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Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a BMJ Rapid Recommendation

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Title page

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Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a *BMJ* Rapid Recommendation

Abstract

Objectives: To identify credible anchor-based minimal important differences (MIDs) for patient-reported outcome measures (PROMs) relevant to a BMJ Rapid Recommendations addressing subacromial decompression surgery for shoulder pain.

Design: Systematic review

Outcome measures: Estimates of anchor-based MIDs, and their credibility, for PROMs judged by the parallel BMJ Rapid Recommendations panel as important for informing their recommendation (Pain, function and health-related quality of life (HRQoL)).

Data sources：MEDLINE, EMBASE, and PsycINFO up to August 2018

Study selection and review methods: We included original studies of any intervention for shoulder conditions reporting estimates of anchor-based MIDs for relevant PROMs. Two reviewers independently evaluated potentially eligible studies according to pre-defined selection criteria. Six reviewers, working in pairs, independently extracted data from eligible studies using a pre-designed, standardized, pilot-tested extraction form and independently assessed the credibility of included studies using an MID credibility tool.

Results: We identified 22 studies involving 5,562 patients that reported 74 empirically-estimated anchor-based MIDs for 10 candidate instruments to assess shoulder pain, function, and HRQoL. We identified MIDs of high credibility for pain and function outcomes and of low credibility for HRQoL We offered median estimates for the systematic review team who applied these MIDs in GRADE evidence summaries and in their interpretations of results in the linked systematic review addressing the effectiveness of surgery for shoulder pain.

Conclusions: Our review provides anchor-based MID estimates, as well as a rating of their credibility, for PROMs for patients with shoulder conditions. The MID estimates inform the interpretation for a linked systematic review and guideline addressing subacromial decompression surgery for shoulder pain, and could also prove useful for authors addressing other interventions for shoulder problems.

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Article summary

Strengths and limitations of this study

Strengths of our review include a comprehensive search for anchor-based MIDs for instruments commonly used in RCTs of shoulder conditions conducted without restrictions of study design or language of publication.

We undertook judgements of MID credibility using a formal instrument with demonstrated reliability. Most studies (n=14) provided highly credible estimates.

The range of reported MIDs was wide for some of the PROMs. Although participants' disease/conditions, sample size, anchors and analytic methods varied among included studies, we cannot convincingly relate these characteristics to variability in estimates. Detect these reasons for the variability in our review due to limit data available.

For some instruments used in RCTs of surgery for shoulder we did not find any study estimating MIDs in our target patient population.

Background

The shoulder is the body's most mobile joint, allowing movement in many directions. Shoulder conditions, including arthritis, adhesive capsulitis, rotator cuff conditions, dislocations, fractures, shoulder instability and shoulder separation are common problems that cause pain and disability [1]. Up to 26% of adults have recently experienced shoulder pain [2]. In the United States, the evaluation and management of one shoulder condition - rotator cuff tears - costs $3 billion each year [3 4].

The relationship between shoulder pain in an individual and the physical cause is often not clear: anatomical abnormalities are frequently not the cause of an individual patient's shoulder pain. Subacromial pain syndrome – also known as shoulder impingement syndrome or rotator cuff disease is a broad diagnosis that includes several specific conditions and is one of most common diagnoses for patients with shoulder or upper extremity pain or disability [5 6]. Subacromial pain syndrome encompasses all non-traumatic shoulder conditions including partial tear of the rotator cuff, tendon cuff degeneration, bursitis, tendinosis, supraspinatus tendinopathy, or biceps tendinitis [6]. It is most often unilateral.

Investigating interventions to address shoulder conditions such as shoulder pain requires measurement of patients' pain and function, best undertaken using patient-reported outcome

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measures (PROMs). PROMs are reported directly by the patient and address aspects of the patient's experience and perspective without interpretation by the clinician or caregiver [7]. Investigators of interventions for shoulder conditions often include PROMs addressing shoulder pain, function and health-related quality of life (HRQoL) as their primary outcomes [1 8-14]. Interpreting PROMs can, however, be challenging. In particular, interpretation requires knowing if an apparent treatment effect is trivial in magnitude, small but important, moderate or large. Statistical significance provides no insight into this issue [15].

To aid interpretation of PROM findings, researchers developed the concept of the minimal important difference (MID): the smallest change – either positive or negative - that patients perceive as important [16 17]. The MID can help clinicians, patients, and clinical practice guideline developers interpret the magnitude of effects of interventions on PROMs [15 18 19].

There are two common approaches for determining the MID: anchor-based and distribution-based methods [20]. Distribution-based methods rely solely on the statistical characteristics of PROMs (e.g., mean and standard deviation of PROM scores). These statistical characteristics do not reflect the patient's perspective, severely limiting the distribution-based approach in aiding interpretation of results [18 21].

Investigators using the anchor-based approach choose an independent interpretable measure as an external criterion or anchor and then examine the relation between the target PROM instrument and that anchor [18]. Although there is no "gold standard" anchor-based methodology, our group has used the existing literature and expert input to develop an instrument that measures the credibility of anchor-based MIDs. Among desirable criteria to establish a trustworthy MID is a requirement for at least a moderate correlation between change in the target PROM instrument and the change on the anchor [20 22].

Although systematic reviews addressing MIDs in shoulder PROMs are available [23-27] , they are dated and have not applied an assessment of credibility. Therefore, we set out to identify the most credible anchor-based MID estimates to inform a systematic review addressing the effectiveness of subacromial decompression surgery for shoulder pain. Our review informed an associated *BMJ* Rapid Recommendations and facilitated interpretation of critical outcomes of interest, including shoulder pain, function, and health-related quality of life (HRQoL). The *BMJ* Rapid Recommendations project is a collaboration between the MAGIC foundation (www.magicproject.org) and the *BMJ*, with the goal of providing timely, trustworthy practice guidelines [28].

A variety of study designs could inform MIDs for PROMs chosen by investigators for the RCTs. Therefore, in this systematic review, we (1) summarize MID estimate that come largely from observational studies for the PROMs chosen by the triallists in RCTs that investigated the effect of surgery on shoulder pain, and (2) assessed the credibility of these MID estimates.

Methods

Protocol

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We conducted this systematic review based on a registered published PROSPERO protocol (No. CRD42018106531).

Guideline panel and patient involvement

The *BMJ* Rapid Recommendations guideline panel provided critical oversight to this systematic review. The panel included academic and community-based practitioners (orthopedic surgeons, general internists, physiotherapists, a rheumatologist, a general practitioner and a geriatrician), methodologists, and patients with lived experience of shoulder pain. The panel members also provided input into the methodology of our review. Patients helped, in particular, to identify the outcomes of interest for which we identified MID estimates [28]. This study builds on methods used in a similar *BMJ* Rapid Recommendation on arthroscopic knee surgery [29 30].

Instruments under consideration

The *BMJ* Rapid Recommendations panel, informed by the Outcome Measures in Rheumatology (OMERACT) shoulder core outcomes set [31], nominated shoulder pain, function, and health-related quality of life (HRQoL) as critical patient-important outcomes of interest in the management of shoulder conditions. Following guidance from the panel, the systematic review team addressing the effectiveness of surgery for subacromial pain syndrome sought evidence for each of these outcomes in the eligible RCTs. We worked closely with that review team and addressed each of the PROMs corresponding to these constructs included as outcomes in the RCTs that proved eligible for the systematic review addressing the impact of shoulder surgery (the subacromial decompression surgery) (Table 1).

Literature search and study identification

This project utilized a database that includes all articles reporting anchor-based MID from 1989 to April 2015 (the MID concept was first described in the medical literature in 1989[16])[32]. We obtained full access to the database of these MIDs – the leaders (ACL, TD, GG) of that project are participants in the current review.

We conducted a comprehensive search for relevant studies addressing MIDs from February 2015 to August 2018 using the MEDLINE, EMBASE, and PsycINFO databases. For outcomes that did not fully meet the definition of patient-reported outcomes (such as Constant score [33 34]) or were not identified in the systematic review informing the database of MIDs, we conducted a comprehensive search for relevant studies from January 1989 to August 2018. We used the MID search strategy filter from the previous MID database development project including a shoulder filter for the relevant PROMs. We also hand searched references from related reviews. There were no language restrictions. Appendix 1 presents the full search strategy.

Study selection

We included studies with any intervention, including expectant management. We included original reports of all studies that estimated MID(s) using anchor-based methods for any candidate PROM (Table 1). If, for a particular PROM, MID(s) were available for a shoulder condition, we restricted ourselves to those MIDs. If no study estimated MIDs in patients with shoulder conditions, we used the results from studies focusing on upper extremity musculoskeletal conditions. We did not

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consider studies that estimated MIDs in patients with lower extremity or other conditions. Because RCTs evaluated the effects of an intervention on pain, function and HRQoL that would require MIDs for improvement, we did not include MIDs for deterioration.

Eligible studies used any design including retrospective and prospective observational studies or clinical trials that compared the results of a target PROM instrument to an anchor, regardless of the credibility of the design, conduct, or results of the study. Two reviewers independently performed title and abstract screening and, subsequently, full-text screening of studies included by either reviewer. At full-text screening, reviewers resolved the disagreement by discussion or, if needed, by consultation with a third reviewer.

Data abstraction

Six reviewers, working in three pairs, independently extracted the following data from eligible studies using a pre-designed, standardized, pilot-tested extraction table: first author name; publication year; country(ies); demographic characteristics of participants (e.g. sample size, age, sex, condition or disease); intervention; characteristics of the PROM (e.g., construct(s), domains(s), and range); anchor details (e.g., construct(s), threshold, range of options, categories or values); details in MID determination methods (e.g. number of participants used to estimate the MID, duration of follow-up from baseline, analysis methods and correlation between the anchor and PROM). Reviewers resolved disagreements by discussion.

Credibility assessment

The MID database project included the development of an instrument to assess the credibility of anchor-based MID estimates and tested its reliability (it proved reliable – manuscript in preparation, data available upon request). We defined the credibility of studies estimating the MIDs as the extent to which the methodology and performance of studies are likely to have protected against misleading estimates [32]. We used an abridged version of the MID credibility tool developed by our group to measure the credibility of MIDs. The tool needs assess many aspects of the MIDs (Table 2) and has proved reliable (manuscript in preparation). Six reviewers, working in three pairs, independently assessed the credibility of included studies. Reviewers resolved disagreements by discussion. We deemed that the MID estimate had high credibility if 3 or more of the 5 criteria were met (either 'Definitely yes' or 'To a great extent' for each item); otherwise, we deemed that the MID had low credibility. We regard the credibility as a dichotomous variable (high and low) and do not quantify the credibility.

Synthesis of results

We described the characteristics of eligible studies including MID estimates, demographic characteristics of participants, intervention, and characteristics of the instrument and anchor. We identified the median, minimum and maximum values across the range of high credibility trustworthy MID estimates generated from the eligible studies for the PROMs of interest. If all MIDs estimates were of low credibility, we presented these estimates.

For each MID with multiple estimates of the MID we considered variables that may influence the

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MID. These included: the intervention type (surgical or non-surgical); and, for transition anchors, the period from first to second instrument administration (< 3 months versus 3 months or more). We tested the subgroup effect by examining the interaction between each variable and the MID (*P*-value of <0.05 was deemed statistically significant).

Results

We found 6 eligible studies from the existing database of anchor-based MIDs and 1 study from the references in related reviews. We identified 2,643 records through our search of electronic databases, of which 534 were duplicates, leaving 2,109 records for the title and abstract screening. We excluded 1,962 records based on our title and abstract screening and assessed 147 full-text articles, of which 15 were eligible. Therefore, 22 studies were eligible for this review. Figure 1 summarizes the study identification process.

Table 3 presents the characteristics of the 22 eligible studies [24 35-55]. Sample sizes ranged from 20 [49] to 1,856 [46], with a total of 5,562 participants providing MID estimates for 2 relevant instruments assessing shoulder pain, 1 assessing function, 5 assessing shoulder symptoms and function and 2 assessing HRQoL (Table 3). The 22 studies reported 74 anchor-based MIDs estimates. Twenty-one of 22 studies employed a variety of transition ratings as the anchor to determine the MIDs, of which 5 had a follow-up period of less than 3 months [38 43 44 48 49]. One study used the Pen shoulder score (cut-off point: 8.6) as the anchor to determine the MIDs for pain measurement (PNRS) [42]. Of the 22 studies, 19 reported the absolute estimates for the MIDs and three - addressing the Constant score, quick DASH, and Oxford Shoulder Score (OSS) – relative estimates [35 39 43]. Patients underwent surgical interventions in four studies [36 40 46 47]; four studies used both surgical and non-surgical interventions [41 51 54 55]; 13 used non-surgical interventions [24 35 37-39 42-45 48 49 52 53]; and one did not report the type of intervention [50].

The analysis methods for estimating the MID included mean change in patients who had experienced a small but minimally important difference over time [35-40 48 49 52 54 55]; mean difference in groups perceived to have changed versus not changed [24 40 46 47 53]; and ROC curves [35 38-45 50 51]. Fourteen studies provided highly credible estimates and eight studies provided low credibility estimates [37 39 42 43 47 48 54 55]. Studies with high credibility reported MID estimates for Constant Score, Simple Shoulder Test (SST), Pain Visual Analog Scale (VAS), Disability of the Arm, Shoulder and Hand [DASH], Oxford Shoulder Score (OSS), and SF-12 (Table 1). Studies provided low credibility MID estimates for the Pain Numeric Rating Scale (PNRS), Quick DASH, Neer score, and EQ-5D-3L (Table 1). No studies estimate MIDs for the following instruments in shoulder or upper extremity conditions: PainDETECT Numerical Rating Scale (0-10), Shoulder Disability Questionnaire (SDQ), Project on Research and Intervention in Monotonous work (PRIM) score, Watson-Sonnabend score, 15D, Short Form 36 (SF-36), and Hospital Anxiety and Depression Score [HADS].

