaire; MPUT, Moberg Picking Up Test; NRS, numeric rating scale; OMFAQ, OARS (Older Americans' Resources and Services) Multidimensional Functional Assessment Questionnaire; PRWHE, Patient-Rated Wrist/ Hand Evaluation; ROM, Range of motion; SACRAH, Score for Assessment and Quantification of Chronic Rheumatoid Affections of the Hands; VAS, Visual Analogue Scale.

Table 3. Metric properties of instruments measuring pain, physical function or patient global assessment – reliability*

	First author	Relevant results
<i>Questionnaires</i>		
AUSCAN	Bellamy ²⁵	ICC (Likert / VAS): - pain: 0.70 / 0.84 - function: 0.86 / 0.90
	Dziedzic ²⁷	ICC: - pain: 0.88 - function: 0.87
	Haugen ³⁰	ICC - pain: 0.93 - function: 0.94 - total: 0.96
	Moe ³⁴	ICC, SDD: - pain: 0.80, 1.06 - function: 0.92, 0.80 - total: 0.87, 0.76
Cochin scale	Poiraudeau ³⁶	Interrater ICC: 0.96
	Poole ³⁷	ICC: 0.94
FIHOA	Dreiser ¹³	ICC: 0.95, mean difference 0.17 ± 1.64
	Haugen ³⁰	ICC: 0.88
	Moe ³⁴	ICC: 0.94, SDD 5.55
	Poole ³⁷	ICC: 0.74
	Wittoek ⁴³	ICC: 0.96
<i>Performance- or assessor-based instruments</i>		
Grip strength	Myers ³⁵	Inter-/intra-observer ICC: range per hand 0.91-0.94 / 0.90-0.92
	Ziv ⁴⁴	SDD (right, left): 2.48, 1.94
Pinch strength	Myers ³⁵	Inter-/intra-observer ICC: range per test/hand 0.87-0.94 / 0.89-0.96
	Ziv ⁴⁴	SDD (right, left): range per test 0.40-0.54, 0.42-0.63
Tenderness/pain on palpation	Bijsterbosch ¹⁹	Inter-/intra-observer ICC of Doyle index: 0.88 / range per rater 0.94-0.97
	Myers ³⁵	Inter-/intra-observer κ (% agreement): 0.64 / 0.69 (95 / 96)

* Only instruments assessed in ≥2 studies were included in this table.

AUSCAN, Australian/Canadian Hand OA Index; FIHOA, Functional Index for Hand; ICC, intraclass correlation coefficient; κ, kappa; SDD, smallest detectable difference; VAS, visual analogue scale.

Study characteristics

The characteristics of the 66 included studies are described in Table 1. The source populations were predominantly secondary care (n = 41), in addition to primary care (n = 6), population-based (n = 6) and familial OA studies (n = 5). All studies included more women than men and the mean age was >50 years in almost all studies. Different study designs were included; 26 observational studies, 35 randomized controlled trials and four intervention studies.

Of the included studies, 25 studies primarily aimed at evaluation of metric properties of one or more instruments measuring pain, physical function or patient global assessment.^{13,18,19,23-44} The remaining studies applied these instruments to evaluate the effect of a treatment or intervention (n = 37),⁴⁵⁻⁸¹ or to evaluate disease course over time (n = 4).⁸²⁻⁸⁵

Metric properties of clinical outcome measures

Discrimination: Reliability

Only eleven studies provided data on measures of reliability, including seven instruments.^{13,19,25,27,30,34-37,43,44} The FIHOA and AUSCAN were most frequently evaluated (see Table 3). The AHFT and GAT were evaluated in only one study each.^{18,35} The reported measures of reliability of instruments that were assessed in at least two studies are listed in Table 3.

In general, all evaluated instruments showed good measures of reliability. Three studies evaluated two questionnaires for assessment of physical function, enabling direct comparison of these measures.^{34,37} Haugen et al. reported excellent reliability for both the AUSCAN function subscale and FIHOA,³⁰ Moe et al. reported the same in addition to comparable SDDs for both questionnaires.³⁴ Poole et al. evaluated the FIHOA in addition to the Cochin scale, reporting the highest ICC for the Cochin scale.³⁷

Performance- or assessor-based measures were assessed less frequent but showed good measures of reliability.

In summary, only two instruments (AUSCAN and FIHOA) were extensively tested, showing excellent measures of reliability for both questionnaires. Other instruments, whilst showing good measures of reliability, had only been tested in one or two studies. Therefore, only tentative conclusions can be drawn for these instruments.

Discrimination: Sensitivity to change

Of the 45 studies assessing change over time in pain, physical function or patient global assessment,^{25,26,29,36,42,45,47-85} seven studies did not demonstrate any significant change (one observational study, six RCTs).^{62,69,75,78-81} Six studies only observed a statistically significant change in pain or patient global assessment (one observational study, five RCTs),^{29,50,54,60,61,77} and five studies only observed change in physical function (all RCTs).^{45,47,59,65,76}

The studies that detected change in at least one instrument assessing the corresponding domain are summarized in Table 4. The results of these studies regarding measured change over time are described in the online supplementary table.

