Patients with subacromial pain in primary care

Assessment and efficacy of
physiotherapy-guided exercise treatment

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**Assessment and efficacy of
physiotherapy-guided exercise treatment**

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Linköping 2021

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To Jona, Hanna and Moa!

If you can't explain it simply, you don't understand it well enough!

(Albert Einstein)

CONTENTS

ABSTRACT.....	1
SVENSK SAMMANFATTNING.....	3
LIST OF PAPERS.....	5
DESCRIPTION OF CONTRIBUTION	6
ABBREVIATIONS.....	7
BACKGROUND	9
Anatomy and biomechanics of the shoulder	9
Subacromial pain.....	10
<i>Pathogenesis and etiology of subacromial pain</i>	10
<i>Biomechanics of the shoulder in patients with subacromial pain</i>	11
Assessment of diagnosis and function	11
<i>Function according to the International Classification of Functioning, Disability and Health (ICF)</i>	11
<i>Assessment of patients with subacromial pain</i>	12
Outcome measurements.....	13
<i>Measurement properties</i>	13
Evidence based treatment for patients with subacromial pain	15
<i>Non-surgical treatment for subacromial pain</i>	15
Rationale of the thesis	16
AIMS OF THE THESIS.....	17
Overall aim	17
Specific aims.....	17
METHODS.....	19
Designs	19
Participants	23
<i>Study A - Papers I, II and IV</i>	23
<i>Study B - Papers II and III</i>	23
Clinical assessment	25
<i>Clinical tests for subacromial pain</i>	25

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

<i>Further clinical examination of the shoulder</i>	29
Measurements	31
<i>Shoulder function</i>	31
<i>Pain intensity</i>	32
<i>Health-related quality of life</i>	33
<i>Mental health</i>	33
<i>Perceived change in shoulder function</i>	34
Interventions	35
<i>All patients (Studies A and B)</i>	35
<i>Specific exercises (Studies A and B)</i>	35
<i>Active control exercises (Study A)</i>	36
Data analyses.....	36
<i>Paper I</i>	36
<i>Paper II</i>	37
<i>Paper III</i>	37
<i>Paper IV</i>	38
Ethical considerations	39
RESULTS	41
The DASH 7 (Studies A and B, Papers I and III)	41
<i>Development of DASH 7 (Study A, Paper I)</i>	41
<i>Responsiveness of DASH 7 and DASH 30 (Studies A and B, Papers I and III)</i>	43
Heterogeneity based on clinical presentation (Studies A and B, Paper II)	48
<i>Clinical presentation</i>	48
<i>Clinical presentation and association with self-reported measurements</i>	50
Effect of a specific exercise strategy (Study A, Paper IV).....	53
DISCUSSION	57
The DASH 7 questionnaire.....	57
<i>MIC for improvement in DASH 7</i>	58
<i>Usability of the DASH 7</i>	60
Heterogeneity based on clinical presentation.....	61

Efficacy of a specific exercise strategy.....	62
CONCLUSIONS	65
Clinical implications.....	66
Future research	67
ACKNOWLEDGEMENTS.....	69
REFERENCES	71

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ABSTRACT

Background: Shoulder pain is a common musculoskeletal disorder and 40-74% of the patients attending primary healthcare with a shoulder disorder are diagnosed with subacromial pain. Subacromial pain is characterized by restricted and painful movement of the arm that leads to difficulties in performing arm-related activities and often affects the quality of life profoundly, with respect to everyday function, work capacity, sleep quality and mental health. It is crucial that the measurements used to evaluate shoulder function and treatment response have acceptable psychometric properties and also that they are patients-specific and time-efficient to administer. For patients with subacromial pain, exercises are recommended as first-line treatment but consensus about which exercises and dosage to recommend has not been reached. The lack of evidence for one specific exercise model may be partly due to heterogeneity among this group of patients.

The overall aim of this thesis were to evaluate the efficacy of a previously tested exercise strategy for patients with subacromial pain in a primary care setting, to describe the heterogeneity with possible subcategories among patients with subacromial pain, and finally to validate and adjust the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire for more diagnosis-specific clinical assessment.

Methods: The four papers in this thesis are based on two clinical studies, one randomized controlled trial (RCT) and one clinical cohort. The participants in both studies were patients with subacromial pain attending physiotherapist (PT) in a primary care setting. Two of the papers are based on psychometric analyses, with evaluation of construct validity and responsiveness for the DASH when used to evaluate shoulder function in patients with subacromial pain, and also calculation of minimal important change (MIC) for a diagnosis-specific short version of DASH (DASH 7). A third paper describe clinical presentation in patients with subacromial pain, based on the components active range of motion (AROM), rotator cuff function and scapular kinematics and the fourth paper evaluated the efficacy of a 3-month specific exercise strategy in comparison to an active control strategy.

Results: Seven items from the original DASH were identified as being the most important in evaluating patients with subacromial pain (resulting in the DASH 7 questionnaire). The DASH 7 shows good responsiveness, can discriminate between patients who perceive themselves as improved and those who do not, and maintain a high level of internal consistency for the assessment of shoulder function in patients with subacromial pain, using only a quarter of the items of the original DASH. Based on clinical presentation, patients with subacromial pain in the primary care setting comprise a heterogeneous group. Rotator cuff dysfunction, defined as pain during resisted isometric muscle-testing, is very frequently present while limitation in active range of motion and scapular dyskinesia are less common. After three months of exercise, both groups in the RCT had significantly improved with no between group difference as measured with the primary CM-score. However, as measured with the DASH and the DASH 7, the patients in the specific exercise group was significantly more improved compared to those in the active control group.

Conclusions: The DASH 7 questionnaire is a short patient-reported outcome measurement (PROM) with good responsiveness, specific for patients with subacromial pain. Heterogeneity was confirmed with identified variability in AROM, rotator cuff function and scapular kinematics in clinical presentation which confirms that these components are important in the clinical examination of patients with subacromial pain. Shoulder function evaluated with the CM score did not improve to a significantly different degree between the two groups studied. The specific exercises might not be necessary for all patients in the primary care setting to achieve a clinically relevant improvement. However, the specific exercise strategy was significantly better when improvement was assessed by DASH and DASH 7, and this leads us to recommend this strategy, with its progressive loading of the rotator cuff muscles and scapula stabilizers, as first choice, provided that it is tolerated by the patient.

SVENSK SAMMANFATTNING

Bakgrund: Axelsmärta är ett vanligt problem i befolkningen och bland de som söker hjälp för sin axelsmärta inom primärvården är subacromial smärta den vanligaste diagnosen. Subacromial smärta karaktäriseras av smärta vid armaktivitet, främst vid aktivitet i och över axelhöjd samt bakom ryggen. Det är vanligt att denna smärta ger störd sömn och svårighet att utföra fritidsaktiviteter och dagligt arbete vilket kan bidra till försämrad psykisk hälsa och livskvalitet. Det är viktigt att kunna mäta och utvärdera skulderfunktion samt effekt av behandling på ett tillförlitligt sätt och att de instrument som används känns relevanta för patienten samt är tids-effektiva att administrera. Träning är den behandling som i första hand rekommenderas för patienter med subacromial smärta men det saknas fortfarande tydliga riktlinjer gällande vilka övningar och vilken dosering som är den bästa. En diskuterad anledning till att det är svårt att påvisa sådana riktlinjer kan vara att patientgruppen är heterogen.

Det **övergripande syftet** med den här avhandlingen var att utvärdera effekten av en specifik träningsstrategi för patienter med subacromial smärta i primärvård, att identifiera och beskriva variationen i klinisk presentation hos patienter med subacromial smärta samt att validera och justera självskattningsformuläret DASH för dignosspecifik bedömning.

Metoder: De fyra delarbeten som ingår i den här avhandlingen baseras på två kliniska studier. Samtliga studiedeltagare var patienter med subacromial smärta som sökte vård hos fysioterapeut inom primärvården i Östergötland. I två delarbeten analyseras mätgenskaper för självskattningsformulär, gällande validitet och responsiveness (förmåga att mäta förändring över tid) hos DASH för patienter med subacromial smärta samt gällande kliniskt relevant förändring hos den diagnosspecifika kortversionen, DASH 7. Ett tredje delarbete beskriver klinisk presentation hos patienterna utifrån komponenterna aktiv rörlighet, muskelfunktion i rotatorkuff samt skulderbladets rörelsemönster och det fjärde delarbetet utvärderar effekten av en specifik träningsstrategi jämfört med en aktiv kontrollstrategi för patienter med subacromial smärta i primärvård.

Resultat: Sju av de ursprungliga 30 frågorna i DASH identifierades som de viktigaste för att utvärdera skulderfunktion hos patienter med subacromial smärta (vilket resulterade i ett nytt självskattningsformulär,

DASH 7). DASH 7 uppvisar god responsivens och kan skilja mellan de patienter som upplever sig förbättrade och de som inte gör det, samt bibehåller hög intern konsistens för bedömning av skulderfunktion hos patienter med subacromial smärta, med endast en fjärdedel av frågorna från DASH. Baserat på klinisk presentation, konstateras att patienter med subacromial smärta i primärvård är en heterogen grupp. Störd funktion i rotatorcuffens muskulatur, definierat som smärta vid isometriska muskeltester, är vanligt förekommande medan inskränkt aktiv rörlighet och stort rörelsemönster i skulderbladet förekommer mer sällan. Efter tre månaders träning uppvisar patienterna i båda träningsgrupperna en signifikant förbättring i skulderfunktion. Gällande funktion mätt med utvärderingsinstrumentet CM ses ingen skillnad i effekt mellan träningsgrupperna. Däremot, när skulderfunktion utvärderas med DASH och DASH 7, ses att patienterna i den specifika träningsgruppen förbättrats signifikant mer jämfört med patienterna i den aktiva kontrollgruppen.

Konklusioner: DASH 7 är ett kort självskattningsformulär med god förmåga att mäta förändring över tid, specifikt utformat för patienter med subacromial smärta. Heterogenitet konstateras baserat på variationen i klinisk presentation gällande de tre komponenterna: aktiv rörlighet, muskelfunktion i rotatorcuff samt skulderbladets rörelsemönster, vilket visar på att dessa komponenter är viktiga i bedömningen av patienter med subacromial smärta. Förändrad skulderfunktion, utvärderat med CM, visar ingen skillnad i effekt mellan de två träningsgrupperna som testats. Den specifika träningen verkar därmed inte behövas för alla patienter med subacromial smärta i primärvård för att uppnå en kliniskt relevant förbättring. Utvärdering av skulderfunktion med DASH och DASH 7 däremot visar att patienterna i den specifika träningsgruppen blivit signifikant bättre jämfört med de i den aktiva kontrollgruppen. Baserat på dessa resultat rekommenderar vi den specifika träningsstrategin som förstahandsval vid behandling av subacromial smärta, förutsatt att patienten tolererar den belastade träningen för rotatorcuff- och skulderbladsmuskulatur.

LIST OF PAPERS

- I. **Nordqvist J**, Johansson K, Holmgren T, Adolfsson L, Öberg B.
A short activity-related scale for measuring shoulder function in patients with subacromial pain: the DASH 7.
JSES Open Access. 2017;1(2):113-118. Published 2017 May 25.
doi:10.1016/j.jses.2017.04.001
- II. **Nordqvist J**, Öberg B, Adolfsson L, Holmgren T, Johansson K.
Heterogeneity among patients with subacromial pain – variabilities within clinical presentation and its impact on daily life.
Accepted for publication in Physiotherapy, pre-proof print version available doi:10.1016/j.physio.2020.10.001
- III. **Nordqvist J**, Holmgren T, Adolfsson L, Öberg B, Johansson K.
The minimal important change of the DASH 7 questionnaire – assessing shoulder function specific for patients with subacromial pain.
Manuscript submitted to JSES
- IV. **Nordqvist J**, Öberg B, Adolfsson L, Holmgren T, Johansson K.
A specific exercise strategy versus an active control strategy in patients with subacromial pain attending primary care - a randomized controlled trial. *Manuscript*

DESCRIPTION OF CONTRIBUTION

Paper I

Study Design:	Jenny Nordqvist , Birgitta Öberg, Lars Adolfsson, Theresa Holmgren, Kajsa Johansson
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ABBREVIATIONS

AROM	Active range of motion
CM-score	Constant Murley score
DASH	Disability of the arm, shoulder and hand questionnaire
ES	Effect size
EQ5D	EuroQol 5 dimensions
EQVAS	EuroQol visual analogue scale
HAD	Hospital anxiety and depression scale
HR-PRO	Health related-patient reported outcome
ICF	International classification of functioning, disability and health
IQR	Inter quartile range
MDT	Minimal detectable change
MIC	Minimal important change
NRS	Numeric rating scale
PGIC	Patient global impression of change
PROM	Patient reported outcome measurement
PSFS	Patient specific functional scale
PT	Physiotherapist
RCT	Randomized controlled trial
ROM	Range of motion
RTM	Regression to the mean
SD	Standard deviation
SEM	Standard error of measurement
VAS	Visual analogue scale

BACKGROUND

Anatomy and biomechanics of the shoulder

The shoulder joint and its function are a compromise between mobility and stability. The extensive mobility is based on the construction of the glenohumeral joint and the simultaneous motion in all joints of the shoulder girdle (the scapulothoracic, acromioclavicular and sternoclavicular joints). The stability is mainly based on active muscle control by the rotator cuff (the supraspinatus, infraspinatus, teres minor and subscapularis muscles) and the scapular stabilizers (primarily the serratus anterior, trapezius and rhomboideus muscles).^{6, 97, 165} Individual rotator cuff muscles have independent actions as primary and secondary movers of the glenohumeral joint, and together they contribute to the overall stability by centralizing the humeral head into the glenoid.^{6, 66, 97} Weakness and/or a disturbed pattern of activation in the rotator cuff muscles can contribute to a decreased ability of this centralization during arm activity, and can result in migration of the humeral head in a cranial direction.^{97, 122} The independent actions of the scapulothoracic muscles create scapular movement in different directions but one, serratus anterior, are the most important for stabilizing the scapula against the thoracic wall.^{66, 97} During normal elevation of the arm, the scapula moves in three dimensions: upward rotation, posterior tilt, and internal or external rotation, depending on the plane of elevation (abduction or flexion). At the end of range, however, some external rotation occurs independently of elevation plane.^{79, 104, 162} Weakness and/or a disturbed pattern of activation in the scapula stabilizers can lead to a decrease in the ability to stabilize and position the scapula during arm activity, which can be recognized as a disturbance in the humero-scapular rhythm.^{16, 96, 97, 115} Good stability of the scapula within the appropriate position has an impact on the biomechanics of the scapula and the orientation of the glenoid, and is a prerequisite for the optimal function of the rotator cuff muscles during arm activity.^{16, 79, 115}

Figure 1 Anatomy of the shoulder with a posterior and an anterior view of the soft tissue structures in the subacromial space. Picture printed with permission from iStock/medicalstocks

Subacromial pain

Many terms are used to describe subacromial pain and related pathology; “subacromial impingement syndrome”, “rotator cuff tendinopathy”, “rotator cuff syndrome” and “subacromial bursitis” ^{92, 133, 162}. The term used in this thesis is “Subacromial pain” and refers to all pathologies of the subacromial space soft tissue. The “subacromial space” is defined as the space between the coraco-acromial arch and the humeral head ^{13, 162}. In arm movement, especially movement above shoulder level, the humeral head with its tubercles approaches the acromion, which narrows the subacromial space and introduces the risk of impinging the subacromial soft tissue structures. Subacromial pain is characterized by restricted and painful movement of the arm that leads to difficulties in performing arm-related activities.