Table 4 presents median, maximum, and minimum estimates of MIDs according to credibility, with the best estimates suggested to the systematic review team shaded. For the MID estimates with high credibility, MIDs for the SST (1.5 to 2.1) and overall pain VAS (1.4 to 1.6) were consistent across the 2 available estimates. The MIDs for the Constant Score (3 to 16.6), DASH (4.4 to 25.4), and OSS (4.0 to 14.7) were, however, inconsistent among 6-10 estimates provided.

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Available evidence permitted subgroup analyses exploring potential sources of heterogeneity only for surgical versus non-surgical interventions for the Constant Score and Simple Shoulder Test (SST) and follow-up time (less than 3 months or ≧ 3 months) for the Oxford Shoulder Score (OSS). In no case did these differences explain the variation in the MID. Appendix 2 provides details of the MID estimates and the results of subgroup analysis.

Discussion

We identified 22 studies involving 5,562 patients that reported 74 empirically-estimated anchor-based MIDs for 10 candidate instruments to assess shoulder pain, function, and HRQoL. The majority of studies used a global rating of change (transition rating) as the anchor and had a follow-up period of over 3 months. We identified MIDs of high credibility for pain and function outcomes and of low credibility for HRQoL. MIDs estimates often varied widely; we offered median estimates for the systematic review team and guideline panel. We also provided the systematic review team with the median, minimum and maximum values across the range of high credibility trustworthy MID estimates generated from the eligible studies for the PROMs of interest. The only instance in which the variability in scores was sufficiently great that choice of one of the extremes rather than the median could substantially influence conclusions was for the Constant score.

Authors of the linked review used these MIDs (Pain VAS 0-10 1.5 units, the Constant score 0-100 scale 8.3 units, and EQ 5-D, 0.07 units) to gauge the importance of possible difference patients in GRADE evidence summaries and to dichotomize the improvements (proportions of patients achieving MID or more); the *BMJ* Rapid Recommendations guideline panel used them to inform their judgements of magnitude of effect in formulating their recommendations. The systematic review informed the *BMJ* Rapid Recommendations panel in their development of the guideline.

Strengths of our review include a comprehensive search for anchor-based MIDs for instruments commonly used in RCTs of shoulder conditions conducted without restrictions of study design or language of publication. We undertook judgements of MID credibility using a formal instrument with demonstrated reliability. Most studies (n=14) provided highly credible estimates. These MIDs not only can help clinicians, patients, and clinical practice guideline developers interpret the magnitude of effects of interventions on PROMs, they also can be used in power calculations in future trials on shoulder conditions.

For the credibility assessment, we found that the anchor instrument directly addressed the patient's perspective, and judged the understanding the anchor instrument for patients as 'Definitely yes' or 'To a great extent', for all the MID estimates. Approximately half of the estimates did not report the correlation between the anchor and the PROM. We judged the precision of the MID estimation and the threshold or difference between groups on the anchor used to estimate the MID as "Definitely no" or "Not so much" for most MID estimates.

The results of our systematic review have limitations. The range of reported MIDs was wide for some of the PROMs (*e.g.,* 0.3 to 30 for Constant score; 4.4 to 25.41 for Disabilities of the Arm,

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Shoulder and Hand (DASH)). Baseline characteristics (participants' disease/conditions, sample size, PROMs or instruments), anchors and analytic methods varied among included studies; though others have detected associations between methodological approaches and MIDs [56], our attempts to establish a clear relation between these variables and the MID were not successful. For some instruments used in RCTs of surgery for shoulder pain - the Shoulder Disability Questionnaire (SDQ), Short Form 36 (SF-36), and 15D - we did not find any study estimating MIDs in our target patient population. For others, MIDs for shoulder conditions closely related to subacromial syndrome, or for shoulder conditions at all, were not available, and we therefore relied on estimates from any upper extremity problem population.

With respect to the assessment of credibility, a formal assessment of the validity of the instrument has not been undertaken. Moreover, one might challenge our judgment in inferring high credibility if 3 or more criteria were met. Finally, investigators used different methods to relate the anchor to a transition rating; the optimal approach remains uncertain [56 57].

Our results are consistent with previous studies [23-25]. A previous review of MIDs of upper extremity instruments that appeared in selected orthopedic journals from 2014 to 2016 found a wide range of MIDs for the Constant Score (8-36) and reported a pain VAS MID of 1.4 on 10-point scale [26]. Reviews of pain VAS MIDs in shoulder injuries found a range of 0.5to 3.0 [24 36 46 47]. A review of pain ratings in a wide variety of conditions reported VAS MIDs of 0.1 to 8.2 and noted that absolute MIDs are higher in patients with more pain at baselines [27]. Only one study included in our review reported MID estimates separately according to the baseline severity [48] but these estimates had low credibility due to problems in the anchor selected and failure to report the correlation between the anchor and the instrument. Two other reviews of shoulder instrument MIDs, primarily from rotator cuff injuries reported MID values of 10.2 to 20 for DASH, and 4.0 to 13.4 for OSS [23 25]. Participants' disease/conditions, baseline scale score, and inappropriate analytic methods can cause serious bias in determining MIDs [56 58]; researchers should pay more attention to these factors during the MID estimation studies.

Conclusion

Our review provides anchor-based MID estimates, as well as a rating of their credibility, for PROMs for measurement instruments addressing patients with shoulder conditions. The review identified methodological limitations of the primary studies, future studies should strive for high precision of MID estimation, seek to identify difference between groups and reasons for those differences, and report correlations between the anchor and the PROM [56 58].

The MID estimates inform the interpretation for a linked systemtatic review and guideline on arthroscopy for shoulder pain. Researchers addressing a wide variety of shoulder conditions can in future make use of our summary MIDs to inform sample size and aid in interpretation of results.

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their review of this manuscript.

Contributors statement

GG and RAS conceived the study idea; QH designed the search strategy; QH, YW, DZ and screened studies for eligibility; QH, TD, YW, DZ, RAS, and AQ extracted data and assessed the credibility; QH wrote the first draft of the manuscript; GG, TD, POV, TL, TA, ACL and RAS interpreted the data analysis and critically revised the manuscript. QH is the guarantor.

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Competing interests' statement

All authors have completed the ICMJE uniform disclosure form and declare no support from any organization for the submitted work. There are no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval statement: Not required.

Data sharing statement: No additional data available.

Appendices

Appendix 1: Search terms and strategies.
Appendix 2: Description of MIDs according to subgroups and the results of subgroup analysis.
Appendix 3: Reporting checklist (PRISMA checklist).

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Figure 1: Flowchart for eligible studies identification according to PRISMA guidelines

Table 1: Patient-reported outcome measure instruments considered in this review

Instrument with full name and abbreviation	General score range	Higher scores are better or worse	Construct(s) measured
Pain Numeric Rating Scale (PNRS)	0-10/0-100	Worse	Pain
Pain Visual Analogue Scale	0-10/0-100	Worse	Pain

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(VAS)			
PainDETECT Numerical Rating Scale	0-10/0-100	Worse	Pain
Disability of the Arm, Shoulder and Hand (DASH)	0-100	Worse	Symptom and function
Quick DASH	0-100	Worse	Symptom and function
Shoulder Disability Questionnaire (SDQ)	0-100	Worse	Pain-related function of the shoulder
Simple Shoulder Test (SST)	0-12	Better	Shoulder comfort and function
Oxford Shoulder Score (OSS)	0-48	Better	Shoulder function and pain
Project on Research and Intervention in Monotonous work (PRIM) score	0–36 for each region	Worse	Pain or other complains
Neer score	0-100	Worse	Function
Constant (Murley) Score (CS/CMS)	0-100	Better	Shoulder function, pain, ADL function, the range of motion, strength
Watson-Sonnabend score	Pain: 0-10; Function: 0-42	Pain: worse; Function: better	Satisfaction, pain and 0-3 discrete for 14 function items
Short Form 36 (SF-36)	0-100	Better	Health-related quality of life
Short Form 12 (SF-12)	0-100	Better	Health-related quality of life
EuroQol 5 dimensions 3 level index (EQ-5D-3L)	-0.59-1	Better	Health-related quality of life
15D	0-1	Better	Health-related quality of life
Hospital Anxiety and Depression Score (HADS)	0-42	Worse	Anxiety and depression

Table 2 The criteria for credibility assessment

Item	Assessment aspects	Results
1	Whether the anchor instrument directly addressed the patient's perspective.	0 = No 1 = Yes 2 = Impossible to tell
2	Whether patients could easily understand the anchor instrument.	0 = Definitely no 1 = Not so much 2 = To a great extent

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		3 = Definitely yes 4 = Impossible to tell
3	The correlation between the anchor and the PRO.@	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported
4	The precision of the MID estimation.	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported
5	Whether the threshold or difference between groups on the anchor used to estimate the MID represented a small but important change.	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported

@ For anchors with categorical scales the Spearman rather the Pearson's correlation, is appropriate.

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Table 3: Characteristics of eligible studies

Author (Year)	Disease/conditions	Participants in baseline	Intervention	Instrument/scale	Anchor	Follow-up period
Simovitch 2018	Cuff tear arthropathy, a combination of osteoarthritis and rotator cuff insufficiency	1,865	Total shoulder arthroplasty	Constant score; SST; Pain VAS;	Global rating question	40.2 to 49.7 months
Negahban 2015	Shoulder disorders including impingement syndrome/tendonitis, frozen shoulder, shoulder instability	200	Physiotherapy	DASH (Persian version)	Global rating of shoulder function	1 month
Holmgren 2014	Subacromial impingement syndrome	93	Physiotherapy	Constant (Murley) shoulder assessment score	Patient's global impression of change	3 months
Rysstad 2017	Subacromial pain syndrome (SPS)	50	Physiotherapy	DASH (Norwegian version)	Patient's perceived recovery	3 to 4 months
van de Water 2014	Isolated proximal humeral fracture	20	Active rehabilitation	Constant Score; OSS; DASH	Patient perception of change	1.5 months
Christiansen 2015	8-12 weeks after arthroscopic decompression surgery for subacromial impingement syndrome	112	Physiotherapy	OSS ; Modified Constant Score ;	Patient Global Impression of Change (PGIC)	3 months
Kukkonen 2013	Rotator cuff tears (both partial and full thickness)	781	Arthroscopy	Constant score;	The two-stage question of the patient satisfaction	3 months
Michener 2011	Shoulder pain with or without surgery	136	Rehabilitation	PNRS	Pen shoulder score	3 to 4 weeks
Christie 2011	Rheumatic disease (inflammatory or degenerative disease) undergoing elective shoulder surgery	100	Arthroplasty or other surgery (not specified)	DASH; OSS; Pain VAS at activity; Pain VAS at rest; Constant score	Shoulder symptoms question "At one-year follow-up, the patients were also asked to rate their shoulder symptoms at present compared with baseline"	12 months
Ekeberg 2010	Rotator cuff disease	121	Local ultrasound-guided injections of triamcinolone and xylocain	OSS	Main complaint score (-9 (worst) to 9 (best))	2 to 6 weeks
Mintken 2009	Shoulder pain	101	Physical therapy	PNRS; QuickDASH;	Global rating of change (GRC)	2 to 4 weeks
Tubach 2006	Acute rotator cuff syndrome	252	NSAID therapy or placebo	PNRS; Neer score;	Response to NSAID treatment question	7 days
Mahabier 2017	Humeral shaft fracture	140	Operative and	DASH;	Transition item:	1.5 to 12

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			nonoperative treatment of humeral shaft fracture	Constant (Murley) score;	perception of change in the general condition of the affected upper limb	months
Tashjian 2017	Osteoarthritis, rheumatoid arthritis, rotator cuff arthropathy, advanced rotator cuff disease	326	Total shoulder arthroplasty (primary anatomic or reverse)	SST Pain VAS	Improvement after treatment	3.5 years
Dritsaki 2017	Rheumatoid arthritis with pain and dysfunction of the hands and/or wrists	488	Tailored exercise program	EQ-5D-3L; EQ-5D-3L VAS; SF-12-physical; SF-12-mental	Participant self-rated improvement in their hands and wrist	4 to 8 months
Tashjian 2009	Rotator cuff tendonitis, rotator cuff tear (partial or full-thickness)	81	Non-surgical management	Pain VAS	Four-item anchor instrument: response to treatment	3.6 months
Schmitt 2004	Musculoskeletal proximal upper extremity problem	211	Occupational or physical therapy	DASH	Global disability rating	3 months
van Kampen 2013	Shoulder problems	128	Operative or non-operative treatment	DASH; QuickDASH	Global rating scale for function	6 months
Lundquist 2014	Shoulder conditions (rotator cuff/impingement, adhesive capsulitis, humeroscapular instability, humeroscapular arthrosis, humeral fracture, other or unspecified should disorder)	81	NR	DASH (Danish version)	Global impression of change	2.3 months
Tashjian 2010	Rotator cuff tendonitis, rotator cuff tear (partial or full-thickness)	81	Nonsurgical management	SST	15-item function question; 4-item improvement question	3.6 months
Marks 2014	Trapeziometacarpal joint osteoarthritis	177	Conservative treatment or surgery (resection/suspension/interposition arthroplasty or arthrodesis)	SF-12-physical; SF-12-mental	Patient perceived change in thumb condition	12 months
Castricini 2014	Irreparable rotator cuff Tears	27	Shoulder arthroplasty surgery and rehabilitation	Constant and Murley score	The three-stage question of the patient satisfaction.	27 months

SST: Simple shoulder test; **VAS:** Visual analogue scale; **DASH:** Disabilities of the Arm, Shoulder and Hand; **OSS:** Oxford shoulder score; **SF-12:** Short Form Health Survey 12; **EQ-5D-3L:** Euro-Quality of life 5 dimensions 3 level index; **PNRS:** Pain Numerical Rating Scale; **NR:** Not reported

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Table 4: Summary of MIDs for improvement for interested instruments according to the credibility