Pain was most frequently assessed using the VAS or NRS, detecting change in 88% of these studies. Other applied instruments were the AUSCAN pain scale and pain/tenderness assessed on palpation, detecting change in 78 and 92% of the studies, respectively (see Table 4).^{29,36,48,49,52,54,56,61,72-74,83,84} The ASES pain scale was applied in only one study and therefore not included in the table.⁵⁰

Physical function was most frequently assessed by measured grip strength, detecting change in 75% of these studies. Other commonly applied instruments were the AUSCAN function scale (82% detecting change), FIHOA (67% detecting change), HAQ (50% detecting change) and grip strength (57% detecting change). The Cochin scale and VAS or NRS were less frequently used (see Table 4). The AIMS-2,⁶⁷ COPM,⁵⁹ dexterity,⁶⁸ GAT,⁵⁰ and MPUT77 were all assessed in only one study each.

Patient global assessment was assessed using the VAS global, detecting change in 60% of these studies. The 40% that did not detect change over time did measure change in AUSCAN function, COPM or the number of tender joints. A few number of studies assessed change in patient global assessment using the AUSCAN total (see Table 4).

In summary, the VAS pain was by far the most frequently applied instrument for assessment of change over time of pain in hand OA, followed by the AUSCAN pain subscale and pain on palpation. For assessment of change of physical function, the AUSCAN function subscale, FIHOA and grip strength assessment were commonly used. Change in patient global assessment was most frequently evaluated using the VAS global. The majority of studies that reported change in pain, physical function or patient global assessment detected this change by all applied instruments assessing the corresponding domain, suggesting good sensitivity to change for all evaluated instruments.

Feasibility

The number of items of the different applied instruments is described in Table 2. Although most of these instruments are available in the public domain, payment is required for use of the AUSCAN.

Only four of the included studies reported data on time needed to apply the used instruments.^{13,19,37,39} Two studies reported the completion time of a questionnaire: for completion of the modified SACRAH, a median of 95 seconds was measured (range 80-175 seconds),³⁹ and for completion of the FIHOA, a mean of 165 seconds (standard deviation (SD) 119 seconds, range 50-600) was measured in patients with painful OA whereas inactive OA patients needed on average 136 seconds (SD 97 seconds, range 20-240).¹³ The other two studies reported the time required to administer one or two assessor-/performance-based measures: for the Doyle index, a mean time of 5.1 minutes (range 2.4-7.8) was reported,¹⁹ and the AHFT and HAMIS were reported to require 20-25 and 5 minutes, respectively.³⁷

In summary, questionnaires took less time than assessor-/performance-based measures. The completion time of both assessed questionnaires was short, so both the FIHOA and modified SACRAH are highly feasible.

Validity

Eighteen studies correlated different instruments (mostly questionnaires), providing information on construct validity. The reported correlations between instruments assessing either pain or physical function or patient global assessment are presented in Table 5. Most of the studies (n = 16) reported cross-sectional correlations, whereas correlations or associations between assessed change over time were reported in only three studies.^{23,28,46}

Table 4. Metric properties of instruments measuring pain, physical function or patient global assessment - sensitivity to change.* Only studies demonstrating significant change in pain, physical function or patient global assessment by at least one of the applied instruments are shown.

	No. of studies reporting change in corresponding instrument	No. of studies not reporting change, discordant with other instruments assessing corresponding domain	Percentage of studies that detected change
RCTs/intervention studies			
<i>Questionnaires</i>			
AUSCAN function	5 ^{25,45,48,55,58}	2 ^{47,59}	71%
AUSCAN pain	6 ^{25,29,55,58,61,77}	2 ^{48,60}	75%
AUSCAN total	2 ^{55,57}	0	100%
Cochin scale	1 ⁵⁷	0	100%
FIHOA	6 ^{26,49,51,53,64,72}	3 ^{25,36,48}	67%
HAQ	3 ^{51,56,73}	3 ^{55,59,76}	50%
VAS/NRS pain	21 ^{26,29,42,48,49,51,53-58,60,61,64,66,67,70-72}	3 ^{36,73,77}	88%
VAS global	6 ^{29,42,55,61,72,76}	4 ^{45,52,56,59}	60%
VAS/NRS function	2 ^{42,63}	0	100%
<i>Performance- or assessor-based instruments</i>			
Grip strength	11 ^{26,47,56,63,65,67,68,72,74,76}	4 ^{48,53,55,57}	73%
Pinch strength	4 ^{56,63,65,68}	3 ^{47,48,57}	57%
Tenderness/pain on palpation	9 ^{48,49,52,54,56,61,72-74}	1 ²⁹	90%
Observational studies			
<i>Patient reported instruments</i>			
AUSCAN function	4 ⁸²⁻⁸⁵	0	100%
AUSCAN pain	4 ⁸²⁻⁸⁵	1 ⁵⁰	80%
Cochin scale	1 ³⁶	0	100%
VAS pain	1 ⁵⁰	0	100%
<i>Performance- or assessor-based measures:</i>			
Grip strength	1 ⁸⁴	0	100%
Tenderness/pain on palpation	3 ^{36,83,84}	0	100%

* Only instruments assessed in ≥ 2 studies were included in this table.

AUSCAN, Australian/Canadian Hand OA Index; FIHOA, Functional Index for Hand OA; HAQ, Health Assessment Questionnaire; no., number; NRS, numeric rating scale; VAS, visual analogue scale.

The AUSCAN, grip strength and FIHOA scores were compared with other outcome measures most frequently (see Table 5). Correlations of the ASES pain scale, COPM and MAP-hand with other clinical outcome measures were evaluated in only one study,²⁸ as were the JTHFT,⁴¹ Revel functional index,³⁶ PRWHE,³³ MHQ, HFI and HAMIS.³⁷ These studies were therefore not included in Table 5.