Shoulder pain is the third most common musculoskeletal disorder among the general population, and often affects the quality of life profoundly, with respect to everyday function, work capacity ^{44, 98}, sleep quality ^{112, 155}, and mental health ⁶⁰. About 40-74% of the patients who attend primary healthcare with a shoulder disorder are diagnosed with subacromial pain ^{73, 118, 164}.

Pathogenesis and etiology of subacromial pain

The pathogenesis of subacromial pain is not clear, although it is known that the etiology is multifactorial ^{13, 136, 138, 162}. Subacromial space soft tissues that may be involved in subacromial pain are the rotator cuff tendons, the subacromial bursa, the acromion, the coraco-acromial ligament, and the long tendon of the biceps brachii ^{13, 104, 136, 138}, see Figure 1. The rotator cuff

tendons and the subacromial bursa are considered to be the most commonly involved structures⁹¹.

Impingement is commonly described as occurring in one of two locations: external or internal. External impingement is related to the bursal side of the rotator cuff tendons, while internal impingement relates to the articular side of the tendons^{43, 136}. Both extrinsic factors (also known as “extratendinous” factors, causing compression in the subacromial space) and intrinsic factors (“intratendinous”, associated with degeneration) may be involved in the pathogenesis of subacromial pain^{43, 100, 136, 162}.

Biomechanics of the shoulder in patients with subacromial pain

A disturbed activation pattern of the scapula stabilizers is often found in patients with subacromial pain^{16, 18, 25, 77, 94, 105, 145, 159}. Patients with subacromial pain have less scapular movement (upward rotation, posterior tilt and external rotation) during arm elevation than healthy controls^{147, 159, 160, 162}. The difference may be the result of several mechanisms, including deficient scapular and rotator cuff muscle performance^{14, 18, 94, 105}, posterior capsule tightness^{39, 86, 162}, shortening of the pectoralis minor^{111, 166, 172} and an increase of thoracic spine flexion^{86, 95, 119, 162}. It is not clear whether the altered scapular kinematics is a cause or a consequence of the pain.

Assessment of diagnosis and function

Function according to the International Classification of Functioning, Disability and Health (ICF)

The International Classification of Functioning, Disability and Health (ICF) is a framework defined by the World Health Organisation (WHO) to measure health and disability at both individual and population levels¹⁷¹. The ICF is based on a biopsychosocial model and is divided into one list of “Body structure and function” and another list of “Activity and Participation”. In interpreting this ICF terminology, “function” can be measured in the component Body structure and function (impairments), and in the components Activity (activity limitations) and Participation (participation restrictions). Pain and a limited range of motion or muscle function are examples of isolated functions that, according to the ICF, are classified as “impairments”, while difficulty washing the hair or placing something on a high shelf is classified as “activity limitations”. A limited ability to play tennis can be interpreted both as an activity limitation and as a participation restriction. The term “disability” is used as an umbrella

term for impairments, activity limitations and participation restrictions. Further, these factors interact with environmental and personal factors ¹⁷¹.

Assessment of patients with subacromial pain

The assessment of a painful shoulder normally includes the patient's description of symptoms and function, and a clinical examination of the shoulder. The latter includes clinical tests to identify the cause of the pain. Algorithms and flow charts are available ^{83, 91, 117} to guide clinicians in a clinical examination of a painful shoulder, but the structural cause of the symptoms may be difficult to identify. It is important to use clinical tests with high sensitivity and specificity, where high sensitivity ensures accurate identification of true positives, and high specificity ensures accurate identification of true negatives. The clinical tests for subacromial pain are relatively sensitive but less specific. Thus, when classifying shoulder pain as subacromial, it is recommended to use a cluster set of clinical tests that reproduce the patient's symptoms ^{33, 52, 56, 57, 107}.

The clinical presentation of subacromial pain is characterized by reduced strength in abduction ²¹, external ^{21, 38} and internal ³⁸ rotation, a limited range of motion in abduction ²¹, and a non-optimal activation pattern of the muscles in the shoulder girdle, known as "scapular dyskinesia" ^{16, 25, 94}. Patients with subacromial pain are known as a heterogenous group, but knowledge of the range of functional limitations in the clinical presentation is scarce. Better understanding of this heterogeneity is of great importance for the clinical reasoning process which might lead to optimized management with individualized treatment protocols.

Additional techniques in the assessment of subacromial pain

The diagnosis of subacromial pain is primarily clinical but advances in imaging techniques have given clinicians an increased understanding of the pathological process. Examination by ultrasound is a justifiable and cost-effective technique to detect tears in the rotator cuff muscles or the biceps tendon, and to assess the status of the subacromial bursa and the magnitude of the subacromial space ⁷⁰. Injection of local anaesthetic into the subacromial space (the Neer impingement test) ¹¹⁴ can be used to clarify the diagnosis when patient history and clinical examination do not provide sufficient clarity ⁵. Due to their high costs and limited access in the primary care setting, these additional assessments are recommended primarily for patients who do not respond to first-line treatment. Conventional radiography can be used to detect degenerative changes in the skeletal structures of the shoulder joints (primarily the glenohumeral joint and the

acromioclavicular joint), with MRI scans being reserved for more complex cases.

Outcome measurements

The ICF does not list a core set for the assessment of shoulder pain, but a biopsychosocial approach is recommended with measurements that cover all aspects of function (body structure and function, activity and participation) relevant to the individual patient or to the group of patients in focus ¹⁴⁰.

Patient-reported outcome measurements (PROMs) are commonly used to determine patients' response to treatment, both in intervention studies and in clinical practice. These instruments quantify patients' self-reported function, disability, and health ^{139, 163} and can be used to improve patient-clinician communication ^{46, 163}. To maximize patient interest, participation, and goal setting, it is important that the PROMs include items that are relevant to the patient, while demonstrating sensitivity to change over time for a specific group of patients. When the work described in this thesis was being planned, most PROM scores used to assess shoulder function had been applied to broad, heterogeneous groups of patients, and few valid and specific PROMs were available in Swedish to assess shoulder function in patients who experienced pain and disability due to subacromial pathology.

A measure known as the "minimal important change" (MIC) is commonly used to interpret a score change in a PROM. Many different terms are used for this measure, for example "minimal clinical important difference (MCID)", "minimal important difference (MID)", and "subjectively significant difference (SSD)" ^{41, 81}. The MIC is defined as "the smallest change in score in the construct to be measured which the patients perceive as important" ³².

Patients' perception of function in activity and participation may differ from objectively measured function. Several studies have reported on the relationship between self-reported measures and objective measures, and shown that the correlation is, at best, moderate ^{21, 61, 65, 75, 93}, and thus it is valuable to use objective measurements together with PROMs, to catch the full picture of the patients' level of function.

Measurement properties

Given the negative impact and high frequency of shoulder pain, it is crucial that the measurements used to evaluate shoulder function and treatment response have acceptable psychometric properties ¹⁵⁶. A group

known as the COSMIN group (CONsensus-based STANDards for the selection of health MEasurement INSTRUMENTs) has reached an international consensus on the taxonomy, terminology, and definitions of the measurement properties of health-related PROMs ¹⁰⁹. The COSMIN group categorises measurement properties into three quality domains: *reliability, validity and responsiveness* ¹⁰⁹.

Reliability

Reliability is defined as “the degree to which the measurement is free from measurement error” and consists of three measurement properties: *reliability, internal consistency* and *measurement error* ¹⁰⁹. The measurement property *reliability* is defined as “the proportion of the total variance in the measurements which is because of true differences among patients” , *internal consistency* is defined as “the degree of the interrelatedness among the items”, and *measurement error* is defined as “the systematic and random error of a patient’s score that is not attributed to true changes in the construct to be measured” ¹⁰⁹.

Validity

Validity is defined as “the degree to which a health-related patient-reported outcome (HR-PRO) instrument measures the construct(s) it purports to measure” and consists of three measurement properties: *content validity, construct validity, and criterion validity*. *Content validity* is defined as “the degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured” and includes the aspect of measurement property called face validity. *Construct validity* is defined as “the degree to which the scores of an HR-PRO instrument are consistent with hypotheses based on the assumption that the HR-PRO instrument validly measures the construct to be measured”, and includes the aspects structural validity, hypothesis testing, and cross-cultural validity. *Criterion validity* is defined as “the degree to which the scores of an HR-PRO instrument are an adequate reflection of a gold standard” ¹⁰⁹.

Responsiveness

Responsiveness is defined as “the ability of an HR-PRO instrument to detect change over time in the construct to be measured” and consists of only one measurement property: responsiveness ¹⁰⁹.

Evidence based treatment for patients with subacromial pain

Research supports non-surgical treatment as the first choice for patients with subacromial pain, where physiotherapy-guided exercises seem effective to reduce pain and improve shoulder function ^{1, 53, 62}. An active treatment policy has been reported to reduce the risk of developing longstanding pain ¹⁴⁶. Surgery may be considered for patients who do not respond to non-surgical treatment, with standard arthroscopic subacromial decompression/acromioplasty as the most favoured option ^{35, 36}.

Non-surgical treatment for subacromial pain

Several systematic reviews and meta-analyses have examined the effectiveness of non-surgical interventions for patients with subacromial pain ^{36, 49, 54, 85, 116, 142}. Due to the low quality of many of the randomized controlled trials (RCTs) included and difficulty in comparing the results due to methodological differences, the findings are inconclusive as to whether a single intervention is more effective than another.

Most studies support exercise as first-line treatment to improve shoulder function and decrease pain ^{35, 36, 49, 54, 85, 116, 142}, while some suggest that exercise is more effective when combined with other therapies such as kinesiotaping ^{36, 142}, acupuncture ³⁶, extracorporeal shockwave therapy ¹⁴², laser therapy ^{116, 142}, manual therapy ^{54, 85, 116, 142}, and corticoid injection ³⁶.

Exercises as first-line treatment

Several RCTs have evaluated exercise interventions for patients with subacromial pain, but consensus about which exercises and dosage to recommend has not been reached ^{1, 33, 45, 49, 87, 137}. The lack of evidence for one specific exercise model may be partly due to heterogeneity among the patients included in the studies.

Exercise intervention may be effective by improving strength and endurance in the rotator cuff muscles and scapula stabilizers. Interventions often also address flexibility in the posterior shoulder and the teres minor muscle. These are important factors reported to ensure centralization of the humeral head and normal scapular kinematics, which lower the risk of impinging the soft tissue structures in the subacromial space. Several deficiencies have been reported to occur in patients with subacromial pain, including disturbed timing of the activation pattern for the middle and lower trapezius ^{24, 105, 145}, increased activity in the upper trapezius ^{23, 94, 105, 145}, lower protraction strength ²⁵ and a decrease in serratus anterior activity

^{17, 95, 145}. It can also be hypothesized that the exercise intervention address the intrinsic factor, the tendon degeneration, with mechanical loading of the tendon reported essential to facilitate healing ^{2, 80, 168}, since tendinopathy is often part of the etiology in subacromial pain.

Our research team has shown that a specific exercise strategy is effective in reducing pain and improving shoulder function in patients with persistent subacromial pain who are waiting for surgery ⁶². The exercise strategy included daily exercises with external loading to increase strength and endurance in the rotator cuff muscles and the scapula stabilizers, and there is a need to explore whether this strategy is as effective for patients in a primary care setting as for those awaiting surgery.

Rationale of the thesis

As stated above, previous work supports the use of exercise as first-line treatment for patients with subacromial pain, but more knowledge is needed to guide clinical practice. Many RCTs have been performed in an orthopedic setting, and more studies are needed in a primary care setting. One question, for example, is whether the strategy successfully used for patients waiting for surgery is as effective for those in primary care. This is important, since primary care is the first level of rehabilitation for patients with subacromial pain, and the patient group here is more heterogeneous than in secondary care. Further, it is necessary to increase the understanding of the nature of heterogeneity among these patients and, if possible, identify subvariabilities in clinical presentation. Such information will provide valuable knowledge to support the clinical reasoning process.

In addition, further evaluation and development of PROMs optimized for this common group of patients who frequently attend primary care are needed. Such measurements should be time-efficient, easy to administer and feasible both in a clinical and in a research context. The use of valid and reliable PROMs will add valuable tools to the clinical reasoning process and in this way optimize the assessment, management, and treatment of patients with subacromial pain.

AIMS OF THE THESIS

Overall aim

The overall aim of this thesis were to evaluate the efficacy of a previously tested exercise strategy for patients with subacromial pain in a primary care setting, to describe the heterogeneity with possible subcategories among patients with subacromial pain, and finally to validate and adjust the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire for more diagnosis-specific clinical assessment.

Specific aims

- To assess the content validity of DASH for patients with subacromial pain by comparing DASH with the Patient-Specific Functional Scale (PSFS), and to test responsiveness to a modified set of DASH items tailored to these patients.
- To describe heterogeneity and differentiate possible subcategories among patients with subacromial pain based on clinical presentation.
- To determine the minimal important change (MIC) in the score of the DASH 7 questionnaire for patients with subacromial pain after three months of exercise intervention in a primary care setting.
- To compare the effects of a 3-month specific exercise strategy with the effects of an active control strategy on shoulder function and pain in the primary care setting for patients with subacromial pain.

METHODS

Designs

The four papers in this thesis are based on two clinical studies. An overview of the four papers (I-IV) included in this thesis are presented in Table 1.

In 2012, our research team reported successful results from an RCT that had evaluated the effect of a specific exercise strategy as intervention for patients with longstanding subacromial pain who were waiting for surgery. These results strongly supported this specific exercise strategy as intervention for this group of patients, with the result that most patients no longer needed surgery⁶². The research team went on to design and conduct two clinical studies (one starting in 2011 and the other in 2015) to explore whether the same exercise strategy is as successful for patients with subacromial pain in a primary care setting. This thesis is based on data from these two studies, which are further described below.

Study A was a clinical RCT that aimed to evaluate the effects of a specific exercise strategy and compare it with those of an active control strategy for patients with subacromial pain in primary care. Study design are described in Figure 2. The sample size, 46 participants per group, was calculated to give significant results for the primary outcome at three months. This study was an RCT with a single assessor and participant-blinded design. Patients were blinded to the scientific hypothesis, while the research physiotherapist (PT) was blinded to the treatment given. All patients attending the three months follow up were invited to an ultrasound examination, primarily aiming to detect possible rotator cuff tears. Data from Study A are used in Papers I, II and IV.