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate
High credibility				
Absolute MIDs				
Constant score (0-100)[1]	10	8.3	3	16.6
SST (0-12)	2	1.8	1.5	2.1
Pain VAS (overall) (0-10)	2	1.5	1.4	1.6
Pain VAS (Activity) (transfer to 0-10)	1	2.1		
Pain VAS (at rest) (transfer to 0-10)	1	3.0		
DASH (0-100)	6	10.2	4.4	25.4
OSS: (0-48)[2]	8	5.3	4.0	14.7
SF-12 (0-100)	1 1	Physical:1 Mental: 4		
Relative MIDs (relative to baseline)				
Constant score (0-100)	1	15%		

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OSS (0-48)	1	11%		
Low credibility				
Absolute MIDs				
Constant score (0-100)	9	19.0	0.3	36.0
SST (0-100)	6	2.1	1.4	2.9
Pain VAS (overall) (0-10)	5	1.4	0.5	2.7
DASH (0-100)	1	12.4		
PNRS (0-10)	5	3.4	1.1	6.3
Quick DASH (0-100)	1	13.4		
Neer score (0-100)	3	2.0	1.5	3.7
EQ-5D-3L (-0.59 to 1)	2; 2	Raw index: 0.07; VAS: 7.18	0.02; 6.86	0.11 7.50
SF-12 (0-100)	2; 2	Physical: 2.2 Mental: 0.9	2.0; 0.9	2.4; 1.0
Relative MIDs (relative to baseline)				
Constant score (0-100)	1	22%		
Quick DASH (0-100)	1	8%		

1 The range of the Constant score is 2-100 in **van de Water 2014** [49].

2 The range of the OSS is 12-60 in **Christie 2011** [36].

MID: minimal important difference; **SST:** Simple shoulder test; **VAS:** Visual analogue scale; **DASH:** Disabilities of the Arm, Shoulder and Hand; **OSS:** Oxford shoulder score; **SF-12:** Short Form Health Survey 12; **EQ-5D-3L:** Euro-Quality of life 5 dimensions 3 level index; **PNRS:** Pain Numerical Rating Scale; **NR:** Not reported

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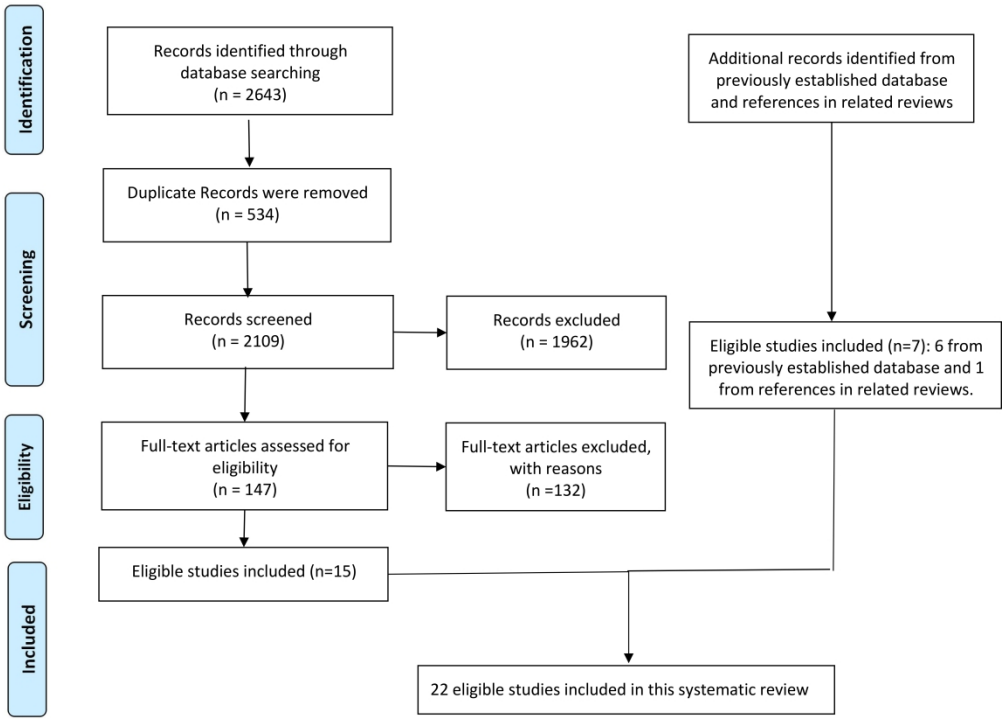

Figure 1 Flowchart for eligible studies identification according to PRISMA guidelines

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Database(s): OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	10562
2	"Quality of Life"/	165230
3	"outcome assessment".mp. or outcome assessment/ or treatment outcome/ or treatment failure/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	948610
4	exp pain/	361898
5	exp disease attributes/ or exp "signs and symptoms"/	2823288
6	or/2-5	3651696
7	1 and 6	5289

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8	health status indicators/ or "severity of illness index"/ or sickness impact profile/ or interviews as topic/ or questionnaires/ or self report/	679871
9	Pain Measurement/	77822
10	patient satisfaction/ or patient preference/	80034
11	or/8-10	794501
12	7 and 11	2391
13	limit 12 to yr="1989 -Current"	2389
14	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	290843
15	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	1196557
16	pain????.mp.	693582
17	((activity or sever* or course) adj3 (disease or disabilit* or symptom*)).mp.	246717
18	or/14-17	2160347
19	1 and 18	6305
20	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	7579315
21	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp.	183341

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22	(patient? report* or patient? observ* or patient? satisf*).mp.	145747
23	anchor base??.mp.	513
24	or/20-23	7657299
25	19 and 24	5474
26	limit 25 to yr="1989 -Current"	5456
27	13 or 26	5548
28	shoulder.mp.	68799
29	shoulder impingement syndrome.mp.	1748
30	subacromial.mp.	2417
31	painful arc syndrome.mp.	10
32	supraspinatus syndrome.mp.	18
33	rotator cuff.mp.	11181
34	upper limb.mp.	16544
35	upper extremity.mp.	24219
36	exp shoulder/	11799
37	exp shoulder Impingement Syndrome/	1610
38	exp rotator Cuff/	5622
39	exp shoulder pain/	4199
40	exp shoulder joint/	17536

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41	((should$ or rotator cuff) adj5 (bursitis or adhesive capsulitis or periarthr iti$ or frozen or impinge$ or tend?nitis or pain$)).tw.	20086
42	exp Upper Extremity/	154603
43	or/28-42	235079
44	limit 43 to yr="1989 -Current"	173628
45	Hawkins-Kennedy.mp.	31
46	("University of California Los Angeles shoulder rating scale" or UCLA).mp.	4559
47	("American Shoulder and Elbow Surgeon questionnaire" or ASES).mp.	1296
48	(Upper Extremity Functional Index or UEFI).mp.	39
49	(Upper Extremity Functional Scale or UEFS).mp.	22
50	("American Shoulder and Elbow Surgeon questionnaire" or ASES).mp.	1296
51	(Penn Shoulder Score or PSS).mp.	8051
52	("Shoulder Pain and Disability Index" or SPADI).mp.	393
53	(Shoulder Disability Questionnaire or SDQ).mp.	1439
54	("Project on Research and Intervention in Monotonous work" or PRIM).mp.	426
55	(Neer score or NS).mp.	63982
56	(Constant Murley Score or CMS or constant score or CS).mp.	64167
57	(Watson-Sonnabend score or WSS).mp.	1467
58	(PainDETECT Numerical Rating Scale or PainDETECT).mp.	209
59	or/45-58	144686

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60	limit 59 to yr="1989 -Current"	132969
61	(simple shoulder test or SST).mp.	4419
62	(Visual Analogue Scale or VAS).mp.	52312
63	(Short form or SF?36 or SF?12 or SF?8).mp.	28488
64	(EuroQol or EQ?5D).mp.	4612
65	15?D.mp.	1850
66	(Oxford shoulder score or OSS).mp.	2487
67	(RC-Quality Of Life or RC-QOL).mp.	14
68	(Western Ontario Rotator Cuff Index or WORC).mp.	150
69	("Disability of the Arm, Shoulder and Hand" or DASH).mp.	5639
70	(Medical outcomes study or MOS).mp.	10247
71	(Health Assessment Questionnaire or HAQ or HAQ?DI).mp.	4471
72	(Numerical Rating Scale or NRS).mp.	7528
73	(Numeric pain rating scales or NPRS).mp.	402
74	("Hospital Anxiety and Depression Score" or HADS).mp.	4327
75	or/61-74	115635
76	limit 75 to yr="2015 -Current"	35330
77	27 and 76	579
78	44 or 60	301674
79	27 and 78	393

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80	77 or 79	900

Database(s): **Embase** 1974 to 2018 August 10

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	16030
2	"Quality of Life"/	371636
3	"outcome assessment(health care)".mp. or treatment outcome/ or treatment failure/ [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	830270
4	exp pain/	1079551
5	exp disease course/ or exp "physical disease by body function "/	9191603

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6	or/2-5	9628948
7	1 and 6	11859
8	health status indicators/ or "severity of illness index"/ or sickness impact profile/ or interviews/ or questionnaire/ or self report/	786093
9	Pain Measurement/	5221
10	patient satisfaction/ or patient preference/	125926
11	or/8-10	888283
12	7 and 11	2911
13	limit 12 to yr="1989 -Current"	2904
14	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	462977
15	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	1540053
16	pain????.mp.	1106808
17	((activity or sever* or course) adj3 (disease or disabilit* or symptom*)).mp.	1088931
18	or/14-17	3576012
19	1 and 18	9705
20	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	9331391

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21	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp.	242895
22	(patient? report* or patient? observ* or patient? satisf*).mp.	214735
23	anchor base??.mp.	694
24	or/20-23	9449030
25	19 and 24	8469
26	limit 25 to yr="1989 -Current"	8423
27	13 or 26	8714
28	shoulder.mp.	83119
29	shoulder impingement syndrome.mp.	2389
30	subacromial.mp.	2767
31	painful arc syndrome.mp.	17
32	supraspinatus syndrome.mp.	16
33	rotator cuff.mp.	13465
34	upper limb.mp.	26023
35	upper extremity.mp.	23277
36	exp shoulder/	55236
37	exp shoulder Impingement Syndrome/	2303
38	exp rotator Cuff/	6589
39	exp shoulder pain/	13048

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40	exp shoulder joint/	55236
41	((should$ or rotator cuff) adj5 (bursitis or adhesive capsulitis or periarthr iti$ or frozen or impinge$ or tend?nitis or pain$)).tw.	25617
42	exp Upper Extremity/	247960
43	or/28-42	321155
44	limit 43 to yr="1989 -Current"	290504
45	Hawkins-Kennedy.mp.	46
46	(University of California Los Angeles shoulder rating scale or UCLA).mp.	6102
47	((American Shoulder and Elbow Surgeon questionnaire) or ASES).mp.	1600
48	(Upper Extremity Functional Index or UEFI).mp.	50
49	(Upper Extremity Functional Scale or UEFS).mp.	35
50	((American Shoulder and Elbow Surgeon questionnaire) or ASES).mp.	1600
51	(Penn Shoulder Score or PSS).mp.	10814
52	((Shoulder Pain and Disability Index) or SPADI).mp.	555
53	(Shoulder Disability Questionnaire or SDQ).mp.	1990
54	((Project on Research and Intervention in Monotonous work) or PRIM).mp.	521
55	(Neer score or NS).mp.	85103
56	(Constant Murley Score or CMS or constant score or CS).mp.	82387
57	(Watson-Sonnabend score or WSS).mp.	1851
58	(PainDETECT Numerical Rating Scale or PainDETECT).mp.	357

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59	or/45-58	189411
60	limit 59 to yr="1989 -Current"	177302
61	(simple shoulder test or SST).mp.	5180
62	(Visual Analogue Scale or VAS).mp.	76248
63	(Short form or SF?36 or SF?12 or SF?8).mp.	47823
64	(EuroQol or EQ?5D).mp.	7284
65	15?D.mp.	2744
66	(Oxford shoulder score or OSS).mp.	2838
67	(RC-Quality Of Life or RC-QOL).mp.	14
68	(Western Ontario Rotator Cuff Index or WORC).mp.	186
69	((Disability of the Arm, Shoulder and Hand) or DASH).mp.	5405
70	(Medical outcomes study or MOS).mp.	17455
71	(Health Assessment Questionnaire or HAQ or HAQ?DI).mp.	11808
72	(Numerical Rating Scale or NRS).mp.	10819
73	(Numeric pain rating scales or NPRS).mp.	640
74	((Hospital Anxiety and Depression Score) or HADS).mp.	9146
75	or/61-74	178346
76	limit 75 to yr="2015 -Current"	51547
77	27 and 76	937
78	44 or 60	460897

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79	27 and 78	763
80	77 or 79	1600

Database(s): **PsycINFO** 1987 to August Week 1 2018

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	2062
2	("Quality of Life" or "outcome assessment" or "treatment outcome" or "treatment failure" or pain or "disease attributes" or "signs and symptoms").mp.	157999
3	1 and 2	720

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4	("health status indicators" or "severity of illness index" or "sickness impact profile" or "interviews" or questionnaires or "self report" or "pain measurement" or "patient satisfaction" or "patient preference").mp.	298303
5	3 and 4	185
6	limit 5 to yr="1989 -Current"	185
7	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	67910
8	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	89594
9	pain????.mp.	93558
10	(activity or sever* or course or (disease or disabilit* or symptom*)).mp.	1112369
11	or/7-10	1224703
12	1 and 11	1648
13	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	1776162
14	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	148082