Varying correlation coefficients were reported among the different studies. In general, correlations between different questionnaires were stronger than correlations of performance-based measures with other performance-based measures or with questionnaires. Correlations between different instruments assessing physical function ranged from 0.52 to 0.89 between questionnaires, from 0.05 to 0.67 between questionnaires and performance-based measures and from 0.25 to 0.96 between performance-based measures. For assessment of pain, correlations between 0.55 and 0.81 were observed between questionnaires, and correlations between 0.47 and 0.65 between questionnaires and pain on palpation. However, only few correlation coefficients above 0.90 were observed, suggesting that different instruments catch different aspects of the assessed domain.

Two of the three studies associating change over time by different instruments presented correlation coefficients, which were in line with the results described above.^{28,46} The third study calculated beta coefficients for the association of change of the AUSCAN and grip and pinch strength with global assessment of change, adjusted for age, gender, number of osteoarthritic hand joints and time between assessments. The strongest association with global assessment of change was observed for the AUSCAN.²³

In summary, construct validity of various instruments measuring pain, physical function or patient global assessment has been assessed in multiple cross-sectional studies but only few longitudinal data are available. Moderate to good correlations were observed, especially between questionnaires, suggesting good construct validity.

Table 6 summarizes the available information of metric properties per domain for the six most frequently applied instruments for assessment of pain, physical function and patient global assessment. Information of metric properties was considered established when supporting results were observed in at least three studies. The non-availability of the AUSCAN in the public domain is included as negative evidence regarding the feasibility.

Table 5. Metric properties of instruments measuring pain, physical function or patient global assessment – validity.* Correlations between different instruments as observed in cross-sectional and longitudinal studies are shown.

	First author	Correlation with:
Cross-sectional studies		
<i>Questionnaires</i>		
AIMS-2	MacIntyre ³²	- Dexterity small/large objects: r range per item 0.23 to 0.40 / 0.14 to 0.31# - Grip strength: r range per item -0.23 to -0.37#
	Moe ³⁴	AIMS-2 physical / arm / hand: - AUSCAN function: r 0.83 / 0.70 / 0.77*** - FIHOA: r 0.80 / 0.71 / 0.69***
AUSCAN function	Stamm ⁴¹	- JTHFT: r 0.67****
	Allen ²⁴	- Grip strength right, left: r -0.42,-0.40*** - Pinch strength right, left: r -0.23,-0.16***
	Bellamy ²⁵	Likert, VAS: - Global function (0-4): r 0.72, 0.74** - FIHOA (original): r 0.78, 0.86** - HAQ: r 0.65, 0.68** - Grip strength: r -0.39, -0.45** - Pinch grip: r -0.31, -0.36**
	Dziedzic ²⁷	- GAT: r 0.54** - Grip strength: r -0.56** - Pinch strength: r -0.60**
	Fernandes ²⁸	- MAP-hand: r 0.76#
	Moe ³⁴	- AIMS-2 physical: r 0.83, arm: r 0.70, hand: r 0.77*** - FIHOA: r 0.88*** - HAQ: r 0.80*** - Grip strength: r -0.62*** - MPUT right, left: r 0.58,0.63***
	Sautner ⁴⁰	- VAS global: r 0.55****
	Stamm ⁴¹	- JTHFT: r 0.386****
	Wittoek ⁴³	- FIHOA: r 0.81***
	AUSCAN pain	Allen ²⁴
Bellamy ²⁵		Likert, VAS: - Global pain (0-4): r 0.57, 0.64** - HAQ pain: r 0.57, 0.66** - Doyle: r 0.56, 0.47**
Bijsterbosch ¹⁹		- Doyle hand, total: r 0.65, 0.61***
Moe ³⁴		- VAS pain: r 0.77***
Wittoek ⁴³		- VAS pain: r 0.79***
Cochin scale	Poiraudeau ³⁶	- FIHOA: r 0.87# - Revel functional index: r 0.86 - VAS handicap: r 0.67
	Poole ³⁷	- FIHOA: r 0.89** - MHQ: r -0.82** - AHFT: r range per item -0.64 to 0.57** - HFI: r 0.55, HAMIS: r 0.49**

Table 5. Continued

	First author	Correlation with:
	Stamm ⁴¹	- JTHFT: r 0.369**
FIHOA	Bellamy ²⁵	Original / Likert / VAS: - AUSCAN function (Likert, VAS): r 0.78, 0.86 / 0.80, 0.85 / 0.80, 0.88**
	Moe ³⁴	- AIMS-2 physical / arm / hand: r 0.80 / 0.71 / 0.69*** - AUSCAN function: r 0.88*** - HAQ: r 0.73*** - Grip strength: r -0.5*** - MPUT right / left: r 0.55 / 0.59***
	Poiraudeau ³⁶	- Cochin scale: r 0.87#
	Poole ³⁷	- Cochin: r 0.89** - MHQ: r -0.86** - AHFT: r range per item -0.57 to 0.46** - HFI: r 0.53, HAMIS: r 0.50**
	Stamm ⁴¹	- JTHFT: r 0.387****
	Wittoek ⁴³	- AUSCAN function: r 0.81***
HAQ	Bellamy ²⁵	- AUSCAN function (Likert, VAS): r 0.65, 0.68**
	Fernandes ²⁸	Modified HAQ with MAP-hand: r 0.46#
	Moe ³⁴	- AUSCAN function: r 0.80*** - FIHOA: r 0.73***
	Stamm ⁴¹	- JTHFT: r 0.424****
SACRAH	Rintelen ³⁸	Short Form-SACRAH with Modified-SACRAH: r 0.699***
	Sautner ³⁹	Modified-SACRAH: - SACRAH: r 0.978 (range subscales 0.912-0.958)**** - VAS global: r 0.64****
	Sautner ⁴⁰	Modified-SACRAH function / total with VAS global: r 0.55 / 0.65****
	Stamm ⁴¹	SACRAH / M-SACRAH: - JTHFT: r 0.436 (range per scale 0.371-0.437) / 0.388****
VAS global	Sautner ³⁹	- Modified-SACRAH: r 0.64****
	Sautner ⁴⁰	- Function AUSCAN / modified-SACRAH: r 0.55 / 0.55**** - Pain AUSCAN / modified-SACRAH: r 0.59 / 0.56**** - Total modified-SACRAH: r 0.65****
VAS pain	Moe ³⁴	- AUSCAN pain: r 0.77***
	Wittoek ⁴³	- AUSCAN pain: r 0.79***