Study B was a clinical cohort extracted from a larger unpublished study that aimed to implement the specific exercise strategy from the earlier RCT⁶² as first line treatment for patients with subacromial pain in primary care. Thus, only the methods used to collect and examine the data from the clinical cohort are described here, see study design in Figure 3. Data from Study B are used in Papers II and III.

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

Figure 2 Design of Study A, the randomized controlled trial including patients with subacromial pain in primary care. CM score = Constant Murley score, DASH 7 = Disability of the Arm, Shoulder and Hand, a 7-item version specific for patients with subacromial pain, DASH = Disability of the Arm, Shoulder and Hand, original 30-item version evaluating upper extremity function, VAS = Visual analogue scale, PSFS = Patient specific functional scale, EQ5D = EuroQol 5 dimensions, EQVAS = EuroQol Visual Analogue Scale, HAD scale = Hospital Anxiety and Depression Scale, PGIC = Patient global impression of change scale

Figure 3 Design of Study B, the clinical cohort of patients with subacromial pain in primary care. DASH = Disability of the Arm, Shoulder and Hand, original 30-item version evaluating upper extremity function, DASH 7 = Disability of the Arm, Shoulder and Hand, a 7-item version specific for patients with subacromial pain, VAS = Visual analogue scale, EQ5D = EuroQol 5 dimensions, EQVAS = EuroQol Visual Analogue Scale, HAD scale = Hospital Anxiety and Depression Scale, PGIC = Patient global impression of change scale

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

Table 1. Overview of the two Studies (A and B) and the four Papers (I-IV) included in this thesis

Design	Study A		Study A and B	Study B
	Paper I	Paper IV	Paper II	Paper III
	Psychometric study	RCT	Descriptive study	Psychometric study
Participants	Patients, 30-67 years old, with subacromial pain seeking physiotherapy in a primary care setting			
Number of participants	n = 127	n = 164	n = 164	n = 70
Time for recruitment	Between September 2011 and January 2015, and between November 2018 and February 2020			
	January 2015 and September 2017			
Follow ups	At 3, 6 and 12 months after inclusion			
Aim	To assess the content validity of DASH for patients with subacromial pain by comparing DASH with the PSFS, and to test responsiveness to a modified set of DASH items tailored to these patients.	To compare the effect of a 3-month specific exercise strategy with an active control strategy on shoulder function and pain in a primary care setting for patients with subacromial pain.	To describe and differentiate subcategories, if any, among patients with subacromial pain based on clinical presentation to better understand heterogeneity.	To determine the minimal important change (MIC) in the DASH 7 questionnaire for patients with subacromial pain after a three-month exercise intervention in a primary care context.
Methods	A three-step process to assess the content validity of DASH for patients with subacromial pain by comparison with the PSFS, with item match performed by five PTs. Further, responsiveness was tested against a modified set of DASH items tailored to these patients.	A single-assessor blinded design for comparison of the effects of a 3-month specific exercise strategy with those of an active control strategy, focusing on shoulder function and pain.	A description of clinical presentation in patients with subacromial pain, based on the components AROM, rotator cuff function and scapular kinesis.	Calculations of the minimal important change (MIC) for the DASH 7 questionnaire, using the anchor-based MIC-distribution method.
Data analysis	Descriptive statistics and test for internal consistency (Cronbach's alpha) and responsiveness (effect size according to Cohen's d).	Descriptive statistics, group comparison with chi squared test and independent sample t-test.	Descriptive statistics, phi correlation coefficient and univariate analysis of variance (normally distributed data), or a Kruskal-Wallis H-test (non-normally distributed data) to analyze correlations.	Descriptive statistics, Spearman correlation coefficient and ROC analyses for calculations of MIC.
Ethical approval	Ref. no.: 2011/320-31	Ref. nos.: 2011/320-31 and 2018/445-32	Ref. nos.: 2011/320-31 and 2014/343-31 with additional approval: 2017/492-32	Ref. no.: 2014/343-31 with additional approval: 2017/492-32

Participants

Study A - Papers I, II and IV

The patients were recruited when seeking PT care for shoulder pain at a large Swedish primary healthcare unit, with 33 full-time PTs in the county of Östergötland, Sweden. Patients were eligible if they described a duration of subacromial pain, defined as pain located at the lateral upper arm, especially during elevation, of more than two weeks, with positive results for three out of the following four clinical tests: impingement sign according to Neer ¹¹³, impingement test according to Hawkins-Kennedy ⁵⁵, the Patte maneuver ⁸⁹, and the Jobe supraspinatus test ⁶⁸. A further inclusion criterion was age 30-67 years, where the lower age limit was set to exclude patients with secondary impingement related to hypermobility and the upper age limit to include participants who were in employment, and exclude patients with serious degenerative disease. Table 2 lists the exclusion criteria. All patients were recruited by the same PT. Table 3 gives the baseline characteristics, while Figure 4 gives an overview of the participants in each paper.

Study B - Papers II and III

The patients were recruited when seeking PT care for shoulder pain at any one of the thirteen participating primary healthcare units in the county of Östergötland, Sweden. The same eligibility criteria were used as those in Study A, with the exception that no criteria for the duration of pain were applied. However, the duration had been longer than two weeks for all patients at the time of inclusion in the study. A further inclusion criterion was positive signs for three out of five clinical tests, with painful arc ⁷⁶ being added to the four tests used in Study A. Table 2 lists the exclusion criteria. Inclusion was performed by PTs who had participated in a one-day pre-study training session designed for the study. Table 3 gives the baseline characteristics, and Figure 4 gives an overview of participants in each paper.

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

Figure 4 Flow chart showing an overview of the participants in Study A and Study B, and their involvement in Papers I-IV

Table 2. Inclusion and exclusion criteria for Study A and Study B, with differences between the studies in bold text

Study A	Study B
Inclusion criteria	
<ul style="list-style-type: none"> ✓ Age 30-67 years ✓ Pain location lateral upper arm ✓ Duration of pain > 2 weeks ✓ At least 3 positive test results from the following: <ul style="list-style-type: none"> • Neer impingement sign • Hawkins-Kennedy impingement test • Jobe supraspinatus test • Patte manouver 	<ul style="list-style-type: none"> ✓ Age 30-67 years ✓ Pain location lateral upper arm ✓ At least 3 positive test results from the following: <ul style="list-style-type: none"> • Neer impingement sign • Hawkins-Kennedy impingement test • Jobe supraspinatus test • Patte manouver • Painful arc
Exclusion criteria	
<p>Verified by clinical assessment:</p> <ul style="list-style-type: none"> • frozen shoulder • instability in any joint in the shoulder girdle • symptoms from the cervical spine • polyarthritis, rheumatoid arthritis or fibromyalgia • inability to understand spoken and written Swedish <p>Patient-reported:</p> <ul style="list-style-type: none"> • malignancy • osteoarthritis in the glenohumeral joint • acromioclavicular arthritis • previous fractures in the shoulder girdle 	

Table 3. Baseline characteristics for the participants in Studies A and B

Baseline characteristics	Participants in Studies A and B (n=296)	Participants in Study A (n=164)	Participants in Study B (n=132)
Individual factors			
Age in years: mean (SD)	52 (9)	52 (9)	52 (10)
Sex: % female	60	60	60
Pain duration: % 0-3 months	40	38	43
Affected shoulder: % right	53	53	53
Bilateral shoulder pain: % yes	10	12	7
Work load ^a : % heavy	33	33	33
On sick leave ^b : % yes	8	9	7
Self-reported measurements			
DASH 7 ^d mean (SD)	46.1 (19.3)	44.5 (18.9)	48.5 (19.8)
DASH ^e mean (SD)	32.2 (14.4)	31 (14.2)	33.6 (14.4)
VAS ^f at rest: median (IQR)	10 (30)	8 (25)	20 (50)
VAS ^f at night: median (IQR)	50 (47)	50 (40)	50 (50)
VAS ^f in activity: mean (SD)	72.3 (19.5)	74 (18.7)	69.1 (20.8)
HADS ^g anxiety: median (IQR)	3 (4)	3 (4)	3 (5)
HADS ^g depression: median (IQR)	1 (2)	1 (2)	1 (2)
EQ-5D ^h index mean (SD)	0.64 (0.21)	0.65 (0.24)	0.62 (0.16)
EQ-VAS ⁱ mean (SD)	70.7 (17.3)	71 (17.9)	70 (16.6)

^aWorkload was defined as heavy if arm activity was performed mainly above the horizontal plane, ^bSick leave was self-reported by the patient, ^cVisual analogue scale (0 = no pain, 100 = highest imaginable pain), ^dDisability of the Arm, Shoulder and Hand, a 7-item version specific for patients with subacromial pain (0 = no difficulty, 100 = severe disability), ^eDisability of the Arm, Shoulder and Hand, original 30-item version evaluating upper extremity function (0 = no difficulty, 100 = severe disability), ^fHospital Anxiety and Depression Scale, (0-7 = normal, >10 abnormal) ^hEuroQol 5 Dimensions (scores range from less than 0 to 1, 0 = a health state equivalent to death, negative values = worse than death, 1 = perfect health), ⁱEuroQol Visual Analogue Scale (0 = the worst health you can imagine, 100 = the best health you can imagine).

Clinical assessment

Clinical tests for subacromial pain

We used several clinical tests to diagnose subacromial pain in the patients included in Studies A and B. These clinical tests are relatively sensitive when used individually, while the specificity is poorer. Thus, we used a cluster set of tests to ensure diagnostic accuracy ^{52, 56, 57, 107}. Three or more positive tests confirm the diagnosis of subacromial pain, while fewer than three rules it out ^{56, 57, 107}. The clinical tests used to determine inclusion in Studies A and B are described below.

Hawkins-Kennedy impingement test

The patient is in a seated position. The examiner places one hand on the patient's scapula and applies a downward force to the acromion to minimize movement of the scapula. The examiner positions the patient's arm at 90 degrees of elevation and the elbow at 90 degrees of flexion, and then forcibly internally rotates the shoulder to its end of range, see Figure 5. The result is positive if the patient's pain reoccurs during the procedure⁵⁵. The sensitivity of this test is 63-92%, and its specificity 25-89%^{11, 57} for the detection of subacromial impingement.

Figure 5 Hawkins-Kennedy impingement test

Neer impingement sign

The patient is in a seated position with the arm relaxed and hanging alongside the thorax. The examiner internally rotates the patient's shoulder and then forcibly performs a passive elevation of the arm in slight abduction with one hand, while the other hand applies a downward pressure onto the acromion to minimize movement of the scapula, see Figure 6. The result is positive if the patient's pain reoccurs during the procedure ¹¹⁴. The sensitivity of this test is 54-89%, and its specificity 10-95% ^{11, 57} for the detection of subacromial impingement.

Figure 6 Neer impingement sign

Jobe supraspinatus test

The examiner positions the patient's arms at 90 degrees of elevation in the scapular plane and internally rotates the shoulders (the "empty can" position). The patient is instructed to maintain this position while the examiner applies a downward force to the patient's distal forearms, see Figure 7. The result is positive if the patient's pain reoccurs, with or without weakness, during the procedure ⁶⁸. When pain is defined as positive test response, the sensitivity of the test is 52-63%, and its specificity 33-55%. When weakness is defined as positive test response, the sensitivity is 50-95% and specificity 65-87% ^{11, 57} for the identification of the patient's pain as being subacromial pain.

Figure 7 Jobe supraspinatus test

Pattes manouever

The patient is in a seated position. The examiner positions the patient's arm at 90 degrees of elevation and the elbow at 90 degrees of flexion, and then internally rotates the shoulder to its end of range. The examiner applies a downward force to the scapula and supports the patient's arm at the elbow with one hand/forearm and uses the other hand to apply a downward force to the patient's wrist, see Figure 8. The patient is instructed to externally rotate the shoulder against the examiner's force on the wrist. The result is positive if the patient's pain reoccurs, with or without weakness, during the procedure⁸⁹. The sensitivity of this test is 58-79%, and its specificity is 60-67%^{11, 57} for identification of subacromial pain.

Painful arc

The patient externally rotates the shoulder and then performs an active abduction, see Figure 9. The result is positive if the patient's pain reoccurs within the range of 60-120 degrees of abduction⁷⁶. The sensitivity of this test is 32-97%, and its specificity is 10-80%^{11, 57} for the detection of subacromial impingement.

Figure 8 Pattes manouever

Figure 9 Painful arc

Further clinical examination of the shoulder

In both Study A and Study B, the first visit to the PT included for all patients a standard clinical examination of the painful shoulder. This examination included, for example, assessment of shoulder range of motion (ROM), shoulder muscle function and scapular movement. Paper II presents a subcategorization of the patients, based on some components in their clinical presentation at baseline. These components from the examination are described below.

Active range of motion (AROM)

Determination of AROM included examination of flexion, abduction and external rotation in the shoulder, and was performed with the patient standing. AROM was defined as limited when the PT found that the range of motion of the affected shoulder was lower than that of the opposite shoulder. When bilateral shoulder symptoms were present, AROM was defined as limited when it was lower than reference values^{99, 148}. AROM was measured with a handheld goniometer.

Rotator cuff function

Rotator cuff function was assessed by examination of resisted isometric testing in two positions. Abduction was tested in approximately 30 degrees of abduction while external and internal rotation were tested with the elbow flexed to 90 degrees and the upper arm alongside the thorax. Abduction was intended to primarily test the supraspinatus, external rotation the infraspinatus and teres minor, and internal rotation the subscapularis. The resisted isometric testing was performed bilaterally with the patient sitting with both feet on the floor. Manual resistance was applied by the PT at the patient's distal forearms, with the patients' wrists and hands at neutral rotation. Rotator cuff dysfunction was defined as present if pain occurred during testing.

Scapular kinematics

Scapular kinematics were assessed with the patient in standing position using the classification of Kibler et al. (2002)⁷⁸. Type IV is defined in this classification as normal scapular kinesia, while types I-III are defined as scapular dyskinesia (see Figure 10). Scapular dyskinesia type I is present if the angulus inferior is winged from the thorax when the arm is alongside the thorax in a relaxed position. Type II is present if the medial border of the scapula is winged from the thorax when the patient leans on straight arms, with the shoulder at 90 degrees of flexion, with hands against the wall. Type III is present if the superior border of the scapula migrates cranially during active arm elevation. These types of scapular dyskinesia may be present individually or in combination⁷⁸.

Figure 10 Scapular dyskinesia Type I-III according to Kibler et al (2002)
Photos printed with permission from Kajsa Johansson

Measurements

Table 4 presents an overview of the measurements used in each paper.