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15	(patient? report* or patient? observ* or patient? satisf*).mp.	14671
16	anchor base??.mp.	108
17	or/13-16	1799670
18	12 and 17	1504
19	limit 18 to yr="1989 -Current"	1502
20	6 or 19	1502
21	(Shoulder or subacromial or "painful arc syndrome" or "supraspinatus syndrome" or "rotator cuff" or "upper limb" or "upper extremity").mp.	6818
22	limit 21 to yr="1989 -Current"	6778
23	("University of California Los Angeles shoulder rating scale" or UCLA or "Hawkins-Kennedy" or "American Shoulder and Elbow Surgeon questionnaire" or ASES or "Upper Extremity Functional Index" or UEFI or "Upper Extremity Functional Scale" or UEFS or "American Shoulder and Elbow Surgeon questionnaire" or ASES or "Penn Shoulder Score" or PSS or "Shoulder Pain and Disability Index" or SPADI or "Shoulder Disability Questionnaire" or SDQ or "Project on Research and Intervention in Monotonous work" or PRIM or "Neer score" or NS or "Constant Murley Score" or CMS or "constant score" or CS or "Watson-Sonnabend score" or WSS or "PainDETECT Numerical Rating Scale" or PainDETECT).mp.	18283
24	limit 23 to yr="1989 -Current"	17923
25	("simple shoulder test" or SST or "Visual Analogue Scale" or VAS or "Short form" or SF?36 or SF?12 or SF?8 or EuroQol or EQ?5D or15?D or "Oxford shoulder score" or	49736

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	OSS or "RC-Quality Of Life" or RC-QOL or "Western Ontario Rotator Cuff Index" or WORC or "Disability of the Arm, Shoulder and Hand" or DASH or "Medical outcomes study" or MOS or "Health Assessment Questionnaire" or HAQ or HAQ?DI or "Numerical Rating Scale" or NRS or "Numeric pain rating scales" or NPRS or "Hospital Anxiety and Depression Score" or HADS).mp.	
26	limit 25 to yr="2015 -Current"	15110
27	20 and 26	93
28	22 or 24	24612
29	20 and 28	55
30	27 or 29	143

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Appendix 2: Description of MIDs according to subgroups and the results of subgroup analysis

Table S1: Summary of all MIDs for improvement for interested PROs or instruments

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Absolute MIDs							
Constant score (0-100)	19	12.80	0.3	36	14.06	9.22	9.62 to 18.51
Simple shoulder text (SST) (0-100)	8	1.93	1.4	2.9	1.99	0.53	1.54 to 2.42
Pain VAS (overall) (0-10)	7	1.40	0.5	2.70	1.58	0.68	0.95 to 2.21
Pain VAS (Activity) (transfer to 0-10)	1	2.1					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	7	10.20	4.4	25.41	11.56	6.73	5.34 to 17.78
Oxford shoulder score (OSS) (0-48)	8	5.3	4	14.7	6.51	10.7	3.59 to 9.43
PNRS (0-10)	5	3.43	1.1	6.25	3.50	2.01	1.00 to 6.00

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Quick DASH	1	13.4					
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
EQ-5D-3L	2; 2	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45	-0.51 to 0.64; 3.11 to 11.25
SF-12 (0-100)	3; 3	Physical: 2.04 Mental: 0.96	1.0; 0.86	2.44; 4.00	1.83; 1.94	0.74; 1.78	-0.02 to 3.67; -2.49 to 6.37
Relative MIDs							
Constant score (0-100)	2	18.6%	15.2%	22%	18.6%	4.8%	-24.60 to 61.8
Oxford shoulder score (OSS) (0-48)	1	11.10%					
Quick DASH	1	8%					

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Table S2: Summary of MIDs for improvement for interested PROs or instruments according to intervention administered during the study to measure the PRO or instrument

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Surgical intervention							
Absolute MIDs							
Constant score (0-100)	7	10.40	0.3	16.6	9.31	6.47	3.34 to 15.29
Simple shoulder text (STT) (0-100)	6	1.65	1.4	2.9	1.92	0.61	1.28 to 2.55
Pain VAS (overall) (0-10)	6	1.5	0.5	2.7	1.62	0.74	0.84 to 2.40
Pain VAS (Activity) (transfer to 0-10)	1	2.1					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	10.1					
Quick DASH	1	13.4					
Oxford shoulder score (OSS) (0-48)	1	6.9					
Non-surgical							

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intervention							
Absolute MIDs							
Constant score (0-100)	10	16	5.1	30	15.99	7.74	10.45 to 21.53
Simple shoulder text (STT) (0-100)	2	2.19	2.05	2.33	2.19	0.20	0.41 to 3.97
Pain VAS (overall) (0-10)	1	1.37	One estimation				
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	3	10.2	4.4	25.41	13.34	10.85	-13.62 to 40.29
Oxford shoulder score (OSS) (0-48)	7	5	4	14.7	6.46	3.77	2.97 to 9.94
PNRS (0-10)	5	3.43	1.1	6.25	3.50	2.01	1 to 6
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
EQ-5D-3L	2; 2;	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45	-0.51 to 0.64; 3.11 to 11.25
SF-12	2 ; 2	Physical: 2.24; Mental: 0.91	2.04; 0.86	2.44; 0.96	2.24; 0.91	0.28; 0.07	-0.30 to 4.78; 0.27 to 1.55
Relative MIDs							
Constant score (0-100)	2	18.6%	15.2%	22.0%	18.6 %	4.81	-24.6 to 61.8

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Oxford shoulder score (OSS) (0-48)	1	11.1%					
Quick DASH	1	8%					
Surgical or non-surgical intervention							
Absolute MIDs							
Constant score (0-100)	2	21.05	6.1	36.0	21.05	21.14	-169 to 211
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	2	9.55	6.7	12.4	9.55	4.03	-26.66 to 45.76
Quick DASH	1	13.4					
SF-12	1 1	Physical:1 Mental: 4					
Not report the intervention							
Absolute MIDs							
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	11.7					

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Table S3: Summary of MIDs for improvement for interested PROs or instruments using transit anchor according to follow-up period

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Less than 3 months							
Absolute MIDs							
Constant score (0-100)	1	11.60					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	25.1					
Oxford shoulder score (OSS) (0-48)	4	4.45	4	7	4.98	1.37	2.79 to 7.16
PNRS (0-10)	4	3.99	1.10	6.25	3.83	2.16	0.40 to 7.26
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
Relative MIDs							
Quick DASH	1	8%					
3 months or more							
Absolute MIDs							

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Constant score (0-100)	18	13.9	0.3	36	14.20	9.47	9.49 to 18.91
Simple shoulder text (STT) (0-100)	8	1.93	1.4	2.9	1.99	0.53	1.54 to 2.43
Pain VAS (overall) (0-10)	7	1.4	0.5	2.7	1.58	0.68	0.95 to 2.21
Pain VAS (Activity) (transfer to 0-10)	1	2.10					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	6	10.15	4.4	12.4	9.25	3.09	6.01 to 12.49
Oxford shoulder score (OSS) (0-48)	4	6.25	5	14.7	8.05	4.50	0.88 to 15.22
PNRS (0-10)	1	2.17					
Quick DASH	1	13.4					
EQ-5D-3L	2; 2	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45;	-0.51 to 0.64; 3.11 to 11.25
SF-12 (0-100)	3 3	Physical: 2.04 Mental: 0.96	1.00; 0.86	2.44; 4.00	1.83; 1.94	0.74; 1.78	-0.02 to 3.67; -2.49 to 6.37
Relative MIDs							

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Constant score (0-100)	2	18.6%	15.2%	22.0%	18.6%	4.81%	-24.6% to 61.8%
Oxford shoulder score (OSS) (0-48)	1	11.1%					

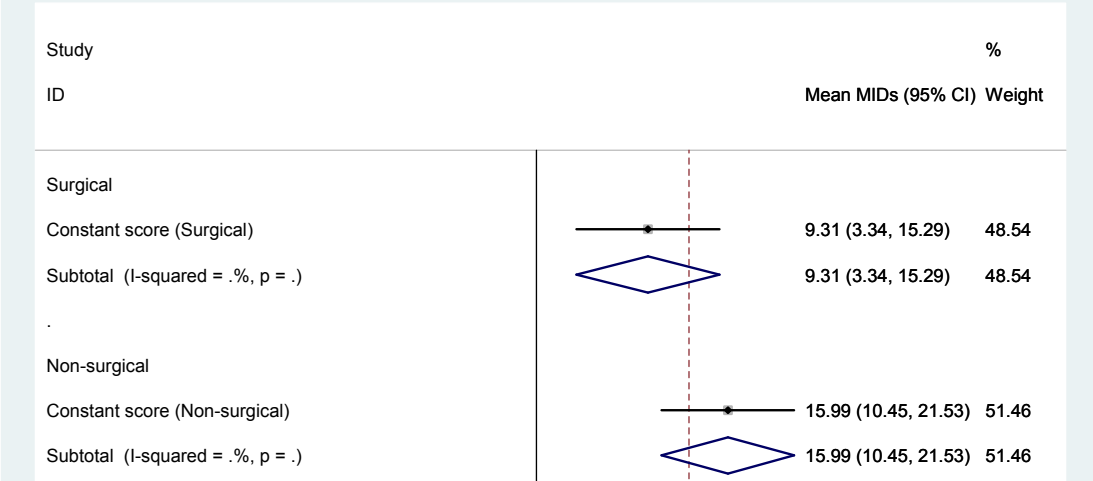

Figure S1: Subgroup analysis for Constant score by intervention type. MID, minimally important difference

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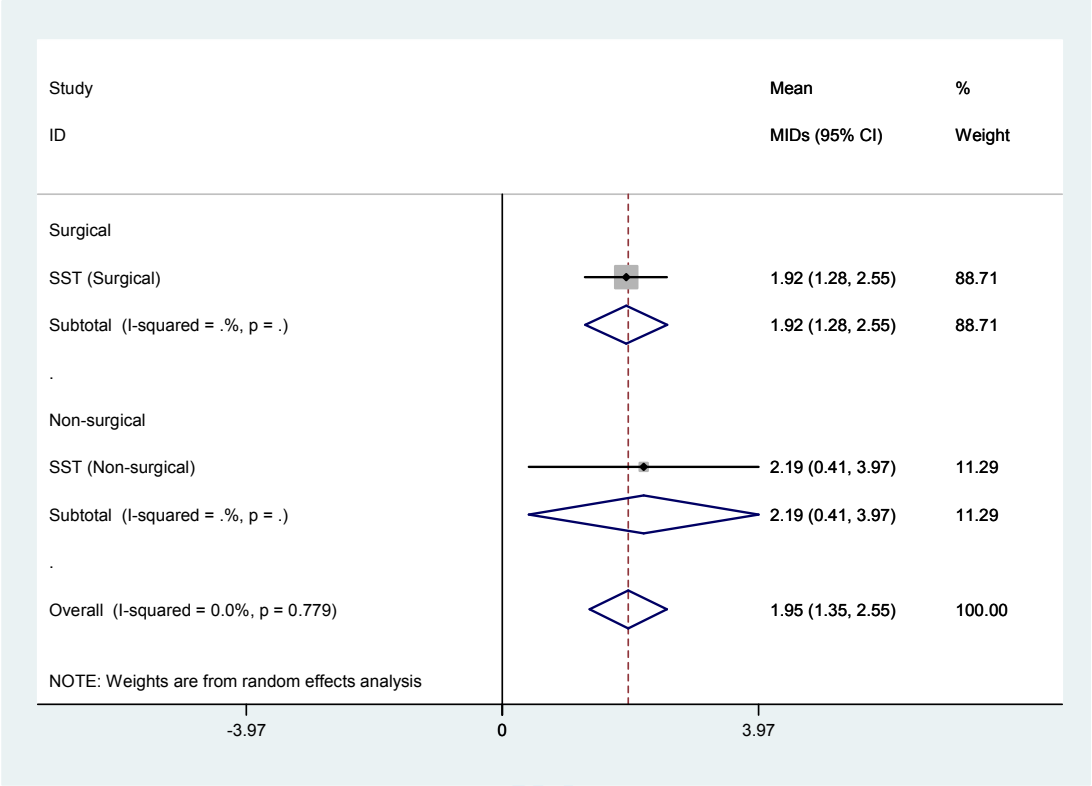

Figure S2: Subgroup analysis for SST by intervention type. MID, minimally important difference; SST: Simple Shoulder Test

Figure S3: Subgroup analysis for OSS by follow-up time. MID, minimally important difference; OSS: Oxford Shoulder Score

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4-5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5-6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	5-6 and figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	6
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	6
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	7
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	7
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	8

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Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a BMJ Rapid Recommendation

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Title page

Title: Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a BMJ Rapid Recommendation

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Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a *BMJ* Rapid Recommendation

Abstract

Objectives: To identify credible anchor-based minimal important differences (MIDs) for patient-reported outcome measures (PROMs) relevant to a BMJ Rapid Recommendations addressing subacromial decompression surgery for shoulder pain.

Design: Systematic review

Outcome measures: Estimates of anchor-based MIDs, and their credibility, for PROMs judged by the parallel BMJ Rapid Recommendations panel as important for informing their recommendation (Pain, function and health-related quality of life (HRQoL)).

Data sources：MEDLINE, EMBASE, and PsycINFO up to August 2018

Study selection and review methods: We included original studies of any intervention for shoulder conditions reporting estimates of anchor-based MIDs for relevant PROMs. Two reviewers independently evaluated potentially eligible studies according to pre-defined selection criteria. Six reviewers, working in pairs, independently extracted data from eligible studies using a pre-designed, standardized, pilot-tested extraction form and independently assessed the credibility of included studies using an MID credibility tool.

Results: We identified 22 studies involving 5,562 patients that reported 74 empirically-estimated anchor-based MIDs for 10 candidate instruments to assess shoulder pain, function, and HRQoL. We identified MIDs of high credibility for pain and function outcomes and of low credibility for HRQoL We offered median estimates for the systematic review team who applied these MIDs in GRADE evidence summaries and in their interpretations of results in the linked systematic review addressing the effectiveness of surgery for shoulder pain.

Conclusions: Our review provides anchor-based MID estimates, as well as a rating of their credibility, for PROMs for patients with shoulder conditions. The MID estimates inform the interpretation for a linked systematic review and guideline addressing subacromial decompression surgery for shoulder pain, and could also prove useful for authors addressing other interventions for shoulder problems.

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Article summary

Strengths and limitations of this study

Our review includes a comprehensive search for anchor-based MIDs for instruments commonly used in RCTs of shoulder conditions conducted without restrictions of study design or language of publication.

We undertook judgements of MID credibility using a formal instrument with demonstrated reliability and most studies provided highly credible estimates.

The range of reported MIDs was wide for some of the PROMs.