Performance- or assessor-based instruments

AHFT	Backman ¹⁸	- OMFAQ instrumental ADL scale: range per item r -0.75 to 0.75*** - OMFAQ physical ADL scale: range per item r -0.67 to 0.68***
	Poole ³⁷	- Cochin scale: r range per item -0.64 to 0.57** - FIHOA: r range per item -0.57 to 0.46** - MHQ: r range per item -0.48 to 0.65**
Dexterity	MacIntyre ³²	Large / small objects: - AIMS-2: r range per item 0.14 to 0.31 / 0.23 to 0.40#

Table 5. Continued

	First author	Correlation with:
	MacIntyre ³³	Large / small objects: - Grip strength: r -0.32 (range digits -0.25 to -0.30) / -0.28 (-0.10 to -0.41)# - Pinch (tripod, narrow, wide key): r -0.37, -0.30, -0.34 / -0.34, -0.25, -0.25#
GAT	Dziedzic ²⁷	- AUSCAN function: r 0.54**
	Fernandes ²⁸	- MAP-hand: r 0.43#
Grip strength	Allen ²⁴	- AUSCAN function (right, left): r -0.42,-0.40***
	Bellamy ²⁵	- AUSCAN function (Likert, VAS): r -0.39, -0.45**
	Dziedzic ²⁷	- AUSCAN function: r -0.56**
	Fernandes ²⁸	- MAP-hand: r -0.32#
	MacIntyre ³²	- AIMS-2: r range per item -0.23 to -0.37#
	MacIntyre ³³	- PRWHE activities: r -0.23# - Dexterity large: r - 0.32, small: -0.28# - Pinch strength (range per test): r 0.76 to 0.78#
	Moe ³⁴	- AUSCAN function: r -0.62*** - FIHOA: r -0.50***
	Stamm ⁴¹	- JTHFT: r -0.395****
MPUT	Moe ³⁴	- AUSCAN function (right, left): r 0.58, 0.63*** - FIHOA (right, left): r 0.55, 0.59***
	Stamm ⁴¹	- JTHFT: r 0.690****
Pinch strength	Allen ²⁴	- AUSCAN function (right, left): r -0.23, -0.16***
	Bellamy ²⁵	- AUSCAN function (Likert, VAS): r -0.31, -0.36**
	Dziedzic ²⁷	- AUSCAN function: r -0.60**
	MacIntyre ³³	- PRWHE activities (range per test): r -0.22 to -0.26# - Dexterity (range per test) large: r -0.30 to -0.37, small: r -0.25 to -0.34# - Grip strength (range per test): r 0.75 to 0.96#
Tenderness/pain on palpation	Bellamy ²⁵	Doyle with AUSCAN (Likert, VAS) pain: r 0.56, 0.47**
	Bijsterbosch ¹⁹	Doyle hand / total with AUSCAN pain: r 0.65 / 0.61***
Longitudinal studies		
<i>Questionnaires</i>		
AUSCAN total	Allen ²³	Association global assessment of change (right, left) with AUSCAN total: β 0.29, 0.27 (P < 0.001). Stronger among greater radiographic OA severity.
AUSCAN function	Fernandes ²⁸	- Change MAP-hand: r 0.52#
AUSCAN pain	Barthel ⁴⁶	- Change VAS pain: r 0.81***
VAS global	Barthel ⁴⁶	- Change AUSCAN function: r 0.71***, pain: r 0.75*** - Change VAS pain: r 0.76***
VAS pain	Barthel ⁴⁶	- Change AUSCAN pain: r 0.81***
<i>Performance- or assessor-based instruments</i>		
GAT	Fernandes ²⁸	- Change MAP-hand: r 0.06#
Grip strength	Allen ²³	- Global assessment of change (right, left): β -0.16, -0.13 (P 0.003, 0.015) Stronger associations among greater radiographic OA severity.
	Fernandes ²⁸	- Change MAP-hand: r -0.05#

Table 5. Continued

	First author	Correlation with:
Pinch strength	Allen ²³	- Global assessment of change (right, left): β -0.13, -0.11 (P 0.022, 0.060) Stronger associations among greater radiographic OA severity.

* Only instruments assessed in ≥ 2 studies were included in this table.

No p-values provided. ** p-value < 0.05. *** p-value < 0.001. **** p-value < 0.0001.