Shoulder function

Shoulder function was measured with both objective and self-reported measurements and included all three components according to the ICF (Body structure and function, Activity and Participation).

Constant Murley (CM) score

The CM score at 3 months' follow up was chosen as a primary outcome in Study A, due to a decision by the European Society for Surgery of the Shoulder and Elbow that this score should be used in all peer-reviewed papers⁸². The CM score measures shoulder function and pain, and includes both subjective and objective measurements (Appendix I)²². The scoring is from 0-100, where 0 represents the "worst possible shoulder function with severe pain" and 100 represents the "best possible shoulder function and no pain". The CM score has a high test-retest reliability ($ICC = 0.8-0.96$)¹³⁰ and intertester reliability ($r = 0.90$)¹²⁷. Its construct validity is comparable to that of the Shoulder Pain and Disability Index (SPADI) ($r = 0.82$) and DASH ($r = 0.76-0.82$)³. Recently, Vrotsou et al. (2018)¹⁶⁷ have criticized the use of the CM score as a gold standard in shoulder evaluation, while accepting its usefulness for assessing subacromial pathology¹⁶⁷.

Disabilities of the Arm, Shoulder and Hand questionnaire (DASH)

The original DASH has 30 items and measures upper extremity function (with a certain focus on activity and participation as defined by the ICF) and pain. It is a self-assessed questionnaire to be completed by the patient. The original DASH will here be referred to as "DASH 30". It scores 30 activities and symptoms from 0-100, where 0 represents "no pain or

dysfunction” and 100 represents “severe pain and dysfunction” (Appendix II)⁶⁴. DASH 30 is reliable, valid and responsive for patients with shoulder pain^{8, 14, 143, 149}, and specifically reported with a test-retest reliability of 0.89, Cronbach alpha of 0.93, a construct validity to Shoulder Pain and Disability index (SPADI) of 0.75⁵¹ and a good responsiveness¹³¹ for patients with subacromial pain. DASH 30 is one of the most commonly used PROMs among clinicians and researchers to measure outcome in shoulder patients¹²².

DASH 7

DASH 7 was developed during the work presented in Paper I and used to measure shoulder function in the work presented in Papers II-IV. It is an activity-related 7-item short version of DASH, developed for patients with subacromial pain (Swedish version in Appendix III, English version in Appendix IV). Paper I shows that the effect size (Cohen’s *d*) for DASH 7 is 0.93, and its Cronbach alpha is 0.84, showing high internal consistency. Paper III shows that the MIC for improvement is 6.5 points.

Patient-Specific Functional Scale (PSFS)

The ability to perform self-chosen activities were measured with the Patient-Specific Functional Scale (PSFS), in which each activity is rated by the patient on a scale from 0-10, where 0 represents “impossible to perform the activity” and 10 represents “no problem in performing the activity, normal function”¹⁴⁴. The patients were asked to identify two or three important activities that they found impossible or difficult to perform as a consequence of the shoulder pain. The PSFS is a reliable, valid and responsive instrument for patients with shoulder pain⁸⁴. PSFS have been reported with an effect size (ES) of 0.7-0.9¹³², an area under the curve (AUC) of 0.67-0.76^{84, 132}, and a MIC of 1.29-2.0 points^{84, 132} with a sensitivity of 71% and specificity of 0.67¹³².

Pain intensity

The patients were asked to rate their pain intensity during provocative activities, at night, and at rest during the previous week using unidimensional pain scales. The VAS and the NRS are strongly correlated ($r=0.86-0.93$) when assessing pain intensity^{88, 129, 158}.

Visual analogue scale (VAS)

The VAS is the most frequently used instrument used to measure pain intensity¹²⁴. This scale, used in Study A, is a horizontal line with the end

points 0 and 100, where 0 represents “no pain” and 100 represents “worst imaginable pain”¹⁵. The VAS has a high internal consistency¹⁵¹ and an adequate validity¹⁵⁸, and a MIC of 1.4 points reported for patients with shoulder disorder¹⁵².

Numeric rating scale (NRS)

The NRS was used in Study B. It is a numerical rating scale from 0-10, where 0 represents “no pain” and 10 represents “worst imaginable pain”. The NRS has adequate reliability¹⁶⁹ and validity^{42, 169}, and good responsiveness⁴².

Health-related quality of life

The EQ-5D and EQVAS are commonly used to assess health-related quality of life in patients with shoulder disorders, but investigations of the measurement properties are rare. However, Grobet et al. (2018) conclude in a recent systematic review that the reliability and validity are good, while the responsiveness is moderate in patients with upper extremity conditions⁴⁸.

EuroQol 5 dimensions (EQ5D) three levels and five levels

The EQ-5D three levels¹²³ was used in Study A and the EQ-5D five levels⁵⁸ was used in Study B. The score for the EQ-5D is an index from 1 to -0.59, where -0.59 represents the “lowest health-related quality of life” and 1 represents the “highest health-related quality of life”¹²³.

EuroQol visual analogue scale (EQVAS)

The EQVAS is a vertical line from 0-100, where 0 represents “worst imaginable health state” and 100 represents “best imaginable health state”¹²³.

Mental health

The purpose with the assessment of mental health was primarily to screen for state of anxiety and depression.

Hospital Anxiety and Depression scale (HAD)

The HAD scale was used to determine the state of anxiety and depression of patients. Anxiety and depression are scored separately in two parts using two scales from 0-21 points, where a score of 7 or less on a part represents “absence of anxiety/depression”; a score at 8-10 represents

doubtful cases; and a score at 11 or more represents “presence of anxiety/depression”¹⁷⁴. The internal consistency and the test-retest reliability for the subscales in the HAD scale are high, and the validity is adequate¹².

Table 4. Description of measurements used in Papers I-IV

Measurements		Paper I	Paper II	Paper III	Paper IV
Shoulder function	CM-score				X
	DASH	X	X		X
	DASH 7		X	X	X
	PSFS	X			X
Pain intensity	VAS		X ^a		X
	NRS		X ^b		
Health-related quality of life	EQ-5D 3L		X ^a		X
	EQ-5D 5L		X ^b		
	EQVAS		X		X
Perceived change in shoulder disability	PGIC			X	X
Mental health	HAD scale		X		X

CM score, Constant Murley score; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; DASH 7, short form of DASH specific for patients with subacromial pain; PSFS, Patient-Specific Functional Scale; VAS, Visual analogue scale for pain; NRS, Numerical rating scale for pain; EQ-5D 3L, EuroQol 5 dimensions, three levels; EQ-5D 5L, EuroQol 5 dimensions, five levels; EQVAS, EuroQol visual analogue scale; PGIC, Perceived Global Impression of Change scale; HAD Scale, Hospital Anxiety and Depression scale; ^aused in Study A; ^bused in Study B

Perceived change in shoulder function

The patients perceived change was assessed at each follow-up (at 3-, 6- and 12 months follow-up)

Patient Global Impression of Change (PGIC)

- 7 point Lickert scale
- 5-point Lickert scale

The PGIC was used to measure how patients perceived that shoulder function and symptoms changed during the time in the study. The PGIC 7-point Likert scale was used in Study A. It has a rating scale from 0-7, where 0 represents “no difference or worse” and 7 represents “much better”⁶⁷. The PGIC 5-point Likert scale⁶² was used in Study B. It has a rating scale from 1-5, where 1 represents “worse” and 5 represents “recovered”. The global assessment scales have been criticized in that a

patient's ability to remember accurately an earlier state of health has been questioned^{134, 135}. Other researchers consider the scales to be valid, since they give a score that is uniquely relevant to the patient^{50, 67, 71, 72}.

Interventions

All patients (Studies A and B)

The PT gave patients information about subacromial pain, advice about ergonomics and daily activities, and recommended corrections in their posture. The patients were informed about the purpose of the exercises and how to perform them. Each patient tested every exercise under the guidance of the PT, in order to reach an optimal performance. All exercises were home-based, and the patients were instructed to perform the exercises once to twice daily for 12 weeks and make daily notes in an exercise diary. Patients received exercise instruction in a first visit of duration approximately 60 minutes, and attended a further five visits of duration approximately 30 minutes during the 12-week exercise period (once every second week) for guidance and instruction in progression of the exercises.

Specific exercises (Studies A and B)

All patients in Study B received the specific exercises, while patients randomized to the specific exercise arm received them in Study A. These exercises focused on increasing the strength and endurance of the rotator cuff muscles and the scapula stabilizers. A package of six exercises was used: five exercises with external loading (two for the supraspinatus and infraspinatus/teres minor, and three for the trapezius middle and lower part, rhomboideus, and serratus anterior), and one exercise without external loading for posterior shoulder flexibility (Appendix V). These exercises have been described in the report from an earlier study⁶². The external load was adjusted for each patient according to the Oddvar Holten diagram⁴⁷ selecting a resistance at which the patient could barely perform 20-25 repetitions. This resistance was then used for 10-15 repetitions in three sets. The progression of load and complexity of each exercise was based on both time and performance. A patient must achieve an exercise performance with high motor control and experience no negative symptoms related to the relevant exercise before progression was allowed. Whether to progress the exercises was assessed regularly at visits to the PT during the 12 weeks. Elastic rubber bands and dumbbells were used for external loading. The patients were instructed to use a pain monitoring model (Figure 11) during exercise that ranged from 0-10, where 0 represented "no pain" and 10 represented "worst possible pain"¹⁵⁷. If pain

that exceeded 5 on the rating scale was experienced, the patient was instructed not to progress^{62, 101}. A minimum compliance criterion was daily exercise during more than ten of the twelve weeks of intervention. Patients with limited range of movement could be given manual mobilization aimed at stretching the posterior structures of the glenohumeral joint by the treating PT.

Figure 11 The pain monitoring model used to handle pain provoked during the exercises¹⁵⁷

Active control exercises (Study A)

The active control group in the RCT study (Paper IV) received exercises aiming at mobility and circulation in the neck and shoulder. Six exercises were given: shoulder abduction in the frontal plane, shoulder retraction, shoulder elevation, neck retraction, and stretching of the upper trapezius and the pectoralis major (Appendix VI). Stretching of the pectoralis major was introduced and added to the program after about 6 weeks of exercise. Each movement exercise was to be repeated 10 times in one set, and the stretch position in two stretch exercises was to be maintained for 20 seconds and repeated 2 times. All to be repeated twice daily. Patients were told that none of the exercises should increase pain, and no equipment was needed except for a wall when stretching the pectoralis major.

Data analyses

Paper I

DASH⁶⁴ was validated by comparison with PSFS¹⁴⁴ activities. The validation process was performed in three steps.

Step 1: DASH items were matched to PSFS activities by five PTs, who independently selected corresponding DASH items for each PSFS activity. If a PT found more than one corresponding DASH item, the item that corresponded most closely was denoted no. 1. All five PTs were experienced in working with patients with subacromial pain, and with administering DASH and the PSFS.

Step 2: A consensus between PTs in matching DASH items to PSFS activities was used to reach a final decision about which DASH item best corresponded to each PSFS activity. Either one or two DASH items were matched to each PSFS activity.

Step 3: DASH items of particular importance to the patient were determined from the distribution of DASH items that matched PSFS activities. Based on this distribution, a cutoff level that included as many patients with corresponding PSFS activities as possible, but with a minimal amount of DASH items, was chosen.

Paper II

Descriptive statistics were used to describe baseline characteristics and the presence of AROM, rotator cuff function and scapular kinematics. Correlations within and between the three components were analyzed by calculating phi correlation coefficients, while a univariate analysis of variance (normally distributed data) or a Kruskal-Wallis H-test (non-normally distributed data) was used to determine correlations between each of the three components and scores on the VAS, DASH 7, HADs, EQ-5D and EQVAS. Statistically significant correlations ($p < 0.05$) were further analysed with Bonferroni-corrected pairwise comparisons. The IBM SPSS Statistics for Windows package, Version 24.0. Armonk, NY: IBM Corp. was used for all statistical calculations.

Paper III

Descriptive statistics of the baseline characteristics were calculated (Table 3). The baseline characteristics of completers and non-completers at the 3-month follow up were compared using the independent samples *t*-test (for normally distributed continuous variables), the Mann Whitney U-test (for non-normally distributed continuous variables), and the chi squared value for categorical data.

The anchor-based MIC distribution method was used to determine the MIC, according to COSMIN guidelines. These include both an anchor-based approach and a distribution-based approach ³⁰. The PGIC was dichotomized into “importantly improved” (large improvement/recovered) and “not importantly improved” (small improvement/unchanged/worse), and used as the external criterion to determine the optimal anchor in the receiver operating characteristic (ROC) curve. Patients who reported deterioration in their condition were excluded from these analyses. The anchor was defined as the point on the ROC curve nearest the upper left corner, which represents the lowest number of erroneously classified patients, with the highest level of sensitivity and

specificity. The sensitivity reflects the proportion of patients correctly classified as importantly improved, while specificity reflects the proportion of patients correctly classified as not importantly improved by the DASH 7 score.

Two values of MIC were calculated. The first was MIC_{ROC}, which is the optimal cut-off point of the ROC curve, at which sensitivity and specificity are equally weighted and the percentage of erroneous classifications is lowest, and the second was MIC_{95% limit}, which is the 95% limit cut-off point (based on the distribution of patients who reported not importantly improved on the external criterion and corresponds to 95% specificity)³⁰. The MIC_{95% limit} was calculated by the formula: $\text{Mean}_{\text{change}} + 1.645 * \text{SD}_{\text{change}}$ for the group of patients classified as “not importantly improved”³⁰. The area under the ROC curve (AUC) was used to measure the ability to discriminate between the two groups (importantly improved/not importantly improved) according to the anchor. A value of AUC greater than 0.70 is adequate¹⁵⁶.

Spearman’s rho was used to determine the correlation between the change in score on the DASH 7 questionnaire and the anchor, where a correlation coefficient of 0.5 or higher is adequate³⁰. The individual changes in the DASH 7 score, from baseline to the 3-month follow up, were compared to the PGIC for all patients and plotted according to the external criterion (PGIC) (Figure 12).

Paper IV

Patient characteristics and outcome scores at baseline for the two intervention groups were analysed using descriptive statistics, Pearson chi squared values, and an independent samples *t*-test, as were dropout analyses. The Kolmogorov-Smirnov test was used to determine whether the data were normally distributed. An independent samples *t*-test was used to compare outcome score change from baseline to the 3-month follow up between the two groups. The scale was dichotomized into “improved” (scale level 6-7) and “not improved” (scale level 1-5) and the Pearson chi squared test was used to compare perceived change in the PGIC between the groups.

Ethical considerations

The studies were performed in accordance with the ethical principles for medical research established by the Declaration of Helsinki. All participants provided written informed consent to participate prior to inclusion. The studies were approved by the Swedish Ethical Review Authority in Linköping (Reference numbers are given in Table 1).

All data were anonymized and stored in a fire-safe security locker at Linköping University in order to fulfil the requirements of data protection regulations for the storage of personal information. Only coded data was discussed among the researchers.