Although participants' disease/conditions, sample size, anchors and analytic methods varied among included studies, we cannot convincingly relate these characteristics to variability in estimates.

For some instruments used in RCTs of surgery for shoulder we did not find any study estimating MIDs in our target patient population.

Background

The shoulder is the body's most mobile joint, allowing movement in many directions. Shoulder conditions, including arthritis, adhesive capsulitis, rotator cuff conditions, dislocations, fractures, shoulder instability and shoulder separation are common problems that cause pain and disability [1]. Up to 26% of adults have recently experienced shoulder pain [2]. In the United States, the evaluation and management of one shoulder condition - rotator cuff tears - costs $3 billion each year [3 4].

The relationship between shoulder pain in an individual and the physical cause is often not clear: anatomical abnormalities are frequently not the cause of an individual patient's shoulder pain. Subacromial pain syndrome – also known as shoulder impingement syndrome or rotator cuff disease is a broad diagnosis that includes several specific conditions and is one of most common diagnoses for patients with shoulder or upper extremity pain or disability [5 6]. Subacromial pain syndrome encompasses all non-traumatic shoulder conditions including partial tear of the rotator cuff, tendon cuff degeneration, bursitis, tendinosis, supraspinatus tendinopathy, or biceps tendinitis [6]. It is most often unilateral.

Investigating interventions to address shoulder conditions such as shoulder pain requires measurement of patients' pain and function, best undertaken using patient-reported outcome measures (PROMs). PROMs are reported directly by the patient and address aspects of the patient's

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experience and perspective without interpretation by the clinician or caregiver [7]. Investigators of interventions for shoulder conditions often include PROMs addressing shoulder pain, function and health-related quality of life (HRQoL) as their primary outcomes [1 8-14]. Interpreting PROMs can, however, be challenging. In particular, interpretation requires knowing if an apparent treatment effect is trivial in magnitude, small but important, moderate or large. Statistical significance provides no insight into this issue [15].

To aid interpretation of PROM findings, researchers developed the concept of the minimal important difference (MID): the smallest change – either positive or negative - that patients perceive as important [16 17]. The MID can help clinicians, patients, and clinical practice guideline developers interpret the magnitude of effects of interventions on PROMs [15 18 19].

There are two common approaches for determining the MID: anchor-based and distribution-based methods [20]. Distribution-based methods rely solely on the statistical characteristics of PROMs (e.g., mean and standard deviation of PROM scores). These statistical characteristics do not reflect the patient's perspective, severely limiting the distribution-based approach in aiding interpretation of results [18 21].

Investigators using the anchor-based approach choose an independent interpretable measure as an external criterion or anchor and then examine the relation between the target PROM instrument and that anchor [18]. Although there is no "gold standard" anchor-based methodology, our group has used the existing literature and expert input to develop an instrument that measures the credibility of anchor-based MIDs. Among desirable criteria to establish a trustworthy MID is a requirement for at least a moderate correlation between change in the target PROM instrument and the change on the anchor [20 22].

Although systematic reviews addressing MIDs in shoulder PROMs are available [23-27] , they are dated and have not applied an assessment of credibility. Therefore, we set out to identify the most credible anchor-based MID estimates to inform a systematic review addressing the effectiveness of subacromial decompression surgery for shoulder pain. Our review informed an associated *BMJ* Rapid Recommendations and facilitated interpretation of critical outcomes of interest, including shoulder pain, function, and health-related quality of life (HRQoL). The *BMJ* Rapid Recommendations project is a collaboration between the MAGIC foundation (www.magicproject.org) and the *BMJ*, with the goal of providing timely, trustworthy practice guidelines [28].

A variety of study designs could inform MIDs for PROMs chosen by investigators for the RCTs. Therefore, in this systematic review, we (1) summarize MID estimate that come largely from observational studies for the PROMs chosen by the triallists in RCTs that investigated the effect of surgery on shoulder pain, and (2) assessed the credibility of these MID estimates.

Methods

Protocol

We conducted this systematic review based on a registered published PROSPERO protocol (No.

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Guideline panel and patient involvement

The *BMJ* Rapid Recommendations guideline panel provided critical oversight to this systematic review. The panel included academic and community-based practitioners (orthopedic surgeons, general internists, physiotherapists, a rheumatologist, a general practitioner and a geriatrician), methodologists, and patients with lived experience of shoulder pain. The panel members also provided input into the methodology of our review. Patients helped, in particular, to identify the outcomes of interest for which we identified MID estimates [28]. This study builds on methods used in a similar *BMJ* Rapid Recommendation on arthroscopic knee surgery [29 30].

Instruments under consideration

The *BMJ* Rapid Recommendations panel, informed by the Outcome Measures in Rheumatology (OMERACT) shoulder core outcomes set [31], nominated shoulder pain, function, and health-related quality of life (HRQoL) as critical patient-important outcomes of interest in the management of shoulder conditions. Following guidance from the panel, the systematic review team addressing the effectiveness of surgery for subacromial pain syndrome sought evidence for each of these outcomes in the eligible RCTs. We worked closely with that review team and addressed each of the PROMs corresponding to these constructs included as outcomes in the RCTs that proved eligible for the systematic review addressing the impact of shoulder surgery (the subacromial decompression surgery) (Table 1).

Literature search and study identification

This project utilized a database that includes all articles reporting anchor-based MID from 1989 to April 2015 (the MID concept was first described in the medical literature in 1989[16])[32]. We obtained full access to the database of these MIDs – the leaders (ACL, TD, GG) of that project are participants in the current review.

We conducted a comprehensive search for relevant studies addressing MIDs from February 2015 to August 2018 using the MEDLINE, EMBASE, and PsycINFO databases. For outcomes that did not fully meet the definition of patient-reported outcomes (such as Constant score [33 34]) or were not identified in the systematic review informing the database of MIDs, we conducted a comprehensive search for relevant studies from January 1989 to August 2018. We used the MID search strategy filter from the previous MID database development project including a shoulder filter for the relevant PROMs. We also hand searched references from related reviews. There were no language restrictions. Appendix 1 presents the full search strategy.

Study selection

We included studies with any intervention, including expectant management. We included original reports of all studies that estimated MID(s) using anchor-based methods for any candidate PROM (Table 1). If, for a particular PROM, MID(s) were available for a shoulder condition, we restricted ourselves to those MIDs. If no study estimated MIDs in patients with shoulder conditions, we used the results from studies focusing on upper extremity musculoskeletal conditions. We did not consider studies that estimated MIDs in patients with lower extremity or other conditions. Because

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RCTs evaluated the effects of an intervention on pain, function and HRQoL that would require MIDs for improvement, we did not include MIDs for deterioration.

Eligible studies used any design including retrospective and prospective observational studies or clinical trials that compared the results of a target PROM instrument to an anchor, regardless of the credibility of the design, conduct, or results of the study. Two reviewers independently performed title and abstract screening and, subsequently, full-text screening of studies included by either reviewer. At full-text screening, reviewers resolved the disagreement by discussion or, if needed, by consultation with a third reviewer.

Data abstraction

Six reviewers, working in three pairs, independently extracted the following data from eligible studies using a pre-designed, standardized, pilot-tested extraction table: first author name; publication year; country(ies); demographic characteristics of participants (e.g. sample size, age, sex, condition or disease); intervention; characteristics of the PROM (e.g., construct(s), domains(s), and range); anchor details (e.g., construct(s), threshold, range of options, categories or values); details in MID determination methods (e.g. number of participants used to estimate the MID, duration of follow-up from baseline, analysis methods and correlation between the anchor and PROM). Reviewers resolved disagreements by discussion.

Credibility assessment

The MID database project included the development of an instrument to assess the credibility of anchor-based MID estimates and tested its reliability (it proved reliable – manuscript in preparation, data available upon request). We defined the credibility of studies estimating the MIDs as the extent to which the methodology and performance of studies are likely to have protected against misleading estimates [32]. We used an abridged version of the MID credibility tool developed by our group to measure the credibility of MIDs. The tool needs assess many aspects of the MIDs (Table 2) and has proved reliable (manuscript in preparation). Six reviewers, working in three pairs, independently assessed the credibility of included studies. Reviewers resolved disagreements by discussion. We deemed that the MID estimate had high credibility if 3 or more of the 5 criteria were met (either 'Definitely yes' or 'To a great extent' for each item); otherwise, we deemed that the MID had low credibility. We regard the credibility as a dichotomous variable (high and low) and do not quantify the credibility.

Synthesis of results

We described the characteristics of eligible studies including MID estimates, demographic characteristics of participants, intervention, and characteristics of the instrument and anchor. We identified the median, minimum and maximum values across the range of high credibility trustworthy MID estimates generated from the eligible studies for the PROMs of interest. If all MIDs estimates were of low credibility, we presented these estimates.

For each MID with multiple estimates of the MID we considered variables that may influence the MID. These included: the intervention type (surgical or non-surgical); and, for transition anchors,

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the period from first to second instrument administration (< 3 months versus 3 months or more). We tested the subgroup effect by examining the interaction between each variable and the MID (*P*-value of <0.05 was deemed statistically significant).

Results

We found 6 eligible studies from the existing database of anchor-based MIDs and 1 study from the references in related reviews. We identified 2,643 records through our search of electronic databases, of which 534 were duplicates, leaving 2,109 records for the title and abstract screening. We excluded 1,962 records based on our title and abstract screening and assessed 147 full-text articles, of which 15 were eligible. Therefore, 22 studies were eligible for this review. Figure 1 summarizes the study identification process.

Table 3 presents the characteristics of the 22 eligible studies [24 35-55]. Sample sizes ranged from 20 [49] to 1,856 [46], with a total of 5,562 participants providing MID estimates for 2 relevant instruments assessing shoulder pain, 1 assessing function, 5 assessing shoulder symptoms and function and 2 assessing HRQoL (Table 3). The 22 studies reported 74 anchor-based MIDs estimates. Twenty-one of 22 studies employed a variety of transition ratings as the anchor to determine the MIDs, of which 5 had a follow-up period of less than 3 months [38 43 44 48 49]. One study used the Pen shoulder score (cut-off point: 8.6) as the anchor to determine the MIDs for pain measurement (PNRS) [42]. Of the 22 studies, 19 reported the absolute estimates for the MIDs and three - addressing the Constant score, quick DASH, and Oxford Shoulder Score (OSS) – relative estimates [35 39 43]. Patients underwent surgical interventions in four studies [36 40 46 47]; four studies used both surgical and non-surgical interventions [41 51 54 55]; 13 used non-surgical interventions [24 35 37-39 42-45 48 49 52 53]; and one did not report the type of intervention [50].

The analysis methods for estimating the MID included mean change in patients who had experienced a small but minimally important difference over time [35-40 48 49 52 54 55]; mean difference in groups perceived to have changed versus not changed [24 40 46 47 53]; and ROC curves [35 38-45 50 51]. Fourteen studies provided highly credible estimates and eight studies provided low credibility estimates [37 39 42 43 47 48 54 55]. Studies with high credibility reported MID estimates for Constant Score, Simple Shoulder Test (SST), Pain Visual Analog Scale (VAS), Disability of the Arm, Shoulder and Hand [DASH], Oxford Shoulder Score (OSS), and SF-12 (Table 1). Studies provided low credibility MID estimates for the Pain Numeric Rating Scale (PNRS), Quick DASH, Neer score, and EQ-5D-3L (Table 1). No studies estimate MIDs for the following instruments in shoulder or upper extremity conditions: PainDETECT Numerical Rating Scale (0-10), Shoulder Disability Questionnaire (SDQ), Project on Research and Intervention in Monotonous work (PRIM) score, Watson-Sonnabend score, 15D, Short Form 36 (SF-36), and Hospital Anxiety and Depression Score [HADS].

Table 4 presents median, maximum, and minimum estimates of MIDs according to credibility, with the best estimates suggested to the systematic review team shaded. For the MID estimates with high credibility, MIDs for the SST (1.5 to 2.1) and overall pain VAS (1.4 to 1.6) were consistent across the 2 available estimates. The MIDs for the Constant Score (3 to 16.6), DASH (4.4 to 25.4), and OSS (4.0 to 14.7) were, however, inconsistent among 6-10 estimates provided.

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Available evidence permitted subgroup analyses exploring potential sources of heterogeneity only for surgical versus non-surgical interventions for the Constant Score and Simple Shoulder Test (SST) and follow-up time (less than 3 months or ≧ 3 months) for the Oxford Shoulder Score (OSS). In no case did these differences explain the variation in the MID. Appendix 2 provides details of the MID estimates and the results of subgroup analysis.

Discussion

We identified 22 studies involving 5,562 patients that reported 74 empirically-estimated anchor-based MIDs for 10 candidate instruments to assess shoulder pain, function, and HRQoL. The majority of studies used a global rating of change (transition rating) as the anchor and had a follow-up period of over 3 months. We identified MIDs of high credibility for pain and function outcomes and of low credibility for HRQoL. MIDs estimates often varied widely; we offered median estimates for the systematic review team and guideline panel. We also provided the systematic review team with the median, minimum and maximum values across the range of high credibility trustworthy MID estimates generated from the eligible studies for the PROMs of interest. The only instance in which the variability in scores was sufficiently great that choice of one of the extremes rather than the median could substantially influence conclusions was for the Constant score.

Authors of the linked review used these MIDs (Pain VAS 0-10 1.5 units, the Constant score 0-100 scale 8.3 units, and EQ 5-D, 0.07 units) to gauge the importance of possible difference patients in GRADE evidence summaries and to dichotomize the improvements (proportions of patients achieving MID or more); the *BMJ* Rapid Recommendations guideline panel used them to inform their judgements of magnitude of effect in formulating their recommendations. The systematic review informed the *BMJ* Rapid Recommendations panel in their development of the guideline.

Strengths of our review include a comprehensive search for anchor-based MIDs for instruments commonly used in RCTs of shoulder conditions conducted without restrictions of study design or language of publication. We undertook judgements of MID credibility using a formal instrument with demonstrated reliability. Most studies (n=14) provided highly credible estimates. These MIDs not only can help clinicians, patients, and clinical practice guideline developers interpret the magnitude of effects of interventions on PROMs, they also can be used in power calculations in future trials on shoulder conditions.