AHFT, Arthritis hand function test; AIMS-2, Arthritis Impact Measurement Scale; ADL, activities of daily living; ASES, Arthritis Self Efficacy Scale; AUSCAN, Australian/Canadian Hand OA Index; β , beta coefficient; CI, confidence interval; COPM, Canadian Occupational Performance Measure; FIHOA, Functional Index for Hand OA; GAT, Grip ability test; HAQ, Health Assessment Questionnaire; JTHFT, Jebsen-Taylor Hand Function Test; MPUT, Moberg Picking Up Test; P, p-value; r, correlation coefficient; SACRAH, Score for Assessment and Quantification of Chronic Rheumatoid Affections of the Hands; VAS, Visual Analogue Scale.

Table 6. Available information of metric properties from at least 3 studies for the most frequently applied instruments (in at least 15 clinical studies) for evaluation of pain, physical function or patient global assessment

	Reliability	Sensitivity to change	Feasibility	Validity
<i>Questionnaires</i>				
AUSCAN	+	+	- #	+
FIHOA	+	+	+**	+
VAS pain		+		+
<i>Performance- or assessor-based instruments</i>				
Grip strength	+*	+		+
Pinch strength	+*	+		+
Tenderness/pain on palpation	+*	+		+*

+ = established evidence

* supporting evidence in only 2 studies

** supporting evidence in only 1 study

not available in public domain

AUSCAN, Australian/Canadian Hand OA Index; FIHOA, Functional Index for Hand OA; VAS, visual analogue scale.

DISCUSSION

The most frequently applied and evaluated instruments for assessment of pain were the AUSCAN pain subscale, VAS pain and pain on palpation. The AUSCAN function subscale, FIHOA and grip and pinch strength were most frequently applied and evaluated for assessment of physical function. Patient global assessment was most frequently evaluated using the VAS global.

In the description of discrimination, the reliability of the AUSCAN and FIHOA were found to be extensively tested and shown to be excellent. The reliability of other instruments was suggested to be good, but only scarce evidence was available.

The VAS pain was by far the most commonly used instrument for assessment of change of pain, followed by the AUSCAN pain subscale and pain on palpation. The AUSCAN function subscale, FIHOA and assessment of grip and pinch strength were regularly applied for assessment of change of physical function. Change of patient global assessment was most often evaluated by the VAS global. The majority of studies detected change by all used instruments, suggesting good sensitivity to change for the evaluated instruments. Change in pain was detected most frequently by the VAS pain or pain on palpation, whereas change in physical function was detected most frequently by the AUSCAN function subscale or measured grip strength.

In the description of feasibility, only few studies reported on time needed to perform instruments. Questionnaires took less time than performance-based measures. Of the frequently applied instruments, only the FIHOA was evaluated and seemed feasible. This is supported by the availability of this questionnaire in the public domain, in contrast with the AUSCAN.

For the description of validity, numerous cross-sectional studies assessed correlations between various instruments but only few longitudinal data was available. The strongest correlations were reported between different questionnaires assessing pain or physical function. Remarkably, the VAS pain, as one of the most frequently applied instruments, was evaluated in only a limited number of studies.

For further evaluation of validity, comparison to an external standard should be performed. However, no external standards for evaluation of pain, physical function and patient global assessment have been agreed upon, perhaps due to varying definitions and measurement of these concepts. For assessment of physical function, observation of the performance of tasks as described by specific instruments assessing physical function may be useful in the evaluation of validity of these instruments.⁸⁶

Based on this review, it is not possible to decide on one instrument that should be recommended for measurement of pain, physical function or patient global assessment in hand OA research. Although no major differences regarding metric properties of the evaluated instruments were observed, the amount of supporting evidence varied extensively between the instruments.

Before consensus can be reached on which instruments should be applied, some aspects need further investigation. The reliability of especially the VAS pain, grip and pinch strength and pain on palpation needs to be further established in a variety of populations. Regarding the sensitivity to change, the minimal clinically important difference of instruments needs to be determined. Only for the AUSCAN a minimal clinically important improvement has been proposed.⁸⁷ Validity of instruments assessing physical function

should be further investigated by comparing these instruments to an external standard. Furthermore, future research should evaluate instruments within specific subtypes of hand OA.

This study has some limitations. We intended to include as many available studies as possible that provided information on instruments and their metric properties, not only studies that actually aimed at evaluating this. Because of the large heterogeneity across studies regarding their purpose (primarily aiming at evaluation instruments or applying instruments for other primary aims) and study design, the methodological quality of the included studies was not assessed. Furthermore, the heterogeneity did not enable pooling of data into a meta-analysis and addressing the presence of publication bias.

Limitations regarding the literature search are the included databases, restriction to English language and exclusion of abstracts and unpublished results.

Within all studies assessing the VAS pain or VAS global, different questions were used. The individual questions were observed to be highly variable, especially regarding the type of pain (global pain, overall disease severity, intensity, not specified) and time settings (last 24 or 48 hours, two days, two weeks, not specified). In future research this phrasing should be standardized. Furthermore, the VAS pain score has been shown to be influenced by the information on the disease and its consequences that is given to patients when determining the VAS,⁸⁸ which could not be addressed due to lack of information on this topic in the included studies. However, future studies evaluating the VAS should take the effect of patient information into account.