RESULTS

The DASH 7 (Studies A and B, Papers I and III)

After matching commonly reported patient-specific activities to the original 30-item DASH ⁶⁴, seven DASH items were identified as being the most important in evaluating patients with subacromial pain. The resulting questionnaire was given the name “DASH 7”. It is able to detect change over time to the same high degree as DASH 30, using only a quarter of the items, while maintaining a high level of internal consistency for the assessment of shoulder function in patients with subacromial pain. The DASH 7 questionnaire can discriminate between patients who perceive themselves as improved and those who do not.

Development of DASH 7 (Study A, Paper I)

Results of the validation process of DASH 30

Step 1: Matching DASH items to PSFS activities for patients with subacromial pain

A total of 271 PSFS activities were recorded and listed from 127 patients who had chosen PSFS activities at baseline. Ninety patients (70.9%) chose three PSFS activities, thirty-five (27.6%) chose two, and two (1.6%) chose one PSFS activity. Nineteen of the items in DASH 30 were identified as corresponding to one or more of the 271 PSFS activities, with eleven DASH items left unmatched to any PSFS activity (Table 5).

Step 2: Agreement between physiotherapists in matching DASH items to PSFS activities

The total agreement among the five PTs was almost 80 percent when identifying the one or two DASH items that best corresponded to each PSFS activity. The PTs were unable to correlate 13 PSFS activities to any of the DASH items, and these were therefore excluded from further analysis. Nine further PSFS activities were excluded because all the physiotherapists had selected different DASH items as matches. An additional four PSFS activities were excluded following the failure of two or more physiotherapists to select a DASH item corresponding to that PSFS activity (Table 6).

Table 5. Distribution of DASH items corresponding to patients' PSFS activities, given as the percentage of patients with corresponding PSFS activities

Item in DASH	Activity or task	Percentage of patients with PSFS activity corresponding to DASH item
1	"Open a jar"	0
2	"Write"	2.3
3	"Turn a key"	0
4	"Prepare a meal"	0
5	"Push open a heavy door"	2.3
6	"Place object on high shelf"	23.8
7	"Do heavy household chores"	17.5
8	"Garden"	6.2
9	"Make a bed"	2.3
10	"Carry a shopping bag"	9.5
11	"Carry a heavy object"	11.7
12	"Change a lightbulb overhead"	3.1
13	"Wash your hair"	13.6
14	"Wash your back"	15.9
15	"Put on a sweater"	43.2
16	"Use a knife to cut food"	0
17	"Recreational activities requiring little effort"	7
18	"Recreational activities in which you take some force through your arm"	38.7
19	"Recreational activities with arm freely moved"	13.7
20	"Manage transportation needs"	5.4
21	"Sexual activities"	0
22	"Shoulder problem interfering with social activities"	2.3
23	"Limitation in work"	27.4
24	"Shoulder pain"	0
25	"Shoulder pain in specific activity"	0
26	"Tingling in arm"	0
27	"Weakness in arm"	0
28	"Stiffness in shoulder"	0
29	"Difficulty sleeping"	24.6
30	"Feeling less capable or confident"	0

DASH scores range from 1 to 5, where 1 = "no difficulty" and 5 = "severe difficulty/unable". Abbreviations. DASH: Disability of the Arm, Shoulder, and Hand questionnaire; PSFS: Patient-Specific Functional Scale. The most commonly matched DASH items are highlighted with colored fields and bold text.

Table 6. PSFS activities excluded from further analysis because all PTs selected different corresponding DASH items, or because two or more of the five PTs could not select a DASH item as corresponding to the PSFS activity

PSFS activities where all the physiotherapists selected different matching DASH items	PSFS activities for which two or more of the five physiotherapists could not select a corresponding DASH item
<ul style="list-style-type: none"> ➤ Push a shopping trolley ➤ Paint/wallpaper ➤ Dress/undress the kids ➤ Dry the table ➤ Add wood to the fireplace ➤ Rapid arm movements ➤ Turn off the lamp by the sofa ➤ Close the car door ➤ Open and close a shutter 	<ul style="list-style-type: none"> ➤ Get dressed/pull up pants ➤ Get out of bed ➤ Crawl under a machine ➤ Put on a car seat belt

Step 3: DASH items of particular importance to patients with subacromial pain

Seven DASH items were identified when a cut-off level of 15% was used for which 122 patients of the 127 (96.1%) had at least one corresponding DASH item represented. The results showed that 23.6%, 49.6%, and 22.9% of the patients had DASH items corresponding to one, two, or three of their PSFS activities, respectively. Cut-off levels of 10% and 20% gave 11 and 5 DASH items, respectively, with 123 and 113 patients, respectively, having corresponding DASH items.

The 15% cut-off level allowed seven important activity-related DASH items to be identified (see bolded items in Table 5), when assessing shoulder function in patients with subacromial pain. Appendices III and IV present the final version of the DASH 7 questionnaire in Swedish and English.

Responsiveness of DASH 7 and DASH 30 (Studies A and B, Papers I and III)

Effect size and internal consistency (Study A, Paper I)

Effect size calculations according to Cohen's *d* demonstrated that both DASH 7 and DASH 30 lie within the range of "a large effect" ¹⁵⁰ (Table 7). Cronbach alphas for DASH 7 and DASH 30 were 0.84 and 0.94, respectively.

Table 7. Responsiveness of the DASH 7 and the DASH 30 questionnaires

	DASH 7 (n = 83)	DASH 30 (n = 83)
Mean score change (SD) 0-3 months	19.41 (20.13)	13.59 (14.32)
Mean score change (SD) in group that rated PGIC as better/much better (n = 40)	28.24 (19.9)	19.81 (14.3)
Mean score change (SD) in group that rated PGIC as slightly better/unchanged/worse (n = 43)	11.2 (16.74)	7.8 (11.81)
Effect size (Cohen's <i>d</i>)	0.93	0.92

MIC for improvement in DASH 7 (Study B, Paper III)

Table 8 presents baseline characteristics for the patients included (n = 70) and those excluded (n = 51).

At the 3-month follow up, 74% of the included patients reported in their PGIC that they were recovered or largely improved, while 26% reported little improvement or no change in their shoulder condition. No patient reported deterioration (Table 9). Table 9 presents PGIC values, and Table 10 DASH 7 scores.

The correlation coefficient between the external criterion (PGIC) and the score change in DASH 7 was 0.67, which was sufficient (>0.5) for further analysis³⁰.

The MIC_{ROC} for improvement lay at a mean change of 6.5 points in the DASH 7 score (Figure 12) with a sensitivity of 0.98 (98%) and a specificity of 0.78 (78%) (Figure 13). This indicates that the shoulder function of a patient who reports a positive score change of 7 points in the DASH 7 questionnaire has been “importantly improved”, with a 24% risk of erroneous classification. Fifty-four of 70 patients (77%) reached this MIC_{ROC} value as their DASH 7 score change at the 3-month follow up. No patient reported being “worse” in their PGIC, which made it impossible to calculate the MIC_{ROC} for deterioration.

Table 8. Baseline characteristics, a comparison of included and excluded patients in Study B

Patient characteristics	Completers (n=70)	Non-completers (n=51)	P value
Age in years, mean (SD)	52.9 (9.7)	50.6 (9.8)	<i>t</i> -test 0.204
Duration of pain in months, mean (SD)	2.5 (0.7)	2.5 (0.7)	<i>t</i> -test 0.969
Women, n (%)	39 (56)	34 (67)	Chi ² 0.224
Heavy load occupation ¹ , n (%)	24 (34)	9 (18)	Chi ² 0.068
Expectations of treatment: recovery, n (%)	59 (84)	43 (84)	Chi ² 0.68
Corticoid injection before start, n (%)	12 (17)	5 (10)	Chi ² 0.31
HAD ² Anxiety, mean (SD)	3.6 (3.1)	4.2 (3.7)	<i>t</i> -test 0.39
HAD ² Depression, mean (SD)	1.7 (1.8)	2.5 (2.5)	<i>t</i> -test 0.053
VAS ³ at rest	19.8 (21)	35.8 (24.9)	<i>t</i>-test 0.002
VAS ³ in activity	68.8 (19.9)	69.7 (22.8)	<i>t</i> -test 0.86
VAS ³ at night	44.9 (28.5)	47 (36.1)	<i>t</i> -test 0.77
DASH ⁴ 30	33.4 (14.2)	34.5 (15.3)	<i>t</i> -test 0.70
DASH 7	48.5 (18.3)	48 (22.1)	<i>t</i> -test 0.90
EQ-5D index ⁵	0.633 (0.148)	0.589 (0.180)	<i>t</i> -test 0.15
EQ VAS ⁶	70.9 (16.6)	68.6 (16.5)	<i>t</i> -test 0.45

¹Heavy load is defined as minimum 50 percent of working hours with arms at or above shoulder height, ² HAD – Hospital Anxiety and Depression scale, ³ VAS – Visual analogue scale, ⁴ DASH – the Disability of the Arm, Shoulder and Hand questionnaire, ⁵ DASH 7 – a short version of the DASH developed for patients with subacromial pain, ⁶ EQ-5D – the EuroQol 5 Dimensions index, ⁷ the EuroQol Visual analogue scale.

The MIC_{95% limit} for improvement lay at a mean change of 25.7 points calculated according to $-4.134 + 1.645 * 18.1057$ (Mean_{change} + 1.645 * SD_{change} for the group of patients whose shoulder function was “not importantly improved”), with a specificity of 95% (Figure 12). Thirty-six patients (51%) reached the MIC_{95% limit} in their DASH 7 score change.

The area under the curve (AUC) was 0.94 (95% CI: 0.88-1.0), which indicates that the DASH 7 questionnaire can distinguish between improved and unimproved patients (where AUC = 0.7 is the threshold value) ¹⁵⁶.

Table 9. Reported DASH 7 score, mean (SD), related to change in the Patient Global Impression of Change (PGIC) scale

Reported PGIC	Number of patients (n=70)	DASH 7 score at baseline: Mean (SD)	DASH 7 score at 3 months: Mean (SD)	DASH 7 score change 0-3 months: Mean (SD)
Recovered	15	49.3 (17.3)	3.8 (7.4)	45.5 (16.2)
Large improvement	37	50 (19.5)	18.3 (15.8)	31.9 (19.1)
Small improvement	14	43.9 (19.1)	46.2 (22.7)	-2.3 (19.8)
Unchanged	4	40.2 (7.4)	50.9 (16.3)	-10.7 (9.2)
Worse	0	0	0	0

Table 10. Change in the Patient Global Impression of Change (PGIC) scale when dichotomized into “not importantly improved” and “importantly improved” relative to reported DASH 7 score, mean (SD), included in ROC analyses

Reported DASH 7 score	Not importantly improved (Small improvement, unchanged) n = 18	Importantly improved (Recovered, large improvement) n = 52	t-test p-value
Mean score at baseline (SD)	43.1 (17)	49.8 (18.7)	0.183
Mean score at 3 months follow-up (SD)	47.2 (21.1)	14 (15.5)	0.000
Mean change from baseline to 3 months follow-up (SD)	-4.1 (18.1)	35.8 (19.2)	0.000

Figure 12 The anchor-based distribution of the score change in DASH 7 for the groups “importantly improved” ($n = 52$) and “not importantly improved” ($n = 18$) presented with the optimal ROC (MIC_{ROC}) and 95% limit ($ROC_{95\% \text{ limit}}$) cut-off points

Figure 13 Receiver operating characteristic (ROC) curve for different cut-off points for change in the DASH 7 score. The curve point that lies nearest the left upper corner represents the best cutoff as an anchor: the number of erroneous classifications is lowest here with the highest sensitivity and the lowest 1-specificity.

Heterogeneity based on clinical presentation (Studies A and B, Paper II)

A total of 164 patients with subacromial pain had complete data, and were included in the analyses of Studies A and B presented in Paper II. The two studies included 255 patients: data regarding at least one of the three components (AROM, rotator cuff function and scapular kinematics) were lacking for 60 of these, and data from the self-reported measurements (VAS, DASH 7, HAD scale, EQ-5D and EQVAS) were lacking for a further 31 patients, which induced that 91 patients were excluded. Table 3 summarizes the baseline characteristics.

Clinical presentation

Of the 164 patients, 24% had positive findings in one of the three components, 50% in two, and 24% in all three components. Two percent of the patients had normal function in all three components (Figure 14). Most of the 24% of patients with one affected component had rotator cuff dysfunction. Limited AROM only was present in 2% of the total, while 3% had scapular dyskinesia alone. The combination of limited AROM and scapular dyskinesia without rotator cuff dysfunction was present in 1% of the patients (Figure 14). The three components were not significantly correlated with each other.

AROM

Limited AROM in one direction or more was present in 46% of the 164 patients. Among these patients, 25% had a limitation in one direction, 45% in two directions, and 30% in all three directions. A limitation in abduction and external rotation was almost equally present among the patients who were limited in one direction, while the most common combination of limitation in two directions were flexion and abduction (Figure 15). All three directions of AROM were significantly correlated with each other ($p < 0.001$, $r = 0.77$ for flexion-abduction, 0.43 for flexion-external rotation, and 0.37 for abduction-external rotation).

Figure 14 Presence of limited active range of motion, rotator cuff dysfunction and scapular dyskinesia in the clinical presentation of patients with subacromial pain in primary care, in percentages (n=164)

Figure 15 The percentages of each direction within the component active range of motion in patients with subacromial pain (n=164)

Rotator cuff function

Ninety-one percent had rotator cuff dysfunction with pain provocation in at least one of the three directions tested (Figure 16). Of these patients, 19% reported pain provocation in one direction, 47% in two directions, and 34% in all three directions. For the different directions tested, 81% of the patients reported pain provocation in abduction, 63% in external rotation and 53% in internal rotation. The most common presentation was pain provocation in two directions, with abduction and external rotation (Figure 16) being significantly correlated ($p < 0.001$, $r = 0.33$).

Figure 16 The percentages of each direction within the component rotator cuff function in patients with subacromial pain (n=164)

Scapular kinematics

At least one of Kibler's three types of scapular dyskinesia ⁷⁸ was visually detected in 57% of the 164 patients. Scapular dyskinesia was commonly present in combination with rotator cuff dysfunction (Figure 14).

Clinical presentation and association with self-reported measurements

Pain

The reported intensity of pain at night was associated with scapular dyskinesia, where patients with dyskinesia reported a significantly lower level of pain than those without dyskinesia (25th-75th percentiles 19.5-68.5 and 30-74.2, respectively, $p = 0.045$). The pain intensities reported using VAS ¹⁵ at rest and in activity were not significantly associated with any of the three components of the clinical presentation (Table 11).