For the credibility assessment, we found that the anchor instrument directly addressed the patient's perspective, and judged the understanding the anchor instrument for patients as 'Definitely yes' or 'To a great extent', for all the MID estimates. Approximately half of the estimates did not report the correlation between the anchor and the PROM. We judged the precision of the MID estimation and the threshold or difference between groups on the anchor used to estimate the MID as "Definitely no" or "Not so much" for most MID estimates.

The results of our systematic review have limitations. The range of reported MIDs was wide for some of the PROMs (*e.g.,* 0.3 to 30 for Constant score; 4.4 to 25.41 for Disabilities of the Arm, Shoulder and Hand (DASH)). Baseline characteristics (participants' disease/conditions, sample size,

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PROMs or instruments), anchors and analytic methods varied among included studies; though others have detected associations between methodological approaches and MIDs [56], our attempts to establish a clear relation between these variables and the MID were not successful. For some instruments used in RCTs of surgery for shoulder pain - the Shoulder Disability Questionnaire (SDQ), Short Form 36 (SF-36), and 15D - we did not find any study estimating MIDs in our target patient population. For others, MIDs for shoulder conditions closely related to subacromial syndrome, or for shoulder conditions at all, were not available, and we therefore relied on estimates from any upper extremity problem population. With respect to the assessment of credibility, a formal assessment of the validity of the instrument has not been undertaken. Moreover, one might challenge our judgment in inferring high credibility if 3 or more criteria were met. Finally, investigators used different methods to relate the anchor to a transition rating; the optimal approach remains uncertain [56 57].

Our results are consistent with previous studies [23-25]. A previous review of MIDs of upper extremity instruments that appeared in selected orthopedic journals from 2014 to 2016 found a wide range of MIDs for the Constant Score (8-36) and reported a pain VAS MID of 1.4 on 10-point scale [26]. Reviews of pain VAS MIDs in shoulder injuries found a range of 0.5to 3.0 [24 36 46 47]. A review of pain ratings in a wide variety of conditions reported VAS MIDs of 0.1 to 8.2 and noted that absolute MIDs are higher in patients with more pain at baselines [27]. Only one study included in our review reported MID estimates separately according to the baseline severity [48] but these estimates had low credibility due to problems in the anchor selected and failure to report the correlation between the anchor and the instrument. Two other reviews of shoulder instrument MIDs, primarily from rotator cuff injuries reported MID values of 10.2 to 20 for DASH, and 4.0 to 13.4 for OSS [23 25]. Participants' disease/conditions, baseline scale score, and inappropriate analytic methods can cause serious bias in determining MIDs [56 58]; researchers should pay more attention to these factors during the MID estimation studies.

Conclusion

Our review provides anchor-based MID estimates, as well as a rating of their credibility, for PROMs for measurement instruments addressing patients with shoulder conditions. The review identified methodological limitations of the primary studies, future studies should strive for high precision of MID estimation, seek to identify difference between groups and reasons for those differences, and report correlations between the anchor and the PROM [56 58].

The MID estimates inform the interpretation for a linked systemtatic review and guideline on arthroscopy for shoulder pain. Researchers addressing a wide variety of shoulder conditions can in future make use of our summary MIDs to inform sample size and aid in interpretation of results.

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Contributors statement

GG and RAS conceived the study idea; QH designed the search strategy; QH, YW, DZ and screened studies for eligibility; QH, TD, YW, DZ, RAS, and AQ extracted data and assessed the credibility; QH wrote the first draft of the manuscript; GG, TD, POV, TL, TA, ACL, and RAS interpreted the data analysis and critically revised the manuscript. QH is the guarantor.

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Competing interests' statement

All authors have completed the ICMJE uniform disclosure form and declare no support from any organization for the submitted work. There are no other relationships or activities that could appear to have influenced the submitted work.

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Appendices

Appendix 1: Search terms and strategies.

Appendix 2: Description of MIDs according to subgroups and the results of subgroup analysis.

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Figure 1: Flowchart for eligible studies identification according to PRISMA guidelines

Table 1: Patient-reported outcome measure instruments considered in this review

Instrument with full name and abbreviation	General score range	Higher scores are better or worse	Construct(s) measured
Pain Numeric Rating Scale (PNRS)	0-10/0-100	Worse	Pain
Pain Visual Analogue Scale (VAS)	0-10/0-100	Worse	Pain
PainDETECT Numerical	0-10/0-100	Worse	Pain

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Rating Scale			
Disability of the Arm, Shoulder and Hand (DASH)	0-100	Worse	Symptom and function
Quick DASH	0-100	Worse	Symptom and function
Shoulder Disability Questionnaire (SDQ)	0-100	Worse	Pain-related function of the shoulder
Simple Shoulder Test (SST)	0-12	Better	Shoulder comfort and function
Oxford Shoulder Score (OSS)	0-48	Better	Shoulder function and pain
Project on Research and Intervention in Monotonous work (PRIM) score	0–36 for each region	Worse	Pain or other complains
Neer score	0-100	Worse	Function
Constant (Murley) Score (CS/CMS)	0-100	Better	Shoulder function, pain, ADL function, the range of motion, strength
Watson-Sonnabend score	Pain: 0-10; Function: 0-42	Pain: worse; Function: better	Satisfaction, pain and 0-3 discrete for 14 function items
Short Form 36 (SF-36)	0-100	Better	Health-related quality of life
Short Form 12 (SF-12)	0-100	Better	Health-related quality of life
EuroQol 5 dimensions 3 level index (EQ-5D-3L)	-0.59-1	Better	Health-related quality of life
15D	0-1	Better	Health-related quality of life
Hospital Anxiety and Depression Score (HADS)	0-42	Worse	Anxiety and depression

Table 2 The criteria for credibility assessment

Item	Assessment aspects	Results
1	Whether the anchor instrument directly addressed the patient's perspective.	0 = No 1 = Yes 2 = Impossible to tell
2	Whether patients could easily understand the anchor instrument.	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes 4 = Impossible to tell

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3	The correlation between the anchor and the PRO.@	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported
4	The precision of the MID estimation.	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported
5	Whether the threshold or difference between groups on the anchor used to estimate the MID represented a small but important change.	0 = Definitely no 1 = Not so much 2 = To a great extent 3 = Definitely yes NR= Not reported

@ For anchors with categorical scales the Spearman rather the Pearson's correlation, is appropriate.

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Table 3: Characteristics of eligible studies

Author (Year)	Disease/conditions	Participants in baseline	Intervention	Instrument/scale	Anchor	Follow-up period
Simovitch 2018	Cuff tear arthropathy, a combination of osteoarthritis and rotator cuff insufficiency	1,865	Total shoulder arthroplasty	Constant score; SST; Pain VAS;	Global rating question	40.2 to 49.7 months
Negahban 2015	Shoulder disorders including impingement syndrome/tendonitis, frozen shoulder, shoulder instability	200	Physiotherapy	DASH (Persian version)	Global rating of shoulder function	1 month
Holmgren 2014	Subacromial impingement syndrome	93	Physiotherapy	Constant (Murley) shoulder assessment score	Patient's global impression of change	3 months
Rysstad 2017	Subacromial pain syndrome (SPS)	50	Physiotherapy	DASH (Norwegian version)	Patient's perceived recovery	3 to 4 months
van de Water 2014	Isolated proximal humeral fracture	20	Active rehabilitation	Constant Score; OSS; DASH	Patient perception of change	1.5 months
Christiansen 2015	8-12 weeks after arthroscopic decompression surgery for subacromial impingement syndrome	112	Physiotherapy	OSS ; Modified Constant Score ;	Patient Global Impression of Change (PGIC)	3 months
Kukkonen 2013	Rotator cuff tears (both partial and full thickness)	781	Arthroscopy	Constant score;	The two-stage question of the patient satisfaction	3 months
Michener 2011	Shoulder pain with or without surgery	136	Rehabilitation	PNRS	Pen shoulder score	3 to 4 weeks
Christie 2011	Rheumatic disease (inflammatory or degenerative disease) undergoing elective shoulder surgery	100	Arthroplasty or other surgery (not specified)	DASH; OSS; Pain VAS at activity; Pain VAS at rest; Constant score	Shoulder symptoms question "At one-year follow-up, the patients were also asked to rate their shoulder symptoms at present compared with baseline"	12 months
Ekeberg 2010	Rotator cuff disease	121	Local ultrasound-guided injections of triamcinolone and xylocain	OSS	Main complaint score (-9 (worst) to 9 (best))	2 to 6 weeks
Mintken 2009	Shoulder pain	101	Physical therapy	PNRS; QuickDASH;	Global rating of change (GRC)	2 to 4 weeks
Tubach 2006	Acute rotator cuff syndrome	252	NSAID therapy or placebo	PNRS; Neer score;	Response to NSAID treatment question	7 days
Mahabier 2017	Humeral shaft fracture	140	Operative and	DASH;	Transition item:	1.5 to 12

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			nonoperative treatment of humeral shaft fracture	Constant (Murley) score;	perception of change in the general condition of the affected upper limb	months
Tashjian 2017	Osteoarthritis, rheumatoid arthritis, rotator cuff arthropathy, advanced rotator cuff disease	326	Total shoulder arthroplasty (primary anatomic or reverse)	SST Pain VAS	Improvement after treatment	3.5 years
Dritsaki 2017	Rheumatoid arthritis with pain and dysfunction of the hands and/or wrists	488	Tailored exercise program	EQ-5D-3L; EQ-5D-3L VAS; SF-12-physical; SF-12-mental	Participant self-rated improvement in their hands and wrist	4 to 8 months
Tashjian 2009	Rotator cuff tendonitis, rotator cuff tear (partial or full-thickness)	81	Non-surgical management	Pain VAS	Four-item anchor instrument: response to treatment	3.6 months
Schmitt 2004	Musculoskeletal proximal upper extremity problem	211	Occupational or physical therapy	DASH	Global disability rating	3 months
van Kampen 2013	Shoulder problems	128	Operative or non-operative treatment	DASH; QuickDASH	Global rating scale for function	6 months
Lundquist 2014	Shoulder conditions (rotator cuff/impingement, adhesive capsulitis, humeroscapular instability, humeroscapular arthrosis, humeral fracture, other or unspecified should disorder)	81	NR	DASH (Danish version)	Global impression of change	2.3 months
Tashjian 2010	Rotator cuff tendonitis, rotator cuff tear (partial or full-thickness)	81	Nonsurgical management	SST	15-item function question; 4-item improvement question	3.6 months
Marks 2014	Trapeziometacarpal joint osteoarthritis	177	Conservative treatment or surgery (resection/suspension/interposition arthroplasty or arthrodesis)	SF-12-physical; SF-12-mental	Patient perceived change in thumb condition	12 months
Castricini 2014	Irreparable rotator cuff Tears	27	Shoulder arthroplasty surgery and rehabilitation	Constant and Murley score	The three-stage question of the patient satisfaction.	27 months

SST: Simple shoulder test; **VAS:** Visual analogue scale; **DASH:** Disabilities of the Arm, Shoulder and Hand; **OSS:** Oxford shoulder score; **SF-12:** Short Form Health Survey 12; **EQ-5D-3L:** Euro-Quality of life 5 dimensions 3 level index; **PNRS:** Pain Numerical Rating Scale; **NR:** Not reported

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Table 4: Summary of MIDs for improvement for interested instruments according to the credibility

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate
High credibility				
Absolute MIDs				
Constant score (0-100)[1]	10	8.3	3	16.6
SST (0-12)	2	1.8	1.5	2.1
Pain VAS (overall) (0-10)	2	1.5	1.4	1.6
Pain VAS (Activity) (transfer to 0-10)	1	2.1		
Pain VAS (at rest) (transfer to 0-10)	1	3.0		
DASH (0-100)	6	10.2	4.4	25.4
OSS: (0-48)[2]	8	5.3	4.0	14.7
SF-12 (0-100)	1 1	Physical:1 Mental: 4		
Relative MIDs (relative to baseline)				
Constant score (0-100)	1	15%		

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OSS (0-48)	1	11%		
Low credibility				
Absolute MIDs				
Constant score (0-100)	9	19.0	0.3	36.0
SST (0-100)	6	2.1	1.4	2.9
Pain VAS (overall) (0-10)	5	1.4	0.5	2.7
DASH (0-100)	1	12.4		
PNRS (0-10)	5	3.4	1.1	6.3
Quick DASH (0-100)	1	13.4		
Neer score (0-100)	3	2.0	1.5	3.7
EQ-5D-3L (-0.59 to 1)	2; 2	Raw index: 0.07; VAS: 7.18	0.02; 6.86	0.11 7.50
SF-12 (0-100)	2; 2	Physical: 2.2 Mental: 0.9	2.0; 0.9	2.4; 1.0
Relative MIDs (relative to baseline)				
Constant score (0-100)	1	22%		
Quick DASH (0-100)	1	8%		

1 The range of the Constant score is 2-100 in **van de Water 2014** [49].

2 The range of the OSS is 12-60 in **Christie 2011** [36].

MID: minimal important difference; **SST:** Simple shoulder test; **VAS:** Visual analogue scale; **DASH:** Disabilities of the Arm, Shoulder and Hand; **OSS:** Oxford shoulder score; **SF-12:** Short Form Health Survey 12; **EQ-5D-3L:** Euro-Quality of life 5 dimensions 3 level index; **PNRS:** Pain Numerical Rating Scale; **NR:** Not reported