In conclusion, our systematic literature review provides an overview of the instruments that are used for measurement of pain, physical function and patient global assessment in hand OA. Most information on the metric properties of these instruments was available for the questionnaires AUSCAN (assessing pain and function), FIHOA (assessing function) and VAS pain, and for the performance- or assessor-based instruments grip and pinch strength and pain on palpation. To enhance comparability across future studies in hand OA, consensus has to be reached on recommended instruments for measurement of pain, physical function and patient global assessment in hand OA. More research has to be performed to compare the different instruments to each other.

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Supplementary table. Results of the studies that detected change in at least one instrument evaluating either pain or physical function of patient global assessment*

	First author	Relevant results	
<i>Questionnaires</i>			
AUSCAN function	Altman ⁴⁵	Mean change intervention: 26.5, control: 19.2 (P 0.017)	
	Bellamy ²⁵	Mean change (Likert, VAS): -0.32 (p 0.001), -8.97 (P 0.001) Average SRM (Likert, VAS): -0.67, -0.76	
	Bijsterbosch ⁸²	Mean change (95%CI): 2.1 (1.3-2.9) Percentage change: 50% increased limitations, 26% decreased	
	Botha-Scheepers ⁸³	Mean change (95%CI): 1.4 (0.5, 2.3), SRM: 0.23 Percentage change: 53% increased, 12% no change, 36% decrease	
	Brosseau ⁴⁷	No significant change (in contrast with grip strength)	
	Dilek ⁴⁸	Median change intervention: -1.65 (P < 0.016), control no significant change.	
	Grifka ⁵⁵	Mean change intervention (1/2) vs control: -4.3 / -6.0 vs -3.1 (P < 0.01)	
	Haugen ⁸⁴	Mean change 1.2, SD 6.3	
	Keen ⁵⁸	Mean change: 159.5 (P < 0.05)	
	Kjeken ⁵⁹	No significant change (in contrast with COPM)	
	Marshall ⁸⁵	Increase: range 1-3 in symptomatic OA patients	
	AUSCAN pain	Bellamy ²⁵	Mean change (Likert, VAS): -0.34 (P 0.001), -6.46 (P 0.003) Average SRM (Likert, VAS): -0.71, -0.84
		Bijsterbosch ⁸²	Mean change (95%CI): 0.7 (0.3, 1.2) Percentage change: 40% increased, 26% decreased
		Botha-Scheepers ⁸³	Mean change (95%CI): 1.0 (0.4, 1.6), SRM: 0.25 Percentage change: 50% increased, 20% no change, 30% decrease
Dilek ⁴⁸		No significant change (in contrast with VAS pain)	
Dziedzic ⁵⁰		No significant change (in contrast with ASES pain, average pain)	
Grifka ⁵⁵		Mean change intervention (1/2) vs control: -3.0 / -3.9 vs -2.1 (P < 0.01)	
Haugen ²⁹		Mean change intervention: -20.5, control: -6.2 (P 0.012), SRM 0.68	
Haugen ⁸⁴		Mean change 0.8, SD 3.4	
Keen ⁵⁸		Mean change: -117.5 (P < 0.05)	
Kovacs ⁶⁰		No significant change (in contrast with VAS pain)	
Kvien ⁶¹		Mean change intervention vs control: -20.5 vs -6.2 (P 0.012)	
Marshall ⁸⁵		Increase: range 0.5-1.5 in symptomatic OA patients	
Stange-Rezende ⁷⁷		Mean change intervention: 0.62, control: -0.33 (P 0.034)	
AUSCAN total		Grifka ⁵⁵	Mean change intervention (1/2) vs control: -7.7 / -10.5 vs -5.6 (P < 0.005)
	Kanat ⁵⁷	Total: mean change intervention: -17, control: -2 (P < 0.001)	
Cochin scale	Kanat ⁵⁷	Mean change intervention: -12, control: -2 (P < 0.001)	
	Poiraudeau ³⁶	Mean change: -2.35, SRM: -0.26, effect size: -0.17	
FIHOA	Bellamy ²⁵	No significant change (in contrast with AUSCAN function) SRM (original, Likert, VAS): -0.31, -0.28, -0.27	
	Dilek ⁴⁸	No significant change (in contrast with AUSCAN function)	
	Dreiser ⁴⁹	Mean change intervention: -5.7, control: -2.8 (P 0.005)	
	Dreiser ²⁶	Mean change: -2.8, SRM: 0.58	