Table 11. Self-reported pain (VAS), shoulder function (DASH 7), state of anxiety and depression (HAD scale) and health-related quality of life (EQ-5D and EQVAS) presented, in relation to components of the clinical presentation (n=164)

	VAS ^a (0-100)			DASH ^{7b} (0-100)		HAD scale ^c (0-21)		EQ-5D ^d EQVAS ^e (0-100)	
	Activity mean (SD)	Night median (IQR)	Rest median (IQR)	mean (SD)		Anxiety median (IQR)	Depression median (IQR)	EQ-5D ^d index mean (SD)	EQVAS ^e mean (SD)
Active Range of Motion (n)									
Normal (88)	73.4 (19.2)	50 (50)	10 (33)	42.3 (18.6)		3 (4)	1 (1)	0.671 (0.201)	72.5 (17.1)
Limitation one direction (19)	71.3 (22.7)	35 (63)	5 (20)	44 (15.9)		3 (5)	2 (3)	0.647 (0.174)	71.6 (18.9)
Limitation two directions (34)	74.6 (19.1)	50 (59)	11 (24)	51.1 (20.3)		2 (5)	1.5 (3)	0.554 (0.281)	66.8 (22.5)
Limitation three directions (23)	75.4 (16.5)	50 (35)	16 (50)	58.9 (22.6)		3 (5)	2 (2)	0.467 (0.321)	63.2 (21.2)
Rotator cuff function (n)									
Normal (14)	72.8 (20.6)	61 (28)	16 (53)	34.9 (21.2)		1.5 (5)	1 (1)	0.655 (0.181)	75.9 (12.8)
Pain one direction (28)	71.5 (18.8)	60 (52)	10 (36)	46.4 (20.7)		3 (2)	1 (2)	0.613 (0.263)	67.8 (21.0)
Pain two directions (71)	71.4 (19.6)	40 (52)	6 (22)	46.4 (18.9)		3 (5)	1 (2)	0.615 (0.231)	71.2 (17.2)
Pain three directions (51)	78.2 (18.0)	52 (48)	12 (36)	50.5 (20.2)		4 (4)	1 (3)	0.606 (0.276)	67.6 (22.2)
Scapular kinematics (n)									
Normal (70)	73.1 (18.5)	51 (44)	15.5 (39)	49.4 (20.1)		3 (5)	1 (2)	0.582 (0.253)	69.0 (17.8)
Scapular dyskinesia (94)	74.1 (19.7)	50 (49)	7 (30)	44.7 (19.9)		3 (3)	1 (1)	0.640 (0.239)	70.5 (20.4)

^aVisual analogue scale (0 = no pain, 100 = highest imaginable pain), ^bDisability of the Arm, Shoulder and Hand, a 7-question version specific for patients with subacromial pain (0 = no difficulty, 100 = severe disability) ^cHospital Anxiety and Depression Scale (0-7 = normal, >10 = abnormal), ^dEuroQol 5 Dimensions (scores range from less than 0 to 1, 0 = a health state equivalent to death, negative values = worse than death, 1 = perfect health), ^eEuroQol Visual analogue scale (0 = the worst health you can imagine, 100 = the best health you can imagine)

Shoulder function

Activity-related shoulder function measured with DASH 7 was significantly associated with a limited AROM. Shoulder disability was significantly higher in patients with limited AROM than in those without limitation ($p = 0.002$, $r^2 = 0.09$). The DASH 7 score was not significantly associated with rotator cuff dysfunction nor with scapular dyskinesia (Table 11).

Anxiety and depression

The levels of depression measured by the HAD scale ¹⁷⁴ were significantly associated with rotator cuff dysfunction. The level of depression was significantly higher for patients with rotator cuff dysfunction, defined as pain in two or three directions ($p = 0.027$ and $p=0.019$) than for those without rotator cuff dysfunction. A level greater than 7 on the HAD scale for depression was reported by 4% of the patients with pain in two directions (range 8-9) and by 12% of those with pain in three directions (range 8-15). The level of depression in all patients without rotator cuff dysfunction was lower than 7 (range 0-4). However, the level of depression measured by HAD ¹⁷⁴ was not significantly associated with scapular dyskinesia nor with limitation in AROM (Table 11). The level of anxiety measured by the HAD scale ¹⁷⁴ was not significant associated with any of the three components of clinical presentation.

Health-related quality of life

The ratings on EQVAS ¹²³ were not associated to the three components of clinical presentation. The EQ-5D ^{58, 123} index value, however, was significantly associated with limited AROM. The EQ-5D index was significantly lower for patients with limited AROM ($p = 0.001$, $r^2 = 0.09$) (Table 11).

Effect of a specific exercise strategy (Study A, Paper IV)

In the RCT, 164 patients were included and assigned at random to undertake one of two exercise strategies: 84 patients to the specific exercise strategy and 80 to the active control strategy. Thirty-nine of the patients diagnosed with subacromial pain declined to participate, most of them for one of three reasons: they felt that six visits were too many, they were not prepared to perform daily exercises, or were not willing to complete the questionnaires. Three hundred and sixty-one patients did not meet the inclusion criteria, mostly due to exclusion criteria (see Table 2 for criteria).

Follow up at 3 months was performed for 126 patients. Six patients in the specific exercise group did not satisfy the minimum compliance criterion (daily exercise during more than ten of the twelve weeks of intervention). Six patients in the active control group had on one occasion received treatment with manual mobilization during the intervention, and this additional manouver did not have a direct positive effect. Analysis was carried out both with these 12 patients included in the total data and without them, with no effect on the results. Therefore, all 126 patients were included in the analyses at the 3-month follow up. (Figure 17).

Completers (n=126) differed significantly from non-completers (n = 38). Non-completers were younger and reported more intense pain at night, a lower level of psychological health, and a lower health-related quality of life (Table 12. Baseline data with patient characteristics and mean scores (SD) for primary and secondary outcomes at baseline). Baseline measurements for the two treatment groups did not differ significantly (Table 12).

Of the 126 completers, 117 underwent an ultrasound examination after the 3-month follow up. Full-thickness tears (FTTs) were identified in five from the specific exercise group, and partial thickness tears (PTTs) in nine, of 57 examined patients. Corresponding numbers in the active control group were FTTs in four patients and PTTs in 12, of 60 examined. Eleven patients received a corticoid injection in the subacromial space on one occasion between baseline and the 3-month follow up: three in the specific exercise group and eight in the active control group. Neither the distribution of rotator cuff tears nor the administration of corticoid injection differed significantly between the groups.

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

Figure 17 Participant flow diagram for the number of patients eligible for inclusion in the study until the 3-month follow up

At the 3-month follow up, the mean CM score had increased in both the specific exercise group and active control group, with no significant difference between the groups. The mean change in CM was 23.1 points (SD 19.1) for the specific exercise group, and 22.1 points (SD 17.9) for the active control group. The MIC for CM score is 17 points for patients with subacromial pain⁶³. This level of change was reached by 59% of patients in the specific exercise group and by 60% in the active control group.

Table 12. Baseline data with patient characteristics and mean scores (SD) for primary and secondary outcomes at baseline

Patient characteristics	Specific exercise (n=61)	Active control (n=65)	P value	Completers (n=126)	Non-completers (n=38)	P value	Statistical test
Age in years, mean (SD)	53.4 (8.2)	52.6 (9.4)	0.59	53 (8.8)	49.6 (7.8)	0.03	t-test
Duration of pain in months, mean (SD)	14.4 (37.6)	13.7 (23.3)	0.9	14 (30.9)	11.4 (16)	0.61	t-test
Women, n (%)	37 (61)	38 (58)	0.8	75 (60)	24 (63)	0.69	Chi ²
Dominant side affected, n (%)	35 (57)	36 (55)	0.82	71 (56)	17 (45)	0.26	Chi ²
Heavy load occupation, n (%)	20 (33)	14 (22)	0.16	34 (27)	16 (42)	0.08	Chi ²
Earlier shoulder pain	8 (13)	9 (14)	0.9	17 (13)	2 (5)	0.21	Chi ²
Expectations for treatment:							
High possibility of work in 6 months, n (%)	53 (87)	55 (85)	0.95	108 (86)	34 (89)	0.49	Chi ²
Expectations of treatment: recovery, n (%)	47 (77)	38 (58)	0.12	85 (67)	22 (58)	0.26	Chi ²
Corticoid injection before start, n (%)	16 (26)	11 (17)	0.2	27 (21)	4 (11)	0.13	Fisher's
HAD scale: Anxiety, mean (SD)	3.1 (2.7)	3.1 (2.6)	0.96	3.1 (2.6)	4.7 (3.2)	0.03	t-test
HAD scale: Depression, mean (SD)	1.8 (1.7)	1.9 (1.8)	0.85	1.9 (1.8)	2.9 (3.4)	0.02	t-test
Outcome measurement, mean (SD)							
CM score	40.6 (15.7)	38.7 (13.3)	0.45	39.6 (14.5)	36.6 (13.2)	0.25	t-test
VAS at rest	16.3 (18.6)	13.7 (18.2)	0.42	14.9 (18.4)	17.3 (24.8)	0.52	t-test
VAS in activity	76.3 (17.7)	71 (19)	0.11	73.6 (18.5)	75.5 (19.3)	0.57	t-test
VAS at night	45.3 (24.9)	44.9 (27.9)	0.93	45.1 (26.4)	54.4 (24.6)	0.06	t-test
DASH	32.4 (14.6)	27.8 (14.1)	0.08	30.1 (14.5)	33.9 (13.2)	0.14	t-test
DASH 7	46.3 (19.1)	41.1 (19.2)	0.13	43.6 (19.3)	47.6 (17.4)	0.26	t-test
EQ index	0.69 (0.19)	0.68 (0.22)	0.85	0.69 (0.2)	0.55 (0.3)	0.01	t-test
EQ VAS	73 (16.5)	73 (16.7)	0.99	72.0 (17.4)	68.2 (19.8)	0.02	t-test
PSFS	3.5 (1.7)	3.8 (1.5)	0.2	3.7 (1.6)	3.7 (1.4)	0.9	t-test

HAD scale, Hospital Anxiety and Depression scale (range 0-21); CM, Constant Murley score (range 0-100 points); VAS, Visual analogue scale for pain (range 0-100 mm); DASH, Disabilities of the Arm, Shoulder and Hand questionnaire (range 0-100 points); DASH 7, short form of DASH, specific for patients with subacromial pain (range 0-100 points); EQ index, EuroQol 5 dimensions (range from -0.59 to 1); EQVAS, EuroQol visual analogue scale (range 0-100 mm); PSFS, Patient-Specific Functional Scale (range 0-10 points)

The improvement of shoulder function measured by DASH 30, and by DASH 7 was significantly greater for the patients in the specific exercise group. The mean change in DASH 30 was 14.6 (SD 14.3) and that in DASH 7 was 20.7 (SD 20.6) points, to be compared with 8.1 (SD 13.6) and 13.2 (SD 19.4) points for DASH 30 and DASH 7, respectively, in the active control group (DASH 30 $p=0.01$, DASH 7 $p=0.04$). Paper III shows that the MIC for improvement in DASH 7 is 6.5 points, and this was reached by 79% of the patients in the specific exercise group and by 59% in the active control group.

Patients with subacromial pain in primary care
Assessment and efficacy of physiotherapy-guided exercise treatment

Perceived positive change (self-rated change on level 6 or 7) in the PGIC, in favor of the specific exercise group with 57% compared to 44% in the active control group was seen at the 3-month follow up ($p=0.062$). The intervention groups did not differ in any other way at the 3-month follow up, but the course for all outcomes was in favor of the specific exercise group (Figure 18).

Figure 18 Comparison of change in mean score (SD) in primary and secondary outcomes between intervention groups from baseline to the 3-month follow up. CM score, Constant Murley score (0-100); DASH 7, short form of DASH specific for patients with subacromial pain (score 0-100); DASH, Disabilities of the Arm, Shoulder and Hand questionnaire (0-100); VAS, Visual analogue scale for pain (0-100); EQ index, EuroQol 5 dimensions (-0.59 to 1); EQVAS, EuroQol visual analogue scale (0-100); PSFS, Patient Specific Functional Scale (0-10)

DISCUSSION

The DASH 7 questionnaire

It is important to further develop PROMs that are relevant to the patient, user-friendly and reliable for use in both intervention studies and clinical practice. Papers I and III show that it is possible to use only seven of the items in DASH 30 to identify the activities most relevant to patients with subacromial pain in a primary care setting, while maintaining internal consistency and satisfactory responsiveness.

Validation is the process in which a measurement is tested in relation to a reference standard. One strength of the validation process used in paper I is that it is based on both a professional and a patient perspective to test construct validity. The validation introduced a patient perspective by using the activities that patients gave priority, using the PSFS as a reference standard, in addition to using the professionals' expert opinions when identifying the best corresponding DASH items. Five PTs independently identified the most suitable DASH item to match each of the 271 PSFS activities, with a level of agreement of almost 80%. The items selected to be included in DASH 7 cover 96% of the patient-selected activities, which shows that DASH 7 is valid, and able to capture the activities that are important to patients with subacromial pain. When the original DASH was developed, item selection was based primarily on expert opinion, and the items were selected from thirteen published and unpublished measurement scales. The initial 821 items were reduced to 78 items, field-tested by patients for face validity, and then reduced to the ultimate 30-item scale ^{64, 103}.

The DASH item "recreational activities with force or impact" was identified during the validation process as one of the most important patient-selected items for patients with subacromial pain. This is in contrast to the study by Kennedy and Beaton (2016) ⁷⁴, based on professionals' expert opinions about the usefulness of various DASH items. They identified this item as informative but problematic and suggested that it be removed from DASH 30. Their study ⁷⁴ was performed with reference to patients with a variety of upper-extremity disorders, whereas the studies presented here examined patients with clinically defined subacromial pain. We can conclude that different items are valid for different groups of patients.

The Swedish version of DASH 30 that was used for the validation process has been translated from the English version, with cross-cultural

adaptation 4. The cultural context in which the instrument is used may affect the order of priority of PSFS activities. However, shoulder function as affected by subacromial pain tends to manifest in the same fashion around the world, which supports our conclusion that the results presented here are generally applicable.

The Cronbach alpha values for the different DASH versions were 0.84 for DASH 7, and 0.94 for DASH 30, which are both acceptable ¹⁵⁰. Tavakol and Dennick (2011) ¹⁵³ state that a Cronbach alpha greater than 0.90 may indicate redundant items, which suggests that the number of items in DASH 30 can be reduced when evaluating shoulder function in patients with subacromial pain. Cronbach alpha for DASH 7 is only slightly lower than that of DASH 30, which confirms its high internal consistency ¹⁵³.