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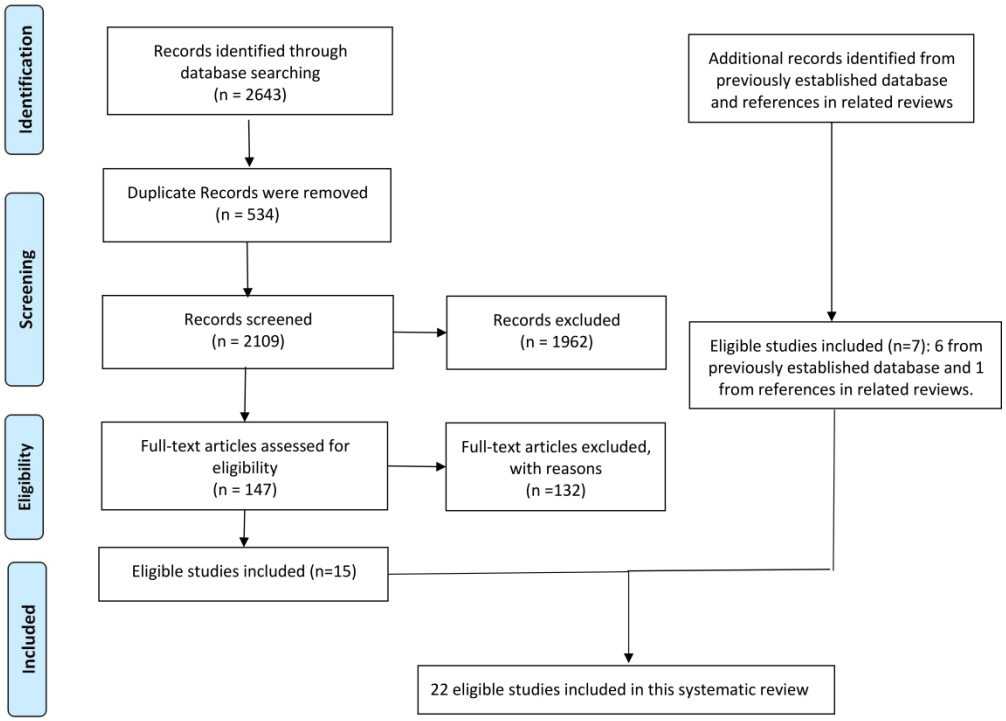

Figure 1 Flowchart for eligible studies identification according to PRISMA guidelines

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Database(s): OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	10562
2	"Quality of Life"/	165230
3	"outcome assessment".mp. or outcome assessment/ or treatment outcome/ or treatment failure/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	948610
4	exp pain/	361898
5	exp disease attributes/ or exp "signs and symptoms"/	2823288
6	or/2-5	3651696
7	1 and 6	5289
8	health status indicators/ or "severity of illness index"/ or sickness impact profile/ or interviews as topic/ or questionnaires/ or self report/	679871
9	Pain Measurement/	77822
10	patient satisfaction/ or patient preference/	80034
11	or/8-10	794501
12	7 and 11	2391
13	limit 12 to yr="1989 -Current"	2389
14	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	290843
15	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	1196557
16	pain????.mp.	693582
17	((activity or sever* or course) adj3 (disease or disabilit* or symptom*)).mp.	246717

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18	or/14-17	2160347
19	1 and 18	6305
20	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	7579315
21	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp.	183341
22	(patient? report* or patient? observ* or patient? satisf*).mp.	145747
23	anchor base??.mp.	513
24	or/20-23	7657299
25	19 and 24	5474
26	limit 25 to yr="1989 -Current"	5456
27	13 or 26	5548
28	shoulder.mp.	68799
29	shoulder impingement syndrome.mp.	1748
30	subacromial.mp.	2417
31	painful arc syndrome.mp.	10
32	supraspinatus syndrome.mp.	18
33	rotator cuff.mp.	11181
34	upper limb.mp.	16544
35	upper extremity.mp.	24219
36	exp shoulder/	11799
37	exp shoulder Impingement Syndrome/	1610
38	exp rotator Cuff/	5622
39	exp shoulder pain/	4199
40	exp shoulder joint/	17536
41	((should$ or rotator cuff) adj5 (bursitis or adhesive capsulitis or periarthr iti$ or frozen or impinge$ or tend?nitis or pain$)).tw.	20086
42	exp Upper Extremity/	154603
43	or/28-42	235079
44	limit 43 to yr="1989 -Current"	173628
45	Hawkins-Kennedy.mp.	31
46	("University of California Los Angeles shoulder rating scale" or UCLA).mp.	4559
47	("American Shoulder and Elbow Surgeon questionnaire" or ASES).mp.	1296
48	(Upper Extremity Functional Index or UEFI).mp.	39

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49	(Upper Extremity Functional Scale or UEFS).mp.	22
50	("American Shoulder and Elbow Surgeon questionnaire" or ASES).mp.	1296
51	(Penn Shoulder Score or PSS).mp.	8051
52	("Shoulder Pain and Disability Index" or SPADI).mp.	393
53	(Shoulder Disability Questionnaire or SDQ).mp.	1439
54	("Project on Research and Intervention in Monotonous work" or PRIM).mp.	426
55	(Neer score or NS).mp.	63982
56	(Constant Murley Score or CMS or constant score or CS).mp.	64167
57	(Watson-Sonnabend score or WSS).mp.	1467
58	(PainDETECT Numerical Rating Scale or PainDETECT).mp.	209
59	or/45-58	144686
60	limit 59 to yr="1989 -Current"	132969
61	(simple shoulder test or SST).mp.	4419
62	(Visual Analogue Scale or VAS).mp.	52312
63	(Short form or SF?36 or SF?12 or SF?8).mp.	28488
64	(EuroQol or EQ?5D).mp.	4612
65	15?D.mp.	1850
66	(Oxford shoulder score or OSS).mp.	2487
67	(RC-Quality Of Life or RC-QOL).mp.	14
68	(Western Ontario Rotator Cuff Index or WORC).mp.	150
69	("Disability of the Arm, Shoulder and Hand" or DASH).mp.	5639
70	(Medical outcomes study or MOS).mp.	10247
71	(Health Assessment Questionnaire or HAQ or HAQ?DI).mp.	4471
72	(Numerical Rating Scale or NRS).mp.	7528
73	(Numeric pain rating scales or NPRS).mp.	402
74	("Hospital Anxiety and Depression Score" or HADS).mp.	4327
75	or/61-74	115635
76	limit 75 to yr="2015 -Current"	35330
77	27 and 76	579
78	44 or 60	301674
79	27 and 78	393
80	77 or 79	900

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Database(s): **Embase** 1974 to 2018 August 10

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	16030
2	"Quality of Life"/	371636
3	"outcome assessment(health care)".mp. or treatment outcome/ or treatment failure/ [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	830270
4	exp pain/	1079551
5	exp disease course/ or exp "physical disease by body function "/	9191603
6	or/2-5	9628948
7	1 and 6	11859
8	health status indicators/ or "severity of illness index"/ or sickness impact profile/ or interviews/ or questionnaire/ or self report/	786093
9	Pain Measurement/	5221
10	patient satisfaction/ or patient preference/	125926
11	or/8-10	888283
12	7 and 11	2911
13	limit 12 to yr="1989 -Current"	2904
14	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	462977
15	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	1540053
16	pain????.mp.	1106808
17	((activity or sever* or course) adj3 (disease or disabilit* or symptom*)).mp.	1088931
18	or/14-17	3576012

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19	1 and 18	9705
20	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	9331391
21	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp.	242895
22	(patient? report* or patient? observ* or patient? satisf*).mp.	214735
23	anchor base??.mp.	694
24	or/20-23	9449030
25	19 and 24	8469
26	limit 25 to yr="1989 -Current"	8423
27	13 or 26	8714
28	shoulder.mp.	83119
29	shoulder impingement syndrome.mp.	2389
30	subacromial.mp.	2767
31	painful arc syndrome.mp.	17
32	supraspinatus syndrome.mp.	16
33	rotator cuff.mp.	13465
34	upper limb.mp.	26023
35	upper extremity.mp.	23277
36	exp shoulder/	55236
37	exp shoulder Impingement Syndrome/	2303
38	exp rotator Cuff/	6589
39	exp shoulder pain/	13048
40	exp shoulder joint/	55236
41	((should$ or rotator cuff) adj5 (bursitis or adhesive capsulitis or periarthr iti$ or frozen or impinge$ or tend?nitis or pain$)).tw.	25617
42	exp Upper Extremity/	247960
43	or/28-42	321155
44	limit 43 to yr="1989 -Current"	290504
45	Hawkins-Kennedy.mp.	46
46	(University of California Los Angeles shoulder rating scale or UCLA).mp.	6102
47	((American Shoulder and Elbow Surgeon questionnaire) or ASES).mp.	1600
48	(Upper Extremity Functional Index or UEFI).mp.	50
49	(Upper Extremity Functional Scale or UEFS).mp.	35

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50	((American Shoulder and Elbow Surgeon questionnaire) or ASES).mp.	1600
51	(Penn Shoulder Score or PSS).mp.	10814
52	((Shoulder Pain and Disability Index) or SPADI).mp.	555
53	(Shoulder Disability Questionnaire or SDQ).mp.	1990
54	((Project on Research and Intervention in Monotonous work) or PRIM).mp.	521
55	(Neer score or NS).mp.	85103
56	(Constant Murley Score or CMS or constant score or CS).mp.	82387
57	(Watson-Sonnabend score or WSS).mp.	1851
58	(PainDETECT Numerical Rating Scale or PainDETECT).mp.	357
59	or/45-58	189411
60	limit 59 to yr="1989 -Current"	177302
61	(simple shoulder test or SST).mp.	5180
62	(Visual Analogue Scale or VAS).mp.	76248
63	(Short form or SF?36 or SF?12 or SF?8).mp.	47823
64	(EuroQol or EQ?5D).mp.	7284
65	15?D.mp.	2744
66	(Oxford shoulder score or OSS).mp.	2838
67	(RC-Quality Of Life or RC-QOL).mp.	14
68	(Western Ontario Rotator Cuff Index or WORC).mp.	186
69	((Disability of the Arm, Shoulder and Hand) or DASH).mp.	5405
70	(Medical outcomes study or MOS).mp.	17455
71	(Health Assessment Questionnaire or HAQ or HAQ?DI).mp.	11808
72	(Numerical Rating Scale or NRS).mp.	10819
73	(Numeric pain rating scales or NPRS).mp.	640
74	((Hospital Anxiety and Depression Score) or HADS).mp.	9146
75	or/61-74	178346
76	limit 75 to yr="2015 -Current"	51547
77	27 and 76	937
78	44 or 60	460897
79	27 and 78	763
80	77 or 79	1600

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Database(s): **PsycINFO** 1987 to August Week 1 2018

Search Strategy:

#	Searches	Results
1	(clinical* important difference? or clinical* meaningful difference? or clinical* meaningful improvement? or clinical* relevant mean difference? or clinical* significant change? or clinical* significant difference? or clinical* important improvement? or clinical* meaningful change? or mcid or minim* clinical* important or minim* clinical* detectable or minim* clinical* significant or minim* detectable difference? or minim* important change? or minim* important difference? or smallest real difference? or subjectively significant difference?).tw.	2062
2	("Quality of Life" or "outcome assessment" or "treatment outcome" or "treatment failure" or pain or "disease attributes" or "signs and symptoms").mp.	157999
3	1 and 2	720
4	("health status indicators" or "severity of illness index" or "sickness impact profile" or "interviews" or questionnaires or "self report" or "pain measurement" or "patient satisfaction" or "patient preference").mp.	298303
5	3 and 4	185
6	limit 5 to yr="1989 -Current"	185
7	(quality of life or life 1atisfy??? or hrqol or hrql).mp.	67910
8	(assessment? Outcome? or measure? Outcome? or outcome? Studies or outcome? Study or outcome? Assessment? or outcome? management or outcome? measure* or outcome? research or patient? outcome? or research outcome? or studies outcome? or study outcome? or therap* outcome? or treatment outcome? or treatment failure?).mp.	89594
9	pain????.mp.	93558
10	(activity or sever* or course or (disease or disabilit* or symptom*)).mp.	1112369
11	or/7-10	1224703
12	1 and 11	1648
13	(questionnaire? or instrument? or interview? or inventor* or test??? or scale? or subscale? or survey? or index?? or indices or form? or score? or measurement?).mp.	1776162
14	(patient? rating? or subject* report? or subject* rating? or self report* or self evaluation? or self appraisal? or self assess* or self rating? or self rated).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	148082
15	(patient? report* or patient? observ* or patient? satisf*).mp.	14671
16	anchor base??.mp.	108

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17	or/13-16	1799670
18	12 and 17	1504
19	limit 18 to yr="1989 -Current"	1502
20	6 or 19	1502
21	(Shoulder or subacromial or "painful arc syndrome" or "supraspinatus syndrome" or "rotator cuff" or "upper limb" or "upper extremity").mp.	6818
22	limit 21 to yr="1989 -Current"	6778
23	("University of California Los Angeles shoulder rating scale" or UCLA or "Hawkins-Kennedy" or "American Shoulder and Elbow Surgeon questionnaire" or ASES or "Upper Extremity Functional Index" or UEFI or "Upper Extremity Functional Scale" or UEFS or "American Shoulder and Elbow Surgeon questionnaire" or ASES or "Penn Shoulder Score" or PSS or "Shoulder Pain and Disability Index" or SPADI or "Shoulder Disability Questionnaire" or SDQ or "Project on Research and Intervention in Monotonous work" or PRIM or "Neer score" or NS or "Constant Murley Score" or CMS or "constant score" or CS or "Watson-Sonnabend score" or WSS or "PainDETECT Numerical Rating Scale" or PainDETECT).mp.	18283
24	limit 23 to yr="1989 -Current"	17923
25	("simple shoulder test" or SST or "Visual Analogue Scale" or VAS or "Short form" or SF?36 or SF?12 or SF?8 or EuroQol or EQ?5D or15?D or "Oxford shoulder score" or OSS or "RC-Quality Of Life" or RC-QOL or "Western Ontario Rotator Cuff Index" or WORC or "Disability of the Arm, Shoulder and Hand" or DASH or "Medical outcomes study" or MOS or "Health Assessment Questionnaire" or HAQ or HAQ?DI or "Numerical Rating Scale" or NRS or "Numeric pain rating scales" or NPRS or "Hospital Anxiety and Depression Score" or HADS).mp.	49736
26	limit 25 to yr="2015 -Current"	15110
27	20 and 26	93
28	22 or 24	24612
29	20 and 28	55
30	27 or 29	143