Supplementary table. Continued

	First author	Relevant results
	Fioravanti ⁵¹	Intervention decreased, control no change (P < 0.001)
	Gabay ⁵³	Mean change intervention: -2.9, control: -0.7 (P 0.008)
	Myrer ⁶⁴	Mean change intervention: 3.42 (P < 0.05), control no significant change
	Poiraudreau ³⁶	No significant change (in contrast with Cochin scale) SRM: -0.03, effect size:-0.02
	Saviola ⁷²	Mean change intervention 1 (1/2 year): -51/-41% (P 0.026), intervention 2 no significant change.
HAQ	Fioravanti ⁵¹	Mean change intervention: -0.30, control: -0.02 (P < 0.001)
	Grifka ⁵⁵	No significant change (in contrast with AUSCAN function)
	Horvath ⁵⁶	Mean change intervention 2: -0.5, control: -0.1 (P < 0.01), intervention 1 no significant change.
	Kjeken ⁵⁹	No significant change (in contrast with COPM)
	Schnitzer ⁷³	Mean change intervention: 1.5, control: 0.09 (p-value not specified)
	Stamm ⁷⁶	No significant difference (in contrast with grip strength)
VAS/NRS pain	Dilek ⁴⁸	Pain rest: median change intervention: -3.00, control no change (P 0.01) Pain ADL no significant different change
	Dreiser ⁴⁹	VAS pain: mean change intervention: -37.6, control: -16.5 (P 0.001) No. joints pain movement grade 4/5: mean change intervention: -24, control: -13 (P 0.009)
	Dreiser ²⁶	Mean change: -19.5, SRM: 0.87
	Dziedzic ⁵⁰	Average pain severity (0-10): mean difference between intervention 2 and control: 0.53. No difference between intervention 1 and control
	Fioravanti ⁵¹	Intervention reduced, control no change (P < 0.001)
	Gabay ⁵³	Mean change intervention: -20.0, control: -11.3 (P 0.016)
	Garfinkel ⁵⁴	Pain during activity: mean change intervention: -4.29, control: -1.00 (P < 0.01). No significant change in pain at rest
	Grifka ⁵⁵	Mean change intervention 1/2: -28.0 / -30.0, control: -19.3 (P < 0.001)
	Haugen ²⁹	Mean change intervention: -23.5, control: -6.3 (P 0.005), SRM: 0.77
	Horvath ⁵⁶	Mean change intervention 1/2 vs control: - pain rest: -28.9 / -21.5 (P < 0.05) vs no significant change - pain exertion: -28.2 / -23.2 (P < 0.05) vs no significant change
	Kanat ⁵⁷	Pain rest/motion (1-10): mean change intervention: -4 / -7, control no change (P < 0.001)
	Keen ⁵⁸	Mean change most painful:-36.0, all joints:-36.0, global:-39.0 (P < 0.001)
	Kovacs ⁶⁰	Mean change intervention: -35.7, control: -10.5 (P 0.002)
	Kvien ⁶¹	Mean change intervention: -23.5, control: -6.3 (P 0.005)
	Myrer ⁶⁴	Pain rest/movement: mean change intervention: 21.8 / 29.8 (P < 0.05), control no significant change
	Poiraudreau ³⁶	No significant change (in contrast with no. tender joints) SRM: -0.10, effect size: -0.12
	Reeves ⁶⁶	Pain movement: mean change intervention:-1.89, control:-0.62 (P 0.027). No significant change in pain rest/grip
	Rogers ⁶⁷	Pain (0-10): mean change in participants with pain ≥3: -2.15 (P < 0.006)

Supplementary table. Continued

	First author	Relevant results
	Rothacker ⁷⁰	Pain (0-5) decrease after 45 min intervention > control (P 0.046). Intervention vs control: time to pain peak relief 31 vs 48 min (P 0.018)
	Rothacker ⁷¹	Pain (0-5): mean change intervention: -1.3, control: -0.8 (P 0.026)
	Saviola ⁷²	Mean change intervention 1 (1/2 year): -54/-46% (P 0.001), intervention 2 (1 year): 26% (P 0.018)
	Schnitzer ⁷³	No significant change (in contrast with no. tender joints)
	Stange-Rezende ⁷⁷	No significant change (in contrast with AUSCAN pain)
	Tubach ⁴²	MCII (95%CI) absolute / relative improvement: 16 (13-19) / 23 (20-25), PASS: 41 (38-43)
VAS global	Altman ⁴⁵	No significant change (in contrast with AUSCAN function)
	Flynn ⁵²	No significant change (in contrast with no. tender joints)
	Grifka ⁵⁵	Mean change intervention (1/2): -16.3 / -20.9, control: -9.4 (P < 0.001)
	Haugen ²⁹	Mean change intervention: 23.4, control: -4.6 (P 0.001), SRM: 0.92
	Horvath ⁵⁶	No significant change (in contrast with VAS pain, HAQ, grip/pinch strength, no. tender joints)
	Kjeken ⁵⁹	No significant change (in contrast with COPM)
	Kvien ⁶¹	Mean change intervention: -23.4, control: -4.6 (P 0.001)
	Saviola ⁷²	Mean change intervention 1 (1/2 year): 50/70 (P 0.021), intervention 2 (1 year): 10 (P < 0.001)
	Stamm ⁷⁶	Intervention: 65% improvement, control: 20% improvement (P < 0.05)
	Tubach ⁴²	MCII (95%CI) absolute / relative improvement: 15 (12-17) / 20 (16-23), PASS: 42 (40-44)
VAS/NRS function	Moratz ⁶³	Mean change disability score: -0.5 (P < 0.05)
	Tubach ⁴²	VAS functional disability: MCII (95%CI) absolute / relative improvement: 12 (9-14) / 18 (16-20), PASS: 42 (38-46)
Performance- or assessor-based instruments		
Grip strength	Brosseau ⁴⁷	Improvement in intervention group (P 0.041)
	Dilek ⁴⁸	No significant change (in contrast with AUSCAN function)
	Dreiser ²⁶	Mean change: 4.9, SRM: 0.22
	Gabay ⁵³	No significant change (in contrast with FIHOA)
	Grifka ⁵⁵	No significant change (in contrast with VAS, AUSCAN)
	Haugen ⁸⁴	Mean change (SD) right: -0.7 (6.9), left: -1.1 (6.9)
	Horvath ⁵⁶	Mean change intervention (1 / 2) vs control: right hand 3.8 / 3.5 vs -0.1 (P < 0.05 / not significant). Left hand not significant different.
	Kanat ⁵⁷	No significant change (in contrast with Cochin scale)
	Moratz ⁶³	Minimal improvement (3 lb)
	Pastinen ⁶⁵	Change intervention vs control group: 118 vs 91% (P 0.014)
	Rogers ⁶⁷	Mean change: isotonic strength 1.94 (p<0.0003), max. isometric right/left 3.62 (P < 0.002) / 2.95 (P < 0.0005)
	Rogers ⁶⁸	Mean change intervention vs control: range 1.98-2.92 vs no significant change