MIC for improvement in DASH 7

The MIC calculations for improvement show that the DASH 7 questionnaire responds to change over time in patients with subacromial pain in a primary care setting. These calculations show also that DASH 7 can discriminate between patients whose condition improves and those whose condition does not after a 3-month period of a specific exercise strategy. The correlation coefficient between the external criterion and the change of score in DASH 7 was 0.67, and allows the value of the MIC_{ROC} to be calculated as 6.5 points, with a 24% risk of erroneous classification (sensitivity 0.98 and specificity 0.78). The AUC was 0.94 (CI: 0.88-1.0), which is greater than the AUC in earlier studies that evaluated the responsiveness of DASH 30 in patients with subacromial pain (AUC 0.77-0.79, CI 0.63-0.92) ^{106, 131}. An AUC greater than 0.7 shows that the method can distinguish between the improved patients and those not improved ¹⁵⁶. We conclude that DASH 7 is adequately responsive.

Both the MIC_{ROC} and the MIC_{95% limit} describe the variation in the score. The MIC values can guide how the effect of an intervention for a patient in clinical practice or in intervention studies should be interpreted. The MIC value to use depends, however, on the situation. The MIC_{ROC} is based on equally weighted sensitivity and specificity and ensures that the number of erroneously classified patients is a minimum. This value should be used if no reason is given to prioritize between the true positives or the true negatives. The MIC_{95% limit} should be used if it is more important to minimize the risk of classifying a patient as “importantly improved” when the change in score is within the measurement error of the DASH 7 questionnaire. The MIC values should be used in combination with evaluation of patient treatment goals and the end-point score reached when

making an evidence-based classification of a patient's response to treatment ⁹.

MIC values differ between different patient populations ^{27, 29, 31}, contexts ²⁷, and calculation methods ^{9, 27, 31}. A standardized inclusion process was used for both the RCT (Study A) and the clinical cohort (Study B). The clinical tests selected to identify patients with subacromial pain have high intra-examiner and inter-examiner reliabilities (kappa coefficients 0.91-1.0) ⁶⁹. Combining these tests gives acceptable diagnostic accuracy when identifying patients with a subacromial origin of their pain ^{33, 52, 56, 57, 107}. We conclude that the symptoms of the patients included in the two studies were validly labelled as subacromial pain, and that this clinical diagnosis is considered applicable in a primary care setting in which physiotherapists are first-line assessors.

The MIC depends also on the external criteria used to set the anchor. In the MIC calculation for the DASH 7, we used a 5-point Likert scale to determine the change after intervention as perceived by the patients. Global assessment scales have been criticized, since patients may not remember accurately an earlier state of health ^{134, 135}. Other authors, however, have shown that these scores are uniquely relevant to the patient ^{50, 67, 71, 72}. Unfortunately, there is no consensus about the best anchor to use when calculating the MIC, but a global assessment scale has usually been used ²⁶. It is important in this case that the question asked is related to the same construct as the one measured by the score ³⁰. In both studies used in this thesis (Study A and Study B), the patients were asked to assess the change (if any) in activity limitations and symptoms related to their shoulder between the start of the intervention and the 3-month follow up. We conclude that this question in the PGIC is adequately related to what is measured by the DASH 7 questionnaire, where the items focus on activity-related shoulder function.

The method chosen to calculate the MIC was the anchor-based MIC-distribution method, which includes both an anchor-based and a distribution-based approach ³⁰. Each approach has been criticized for inherent limitations, and a gold standard has not been established. One limitation of the distribution-based approach is that it does not help to appreciate the clinical importance of the observed change ³⁰. This criticism must be taken seriously since the main purpose of the MIC is to identify the patient-related clinical importance and distinguish it from the statistical significance. The distribution-based approach also depends on the sample-specific variation, which means that it may not be possible to generalise the value determined ³⁰. In contrast, the anchor-based approach fails to consider the sample-specific variation in the score ³⁰. Therefore, by using a combined method (including both an external criterion with the patient perceived change in focus together with a variability measure with the

patient distribution of change presented in graphs), the results should better display the adequacy of the anchor and the consequences of choosing a specific MIC. A methodological strength of the MIC study was that it followed the requirements of the COSMIN checklist ¹¹⁰, and used an appropriate sample size and design. Description of missing items, the intervention used, and the measurements and proportions of patient-reported change are all covered. This limited bias in the method and improved the quality of the result ^{108, 110}.

Only four patients reported their condition as “unchanged” in the PGIC, which made it impossible to calculate the minimal detectable change (MDC) and the standard error of measurement (SEM). De Vet et al. (2007) recommends that the MIC exceed the MDC and the SEM, to ensure that the change in score can be correctly interpreted, and to calculate a MIC that reflects true change ³⁰. These calculations were not possible from the available data, and further research is required to determine the MDC and SEM for DASH 7.

Another limitation of the MIC calculation is that only 70 of the 121 patients included in the clinical cohort (Study B) could be included in the analyses. However, since the baseline characteristics were similar for those included and those not included, except for a higher pain intensity at rest among those not included, we believe that the MIC values we have calculated can be generally applied for patients with subacromial pain in a primary care setting.

Usability of the DASH 7

One advantage of the DASH 7 questionnaire over the DASH 30 is its brevity. Short questionnaires are less time-consuming and are more attractive to use since they require less administrative time and place less burden on the respondent. The latter leads to greater responsiveness since missing responses are fewer ¹⁰. The results for DASH 7 of the outcome analyses in the RCT (Paper IV) are similar to those of the DASH 30, which supports our conclusion that the shorter DASH 7 can be used for patients with subacromial pain.

The DASH 30 has been compared with the ICF classification ^{34, 37, 128, 140}. When this classification was applied to DASH 7 and DASH 30, it became clear that they both include items that represent each ICF component of function: Body structure and function, Activity, and Participation. Most items are related to the Activity component. This also supports the use of DASH 7 for patients with subacromial pain. However, using the PSFS to develop an activity-related measurement scale meant that some items related to specific symptoms, for example pain, were excluded. Pain is a central cause of shoulder dysfunction in patients with

subacromial pain, and it is therefore important to complement the DASH 7 questionnaire with a separate measurement of pain. Measuring pain and shoulder function separately is in line with the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) ^{40, 154}. It is easier to derive meaningful comparisons of change within different domains if the domains are measured separately. This is true both for changes at the level of the individual, and changes between research studies ^{40, 154}.

Heterogeneity based on clinical presentation

Paper II (in which patients from both Study A and Study B are included) contributes new knowledge about the variability of clinical presentation in patients suffering from subacromial pain and who attend primary care. Heterogeneity was confirmed, and different patterns of positive clinical findings could be categorized based on AROM, rotator cuff function and scapular kinematics. These components were weakly associated with various self-reported factors such as shoulder pain and function, psychological aspects and health-related quality of life.

Defining only whether a component is present or not may be considered to be rather rough. For example, AROM was defined as limited or not, and the parameter was not analyzed with respect to the degree of limitation or its cause. Further, a rotator cuff dysfunction was defined as present if at least one resisted isometric muscle test provoked pain, without any attempt to determine whether the pain originated from a particular muscle. This method was chosen since it is difficult to isolate specific rotator cuff muscle activity in specific joint actions ¹²⁵, and because muscle force is an unreliable measure when pain is present ^{38, 141}. This pragmatic approach gave a categorization based on the patient's shoulder function, rather than a structural diagnosis, which is in line with suggested methods by other researchers ^{90, 126, 133} and it is considered appropriate to differentiate patients with subacromial pain. This manner of categorization also allowed symptoms of different severity within each component, which confirms its eligibility.

The three components chosen to use in clinical presentation were based on research by Clausen et al. (2017) ²¹ and Uhl et al. (2009) ¹⁶⁰, who showed their importance in clinical examination ^{21, 161}. Our results show that the choice is justified, since 98% of the patients with subacromial pain presented with positive clinical findings in at least one of these three components. Shoulder function and health-related quality of life ⁶⁰ are known to be affected negatively by shoulder pain, but their specific association with AROM found in our study is new knowledge. This supports the recommendation to use ROM as a component to be investigated during

the clinical examination used to define impairment, also recently reported as a recommended core outcome ²⁰. Two limitations in this description of clinical presentation are the lack of information about the degree of ROM for each direction, and a report of end-feel from the participating PTs.

Patients with rotator cuff dysfunction that produced pain in two or three directions were more often depressed ($p = 0.027$ and 0.019) than those with dysfunction that produced pain in only one direction, and those with normal rotator cuff function. This finding, however, should be interpreted with some caution, since the median scores are well below the cut-off value of the HAD for depression ¹⁷⁴ and only nine patients (5%) of the 164 reported levels greater than 7. Still, previous research on patients with shoulder pain has also shown this association ⁶⁰, and anxiety and depression are predictors of poor treatment outcome ²⁸. Further, limited ROM and decreased rotator cuff strength in abduction are also predictors of poor treatment outcome, since they are more commonly present among patients who are candidates for surgery ¹⁷⁰. Future research should consider these components to be relevant subvariables.

Patients with scapular dyskinesia experience a lower level of pain intensity at night than those without dyskinesia, but the degree of explanation was low ($p = 0.045$). The mean scores for VAS at rest, EQ-5D index, EQVAS, DASH 7 and the HAD scale (Table 11) all showed that patients with scapular dyskinesia fared better than those without. These findings suggest that scapular dyskinesia is compensatory, which agrees with results from Christiansen et al. (2017) ¹⁹, who reported that scapular motion in patients with subacromial pain became normal in those receiving treatment as often as it did in those who did not ¹⁹. Scapular dyskinesia might partly be a compensatory response to pain, but the correlation with symptoms and treatment response needs further investigation.

Efficacy of a specific exercise strategy

For both exercise strategies, the primary outcome (CM score) in the RCT evaluated at 3 months, showed significantly improved shoulder function and decreased shoulder pain. DASH 30 ($p=0.01$) and DASH 7 ($p=0.04$), however, both improved more for patients in the specific exercise group. This difference in results for different outcome measures needs further consideration. Both the CM and DASH are considered to be relevant outcome measures for patients with subacromial pain, but the difference in results may be a result of their different constructs. The CM score includes assessments both by the patient (35% of total score) and the clinician (65% of total score), whereas DASH contains only patient assessment. The correlation between objectively measured function and self-assessed function can be low ^{21, 61, 65, 75, 93}, and these measures are

considered to be complementary, as they do not measure the same construct⁶¹. Hurd et al. (2018)⁶⁵ reported that shoulder function measured with the DASH 30 improved, but there was no improvement in objectively measured upper limb activity in patients one year after shoulder surgery⁶⁵. DASH 30⁶⁴ and DASH 7 (Paper I) mainly include items related to activity and participation (>80%), while the items in the CM score²² mainly relate to body structure and function (80%). The construct validity of DASH and CM score are adequate when these are compared ($r = 0.76-0.82$)³, but further research is needed to explore the different qualities of the instruments. Roe et al. (2013)¹²⁸ have shown that the contents of measures that evaluate shoulder pain and function relative to the ICF differ significantly, which shows how important it is to clarify the content before selecting measures both for research and in the clinical setting¹²⁸.

The different results in the outcome measurements used should be considered against the background of the two intervention strategies. The patients in the specific exercise group were allowed to experience pain during exercise, using the pain monitoring model¹⁵⁷ to handle pain intensity. Evidence suggest that pain beliefs and self-efficacy are associated with level of disability in shoulder pain¹⁰². It is therefore interesting to speculate about if this strategy contributed to an increased pain self-efficacy and positively affected the self-assessed ability to perform activities as measured by DASH and the PGIC.

Patients in both groups experienced improvement, and this suggests that many patients in primary care will benefit from using strategies that include information about subacromial pain, ergonomics, optimal posture, and advice for using their shoulder in daily activities, combined with daily shoulder exercises. The results measured with the CM score show that specific exercises are not necessary for all patients to achieve a clinically relevant mean change as reported in our earlier study⁶². The specific exercise strategy gave larger improvement in shoulder function measured by DASH 30 and DASH 7. This leads us to recommend this exercise strategy as first-line treatment. It should, however, be used only if tolerated by the patient, since it gives progressive loading of the rotator cuff muscles and scapula stabilizers⁶².

Previous work has not shown that any one exercise strategy for patients with subacromial pain is better than another. The meta-analysis by Shire et al.¹³⁷ examined whether specific resistance exercises are superior to general resistance exercises in the treatment of patients with subacromial pain. Six randomized controlled trials were included, but there was insufficient evidence to recommend one exercise strategy over another. Other studies that compared exercise strategies also failed to establish that any one is better than another^{59, 101, 120}. Many patients improve irrespective of the exercise intervention used, so the natural course of the complaint

might be a strong factor in the outcome of patients treated for subacromial pain. Regression to the mean (RTM) must also be considered: this statistical phenomenon can make natural variation in repeated data appear to be real change ^{7, 173}. This, together with heterogeneity, may explain why it is difficult to detect clinically relevant group differences. The multifactorial cause and etiology have also been described in previous research ^{90, 104, 136, 138}. In summary, future studies should be designed that aim to subcategorize the patients based on the individual components in the clinical presentation, and in this way individually tailor the interventions and also aim to control for natural course.

The intervention in the RCT study described here lasted 12 weeks, and gave significant improvements in both the primary and secondary outcomes. Additionally, 59-60% of the patients reached the MIC level on CM score (17 points), and 59-79% reached the MIC for DASH 7 (6.5 points). This level of effect is similar to those seen in previous intervention research on patients with subacromial pain with a symptom duration of at least 3 months, even if different outcome measures for shoulder function were used ^{59, 101}. Heron et al. (2017) ⁵⁹ reported that 40-43% of patients reached a minimally clinical important change (10 points) in SPADI after 6 weeks of exercise intervention. Maenhout et al. (2013) ¹⁰¹ reported a score change in the SPADI of 25.7-27 points after 12 weeks of exercise. These studies support the idea that a positive effect should be expected within the first 3 months of an intervention. If this does not happen, the intervention should be changed.

Strengths of the RCT described here are the use of a single-assessor blinded design and the reproducibility of the patient selection in a clinical primary care setting. Non-completers differed significantly from completers, which makes it necessary to be cautious in generalizing the results. Non-completers were in general younger, presented with more intense pain at night, and a lower general level of health. The intervention investigated in this study may be less suitable for patients in this sub-group.

CONCLUSIONS

- Seven DASH items out of the original 30 are most important when assessing shoulder function in patients with subacromial pain (DASH 7).
- The DASH 7 questionnaire can detect change over time as reliably as the DASH 30 questionnaire. It has a high level of internal consistency and can discriminate between patients with subacromial pain whose shoulder function improves from those in whom it does not.
- Patients with subacromial pain in primary care comprise a heterogeneous group, as is seen in differences in three components of the clinical presentation: active range of motion, rotator cuff function and scapular kinematics.
- Rotator cuff dysfunction, defined as pain during resisted isometric muscle-testing, is very frequently present in patients with subacromial pain in primary care. In contrast, limitation in active range of motion and scapular dyskinesia are less consistently present. All three components can be found individually and in combination.
- The components of the clinical presentation are significantly correlated with the impact of the patient's condition on daily life. These correlations, however, are rather weak and should be interpreted with caution.
- Improvement measured by CM score did not differ between the groups. This measure focusses primarily on body function with pain-free active range of motion and muscle strength in abduction.
- A specific exercise strategy that focusses on increasing the strength and endurance of the rotator cuff muscles and the scapula stabilizers is superior to an active control strategy. It gives greater improvement in self-reported shoulder function measured by the DASH instruments, which are primarily related to activity.
- A specific exercise strategy might not be necessary to achieve clinically relevant improvement for all patients in the primary care setting. It is, however, recommended as first-line treatment, if it is tolerated by the patient.