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Appendix 2: Description of MIDs according to subgroups and the results of subgroup analysis

Table S1: Summary of all MIDs for improvement for interested PROs or instruments

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Absolute MIDs							
Constant score (0-100)	19	12.80	0.3	36	14.06	9.22	9.62 to 18.51
Simple shoulder text (SST) (0-100)	8	1.93	1.4	2.9	1.99	0.53	1.54 to 2.42
Pain VAS (overall) (0-10)	7	1.40	0.5	2.70	1.58	0.68	0.95 to 2.21
Pain VAS (Activity) (transfer to 0-10)	1	2.1					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	7	10.20	4.4	25.41	11.56	6.73	5.34 to 17.78
Oxford shoulder score (OSS) (0-48)	8	5.3	4	14.7	6.51	10.7	3.59 to 9.43
PNRS (0-10)	5	3.43	1.1	6.25	3.50	2.01	1.00 to 6.00
Quick DASH	1	13.4					
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
EQ-5D-3L	2; 2	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45	-0.51 to 0.64; 3.11 to 11.25
SF-12 (0-100)	3; 3	Physical: 2.04 Mental: 0.96	1.0; 0.86	2.44; 4.00	1.83; 1.94	0.74; 1.78	-0.02 to 3.67; -2.49 to 6.37
Relative MIDs							
Constant score (0-100)	2	18.6%	15.2%	22%	18.6%	4.8%	-24.60 to 61.8
Oxford shoulder score (OSS) (0-48)	1	11.10%					
Quick DASH	1	8%					

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Table S2: Summary of MIDs for improvement for interested PROs or instruments according to intervention administered during the study to measure the PRO or instrument

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Surgical intervention							
Absolute MIDs							
Constant score (0-100)	7	10.40	0.3	16.6	9.31	6.47	3.34 to 15.29
Simple shoulder text (STT) (0-100)	6	1.65	1.4	2.9	1.92	0.61	1.28 to 2.55
Pain VAS (overall) (0-10)	6	1.5	0.5	2.7	1.62	0.74	0.84 to 2.40
Pain VAS (Activity) (transfer to 0-10)	1	2.1					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	10.1					
Quick DASH	1	13.4					
Oxford shoulder score (OSS) (0-48)	1	6.9					
Non-surgical intervention							
Absolute MIDs							
Constant score (0-100)	10	16	5.1	30	15.99	7.74	10.45 to 21.53
Simple shoulder text (STT) (0-100)	2	2.19	2.05	2.33	2.19	0.20	0.41 to 3.97
Pain VAS (overall) (0-10)	1	1.37	One estimation				
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	3	10.2	4.4	25.41	13.34	10.85	-13.62 to 40.29
Oxford shoulder score (OSS) (0-48)	7	5	4	14.7	6.46	3.77	2.97 to 9.94
PNRS (0-10)	5	3.43	1.1	6.25	3.50	2.01	1 to 6
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
EQ-5D-3L	2; 2;	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45	-0.51 to 0.64; 3.11 to 11.25
SF-12	2; 2	Physical: 2.24; Mental: 0.91	2.04; 0.86	2.44; 0.96	2.24; 0.91	0.28; 0.07	-0.30 to 4.78; 0.27 to 1.55
Relative MIDs							
Constant score (0-100)	2	18.6%	15.2%	22.0%	18.6%	4.81	-24.6 to 61.8
Oxford shoulder	1	11.1%					

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score (OSS) (0-48)							
Quick DASH	1	8%					
Surgical or non-surgical intervention							
Absolute MIDs							
Constant score (0-100)	2	21.05	6.1	36.0	21.05	21.14	-169 to 211
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	2	9.55	6.7	12.4	9.55	4.03	-26.66 to 45.76
Quick DASH	1	13.4					
SF-12	1 1	Physical:1 Mental: 4					
Not report the intervention							
Absolute MIDs							
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	11.7					

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Table S3: Summary of MIDs for improvement for interested PROs or instruments using transit anchor according to follow-up period

Instrument/domain (score range)	Number of estimates	Median estimate	Minimum estimate	Maximum estimate	Mean	Standard deviation	95% CI
Less than 3 months							
Absolute MIDs							
Constant score (0-100)	1	11.60					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	1	25.1					
Oxford shoulder score (OSS) (0-48)	4	4.45	4	7	4.98	1.37	2.79 to 7.16
PNRS (0-10)	4	3.99	1.10	6.25	3.83	2.16	0.40 to 7.26
Neer score	3	1.99	1.51	3.73	2.41	1.17	-0.49 to 5.31
Relative MIDs							
Quick DASH	1	8%					
3 months or more							
Absolute MIDs							
Constant score (0-100)	18	13.9	0.3	36	14.20	9.47	9.49 to 18.91
Simple shoulder text (STT) (0-100)	8	1.93	1.4	2.9	1.99	0.53	1.54 to 2.43
Pain VAS (overall) (0-10)	7	1.4	0.5	2.7	1.58	0.68	0.95 to 2.21
Pain VAS (Activity) (transfer to 0-10)	1	2.10					
Pain VAS (at rest) (transfer to 0-10)	1	3.04					
Disabilities of the Arm, Shoulder and Hand (DASH) (0-100)	6	10.15	4.4	12.4	9.25	3.09	6.01 to 12.49
Oxford shoulder score (OSS) (0-48)	4	6.25	5	14.7	8.05	4.50	0.88 to 15.22
PNRS (0-10)	1	2.17					
Quick DASH	1	13.4					
EQ-5D-3L	2; 2	Raw: 0.07; VAS: 7.18	0.02; 6.86	0.11; 7.50	0.07; 7.18	0.06; 0.45;	-0.51 to 0.64; 3.11 to 11.25
SF-12 (0-100)	3 3	Physical: 2.04 Mental: 0.96	1.00; 0.86	2.44; 4.00	1.83; 1.94	0.74; 1.78	-0.02 to 3.67; -2.49 to 6.37
Relative MIDs							
Constant score (0-100)	2	18.6%	15.2%	22.0%	18.6%	4.81%	-24.6% to 61.8%
Oxford shoulder score (OSS) (0-48)	1	11.1%					

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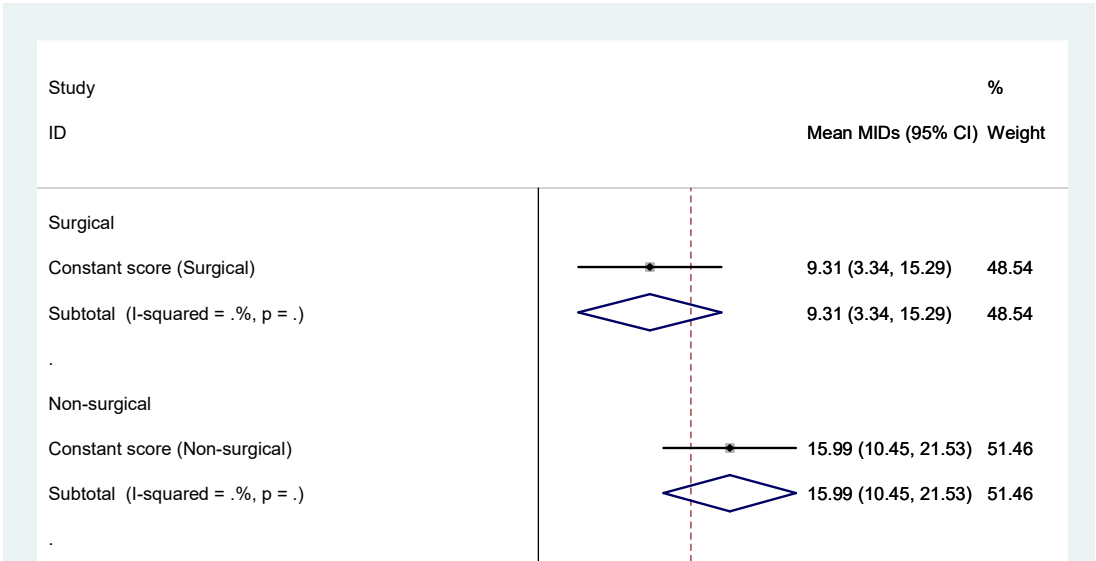

Figure S1: Subgroup analysis for Constant score by intervention type. MID, minimally important difference

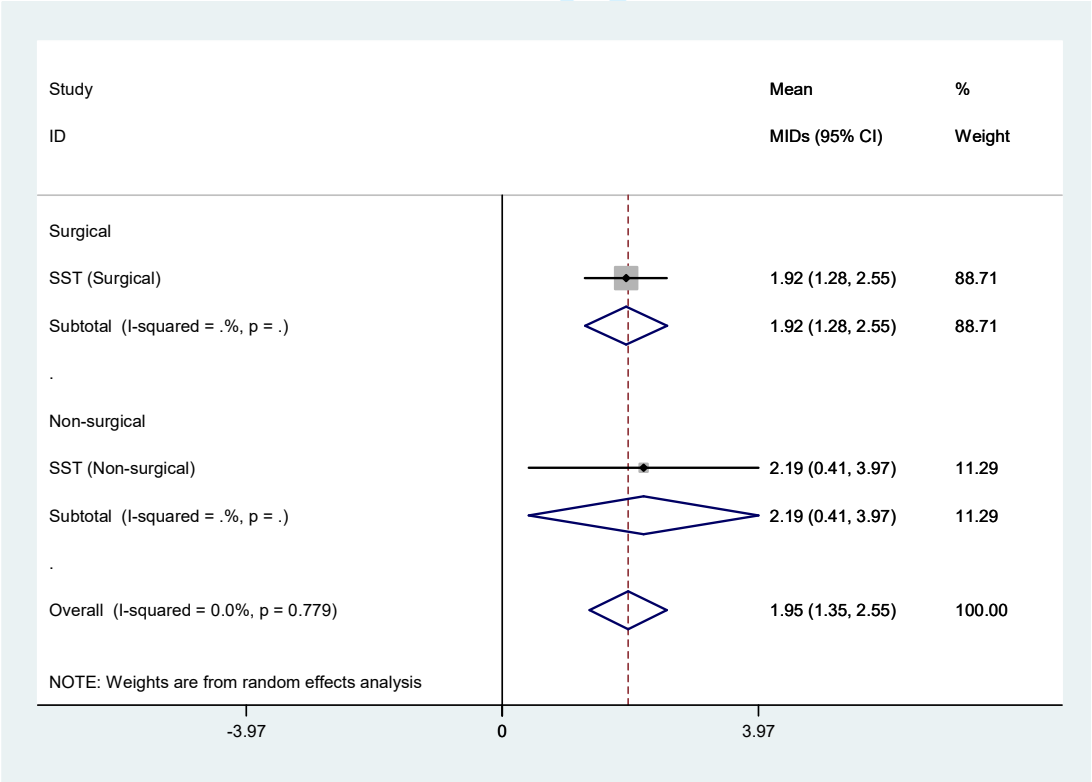

Figure S2: Subgroup analysis for SST by intervention type. MID, minimally important difference; SST: Simple Shoulder Test

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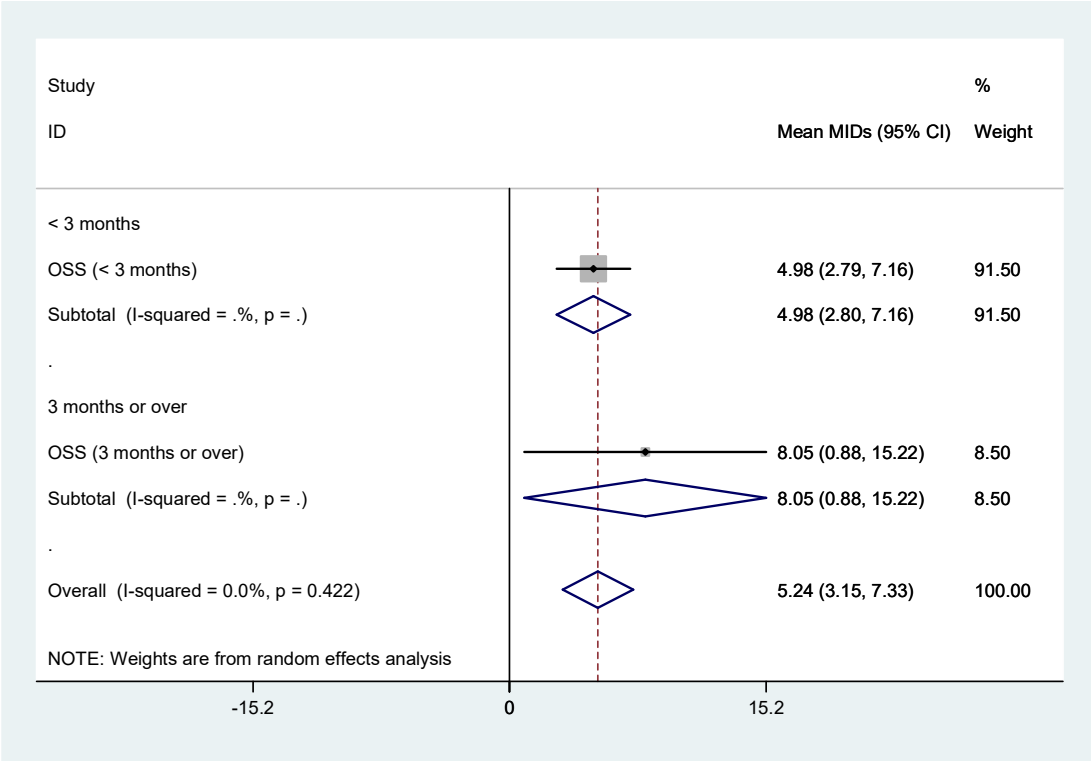

Figure S3: Subgroup analysis for OSS by follow-up time. MID, minimally important difference; OSS: Oxford Shoulder Score

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4-5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5-6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	5-6 and figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	6
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	6
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	7
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	7
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	8

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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