Supplementary table. Continued

	First author	Relevant results
	Saviola ⁷²	Mean change intervention 1 (1/2 year): right 25/25%, left 22/20% (P < 0.05), intervention 2 (1 year) no significant change
	Schnitzer ⁷³	Mean change intervention: 32%, control: 3% (P 0.046)
	Seiler ⁷⁴	Mean change intervention: 21.82 (18%), control: 6.58 (6%) (P < 0.05)
	Stamm ⁷⁶	Mean change right/left intervention: 0.12/0.11, control: 0.03/0.03 (P < 0.0005)
Pinch strength	Brosseau ⁴⁷	No significant change (in contrast with grip strength)
	Dilek ⁴⁸	No significant change (in contrast with AUSCAN function)
	Horvath ⁵⁶	Mean change intervention (1 / 2) vs control: right hand 0.6 / 0.7 vs 0.1 (not significant / P < 0.05). Left hand not significant different.
	Kanat ⁵⁷	No significant change (in contrast with Cochin scale)
	Moratz ⁶³	Minimal improvement (3 lb)
	Pastinen ⁶⁵	Change intervention vs control group: 118 vs 98% (P 0.018)
	Rogers ⁶⁸	Mean change intervention vs control: range 0.56-1.24 vs no significant change
	Tenderness/pain on palpation	Botha-Scheepers ⁸³
Dilek ⁴⁸		No. painful joints: median change intervention: -4 (P < 0.016), control no significant change. No significant change in no. tender joints
Dreiser ⁴⁹		No. painful joints: mean change intervention: -19, control: -10 (P < 0.001)
Flynn ⁵²		No. tender joints: mean change intervention 1: -1.0, control: -0.7 (P 0.02) No significant change intervention 2
Garfinke ⁵⁴		Tenderness right/left: mean change intervention: 2.20/2.14, control: 0.40/0.41 (P < 0.01)
Haugen ²⁹		No. tender joints: mean change intervention: -4.8, control: -2.5 (P 0.084) SRM: 0.46
Haugen ⁸⁴		Mean change -2, range -5 to 1
Horvath ⁵⁶		No. tender joints: mean change intervention 1/2: -4.2 / -5.1, control: -0.4 (P < 0.01)
Kvien ⁶¹		No. tender joints: mean change intervention: -5.0, control: -2.6 (P 0.083)
Poiradeau ³⁶		Tenderness: mean change 1.68, SRM: 0.35, effect size: 0.22
Saviola ⁷²		No. tender joints: mean change intervention 1 (1/2 year): -83/-50% (P 0.011), intervention 2 (1 year) no significant change.
Schnitzer ⁷³		Tenderness: mean change intervention: 21.7%, control: 1.2% (P 0.02)
Seiler ⁷⁴		Mean change intervention vs control: - No. of painful joints: -2.45 (43%) / -0.05 (1%) (P < 0.05) - Pain index: -6.09 (60%) / - 4.10 (30%) (P < 0.05)

* Only instruments assessed in ≥2 studies were included.

AUSCAN, Australian/Canadian Hand OA Index; CI, confidence interval; FHOA, Functional Index for Hand OA; HAQ, Health Assessment Questionnaire; MCII, minimum clinically important improvement; no., number; OA, osteoarthritis; P, p-value; PASS, patient acceptable symptom state; SRM, standardized response mean; VAS, Visual Analogue Scale; vs, versus.

OVERVIEW OF LITERATURE SEARCH PER DATABASE

Total d.d. 20-01-2014: 2244 references, extracted from the following databases:

- PubMed: 1843
- MEDLINE: 840, of which 0 unique
- Embase: 870, of which 317 unique
- Web of Science: 344, of which 38 unique
- COCHRANE: 197, of which 101 unique
- CINAHL: 149, of which 41 unique
- Academic Search Premier: 53, of which 11 unique
- ScienceDirect: 80, of which 17 unique

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OR "Jebsen Hand Function Test" OR "JHFT" OR "Jebsen-Taylor test" OR "Pick-up test" OR "pickup test" OR "Pegboard test" OR "Australian Canadian Osteoarthritis Hand Index" OR "AUSCAN" OR "Functional Index for Hand Osteoarthritis" OR "FIHOA" OR "Michigan Hand Outcomes Questionnaire" OR "MHQ" OR "Cochin hand function scale" OR "Dreiser index" OR "Disabilities of the ARM, Shoulder and Hand" OR "DASH" OR "HandUpper Extremity Function Scale" OR "Health Assessment Questionnaire" OR "HAQ" OR "Arthritis Impact Measurement Scale" OR "AIMS" OR (strength AND (grip OR pinch)) OR dexterity OR stiffness OR "Visual Analogue Scale" OR "Visual Analog Scale" OR "VAS" OR "Doyle index" OR ((pain OR tenderness) AND (self report OR assessment OR measurement)) OR "hand function" OR "hand functions" OR "hand functioning" OR "hand dysfunction" OR "hand dysfunctions" OR "hand dysfunctioning" OR "self report" OR selfreport* OR "Self Report")

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