Clinical implications

The DASH 7 questionnaire is a short PROM with good responsiveness. It is specific for patients with subacromial pain and includes all three components of function defined in the ICF. Efficiency is important for both the patient and the clinician when using outcome measures, which means that DASH 7 is a preferable assessment tool in the clinical every day practice. The DASH 7 MIC values for patients with subacromial pain in a primary care setting can be used in clinical practice and in intervention studies to guide a clinically important level of change of score.

The identification of variability in AROM, rotator cuff function and scapular kinematics in clinical presentation increases our understanding of the inherent heterogeneity of this patient group and confirms that these components are important in the clinical examination of patients with subacromial pain. Most clinicians do follow the recommended procedure to identify patients with subacromial pain, but the clinical presentations, and responses to treatment, of patients differ. We believe that this knowledge about sub-variabilities contributes to the clinical reasoning process, enhances the possibility of tailoring treatment, and can guide the design of future research.

Shoulder function evaluated with the CM score did not improve to a significantly different degree between the two groups studied: one of which used a specific exercise strategy and the other an active control strategy. Shoulder function evaluated with the CM score did not improve to a significantly different degree between the two groups studied: one of which used a specific exercise strategy and the other an active control strategy. The specific exercises might not be necessary for all patients in the primary care setting to achieve a clinically relevant improvement. It could also reflect the construct of CM score, mainly focused on the pain-free active range of motion and muscle strength in abduction. However, the specific exercise strategy is significantly better when improvement is assessed by DASH 30 and DASH 7, and this leads us to recommend this strategy, with its progressive loading of the rotator cuff muscles and scapula stabilizers, as first choice, provided that it is tolerated by the patient.

Future research

The sub-variabilities within clinical presentation that we have identified in patients with subacromial pain need to be explored in more depth to determine their relevance for tailored interventions and more individualized treatment strategies. Further research is needed to determine measurement error and minimal detectable change for DASH 7, before it can be fully implemented into clinical practice and research. A further exploration of the role of scapular dyskinesia in patients with subacromial pain is needed. Its contribution to shoulder function in patients with subacromial pain needs to be further understood to better clarify if scapular dyskinesia is important to include as a basis for tailored interventions.

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Appendix I

CONSTANT-MURLEY SCORE *

Smärta

Svår	0
Måttlig	5
Lätt	10
Ingen	15

ADL

Aktivitetsnivå (Obs! Alla nedanstående rubriker skall bedömas)

Full arbetsförmåga	4
Full idrottslig förmåga	4
Ostörd nattsömn	2

Funktionella armpositioner

Hand i midjan	2
Hand till xiphoideum	4
Hand i nacken	6
Hand på hjässan	8
Hand över huvudet	10

Summa ADL: _____

Aktiv rörlighet

Abduktion och Flexion

	ROM	Poäng	
		<u>Flex.</u>	<u>Abd.</u>
	0-30°	0	0
	31-60°	2	2
	61-90°	4	4
	91-120°	6	6
	121-150°	8	8
	151-180°	10	10

Utåttrotation

Hand bakom huvudet med armbågen rakt fram	2
Hand bakom huvudet med armbågen rakt utåt sidan	2
Hand på hjässan med armbågen rakt fram	2
Hand på hjässan med armbågen rakt utåt sidan	2
Full flexion från positionen på hjässan	2

Appendix I

Inåttrotation

Handrygg på utsidan av låret	0
Handrygg på skinkan	2
Handrygg på lumbo-sacrala övergången	4
Handrygg till 3:e lumbalkotan	6
Handrygg till 12:e thorakalkotan	8
Handrygg till området mellan skulderbladen	10

Muskelstyrka

Mät styrkan med armen eleverad till 90 grader i scapulaplanet.
0.5kg / poäng (max 12.5 kg)

Patientens dominanta hand: **Hö** **Vä**

Besvär: **Hö** **Vä**

Inställning: _____

Resultat: Hö _____ **kg** **Vä** _____ **kg** **25**

Sammanställning:

Smärta	_____
ADL	_____
Aktiv rörlighet	_____
Muskelstyrka	_____

TOTALT: _____ / 100 poäng = _____ %

* Översättning av : Constant, C.R. and Murley, A.H.G. score, Ref. "A Clinical Method of Functional Assessment of the Shoulder", Cli Orthop Relat Res 214: 160-164, 1987.

Appendix II

Hälsoenkät (arm/axel/hand)

sida 1/3

Denna enkät berör Dina symtom och Din förmåga att utföra vissa aktiviteter.

Svara på **varje fråga**, baserat på hur Du har mått **den senaste veckan**, genom att kryssa för ett svarsalternativ för varje fråga.

Om det är någon aktivitet Du inte har utfört den senaste veckan får Du kryssa för det svar som Du bedömer **stämmer bäst** om Du hade utfört aktiviteten.

Det har ingen betydelse vilken arm eller hand Du använder för att utföra aktiviteten. Svara baserat på Din förmåga oavsett hur Du utför uppgiften.

	Ingen svårighet	Viss svårighet	Måttlig svårighet	Stor svårighet	Omöjligt att göra
1. Öppna en ny burk, eller hårt sittande lock	☐	☐	☐	☐	☐
2. Skriva	☐	☐	☐	☐	☐
3. Vrida om en nyckel	☐	☐	☐	☐	☐
4. Förbereda en måltid	☐	☐	☐	☐	☐
5. Öppna en tung dörr	☐	☐	☐	☐	☐
6. Lägga upp något på en hylla över Ditt huvud	☐	☐	☐	☐	☐
7. Utföra tunga hushållssysslor (t ex tvätta golv och väggar, putsa fönster, hänga tvätt)	☐	☐	☐	☐	☐
8. Trädgårdsarbete	☐	☐	☐	☐	☐
9. Bädda sängen	☐	☐	☐	☐	☐
10. Bära matkassar eller portfölj	☐	☐	☐	☐	☐
11. Bära tunga saker (över fem kilo)	☐	☐	☐	☐	☐
12. Byta en glödlampa ovanför Ditt huvud	☐	☐	☐	☐	☐
13. Tvätta eller fäna håret	☐	☐	☐	☐	☐
14. Tvätta Din rygg	☐	☐	☐	☐	☐
15. Ta på en tröja	☐	☐	☐	☐	☐
16. Använda en kniv för att skära upp maten	☐	☐	☐	☐	☐
17. Fritidsaktiviteter som kräver liten ansträngning (t ex spela kort, sticka, boule)	☐	☐	☐	☐	☐
18. Fritidsaktiviteter som tar upp viss kraft eller stöt genom arm, axel eller hand (t ex spela golf, använda hammare, spela tennis, skytte, bowling)	☐	☐	☐	☐	☐
19. Fritidsaktiviteter där Du rör på armen fritt (t ex spela badminton, simma, gympa)	☐	☐	☐	☐	☐
20. Färdas från en plats till en annan	☐	☐	☐	☐	☐
21. Sexuella aktiviteter	☐	☐	☐	☐	☐

Appendix II

sida 2/3

22. Under **de senaste sju dagarna**, i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga umgänge med anhöriga, vänner, grannar eller andra?

☐ Inte alls ☐ Lite ☐ Måttligt ☐ Mycket ☐ Våldigt mycket

23. Under **de senaste sju dagarna**, i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga arbete eller andra dagliga aktiviteter?

☐ Inte alls ☐ Lite ☐ Måttligt ☐ Mycket ☐ Våldigt mycket

Ange svårighetsgraden på Dina symtom **de senaste sju dagarna**:

	Ingen	Lätt	Måttlig	Svår	Mycket svår
24. Värk/smärta i arm, axel eller hand	☐	☐	☐	☐	☐
25. Värk/smärta i arm, axel eller hand i samband med aktivitet	☐	☐	☐	☐	☐
26. Stickningar (sockerdrickskänsla) i arm, axel eller hand	☐	☐	☐	☐	☐
27. Svaghet i arm, axel eller hand	☐	☐	☐	☐	☐
28. Stelhet i arm, axel eller hand	☐	☐	☐	☐	☐

29. Har Du haft svårt att sova, under **de senaste sju dagarna**, på grund av värk/smärta i arm, axel eller hand?

☐ Inte alls ☐ Viss svårighet ☐ Måttlig svårighet ☐ Stor svårighet ☐ Mycket stor svårighet

30. Jag känner mig mindre kapabel, har sämre självförtroende eller känner mig mindre behövd på grund av mina arm-, axel- eller handproblem.

☐ Instämmer absolut inte ☐ Instämmer inte ☐ Vet inte ☐ Instämmer ☐ Instämmer absolut

Appendix III

DASH 7 (för patienter med subacromial smärta)

Denna enkät berör Din förmåga att utföra vissa aktiviteter. Besvara varje fråga, baserat på hur Du har mått den senaste veckan, genom att ringa in ett svarsalternativ för varje fråga. Om det är någon aktivitet Du inte har utfört den senaste veckan får Du ringa in det svar som Du bedömer stämmer bäst om Du hade utfört aktiviteten. Det har ingen betydelse vilken arm eller hand Du använder för att utföra aktiviteten. Svara baserat på Din förmåga oavsett hur Du utför uppgiften.

	Ingen svårighet	Viss svårighet	Måttlig svårighet	Stor svårighet	Omöjligt att göra
1. Lägga upp något på en hylla över Ditt huvud	1	2	3	4	5
2. Utföra tunga hushållssysslor (t ex tvätta golv och väggar, putsa fönster, hänga tvätt)	1	2	3	4	5
3. Tvätta Din rygg	1	2	3	4	5
4. Ta på en tröja	1	2	3	4	5
5. Fritidsaktiviteter som tar upp viss kraft eller stöt genom arm, axel eller hand (t ex spela golf, använda hammare, spela tennis, skytte, bowling)	1	2	3	4	5

	Inte alls	Lite	Måttligt	Mycket	Väldigt mycket
6. Under de senaste sju dagarna, i vilken utsträckning har Dina arm-, axel- eller handproblem stört Ditt vanliga arbete eller andra dagliga aktiviteter?	1	2	3	4	5

	Ingen svårighet	Viss svårighet	Måttlig svårighet	Stor svårighet	Mycket stor svårighet
7. Har Du haft svårt att sova, under de senaste sju dagarna, på grund av värk/smärta i arm, axel eller hand?	1	2	3	4	5

DASH 7 bör ej sammanräknas om svar utelämnats på mer än en fråga.

DASH 7 totalpoäng = summerna poäng för alla besvarade frågor, dividera med antalet besvarade frågor, minus 1, multiplicera med 25.

Totalpoäng 0-100, där 0 representerar ingen svårighet och 100 representerar stor svårighet.

Svensk version: Jenny M. Nordqvist, Kajsa M. Johansson, Theresa M. Holmgren, Lars E. Adolfsson, Birgitta E. Öberg, A short activity-related scale for measuring shoulder function in patients with subacromial pain: the DASH 7, JSES Open Access (2017), doi: 10.1016/j.jses.2017.04.001

Appendix IV

The **DASH 7** *(for patients with subacromial pain)*

Instructions:

This questionnaire asks about your symptoms as well as your ability to do certain activities. Please answer every question, based on your condition in the last week, by circling the appropriate number. If you did not do an activity in the last week, please give your best guess which response would be most accurate. It doesn't matter which hand or arm you use to do the activity; please answer based on your ability regardless of how you do the task.

Please rate your ability to do the following activities in the last week by circling the appropriate number.

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
1. Place an object on a shelf above your head	1	2	3	4	5
2. Do heavy household chores	1	2	3	4	5
3. Wash your back	1	2	3	4	5
4. Put on a pullover sweater	1	2	3	4	5
5. Recreational activities in which you take some force or impact through your arm, shoulder or hand	1	2	3	4	5

	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable
6. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder, or hand problem?	1	2	3	4	5

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much difficulty that I can't sleep
7. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder, or hand?	1	2	3	4	5

A DASH 7 score may not be calculated if there is more than 1 missing item.

DASH 7 score = sum of responses divided by the number of items completed, minus 1, multiplied by 25
Scores range from 0-100, where 0 indicates no difficulty or symptoms and 100 denotes severe disability.

Nordqvist et al. A short activity-related scale for measuring shoulder function in patients with subacromial pain: the DASH 7 JSES Open Access 2017 doi:10.1016/j.jses.2017.04.001

Appendix V

Specific exercise program

- To perform twice a day for the first 8 weeks then once a day for the last 4 weeks

Exercise 1

Week 1-12 Shoulder retraction, exercise for the scapula stabilisers

15 repetitions*3

Exercise 2

Week 1-8 Full can eccentric exercise for m. supraspinatus 15 repetitions *3

Week 9-12 Full can concentric/eccentric exercise for m. supraspinatus 10 repetitions*3 ⇒

15 repetitions*3

Exercise 3

Week 1-8 Eccentric exercise for m. infraspinatus and m. teres minor 15 repetitions*3

Week 9-12 Concentric/eccentric exercise 10 repetitions*3 ⇒

15 repetitions*3

Exercise 4

Week 1-8 Concentric/eccentric exercise for m. serratus anterior 15 repetitions *3

Week 9-12 Push up plus exercise 10 repetitions *3 ⇒
15 repetitions *3

Exercise 5

Week 5-8 Bilateral external rotation; a combined exercise for the rotator cuff and the scapula stabilisers 10 repetitions*3 ⇒

15 repetitions *3

Week 9-12 Elevation with bilateral external rotation 10 repetitions *3

Exercise 6

Week 1-12 Posterior shoulder stretch

30-45 seconds*3

Endast i utbildningssyfte LIU

Linköping Universitet Lärarteam

Av: Jenny Nordqvist

Träningsprogram Rörlighet och cirkulation skuldra DEL 2

Övning	Illustration	Träningsfokus	Övningsdata	Kommentar
1 - Retraktion nacke				Håll huvudet i neutralställning. Dra in hakan och förskjut huvudet bakåt. Upprepa 10 ggr. Du ökar den viktiga sträckningen i nacken...
2 - Sammandrag ning av skulderblad				Stå eller sitt med armarna hängande längs sidorna. För axlarna bakåt så att skulderbladen dras ihop. Upprepa 10 ggr. Du motverkar en ihopsjunken hållning....
3 - Skulderblads kontroll				Stå eller sitt. Dra upp skulderbladen/axlarna mot öronen. Håll 5 sekunder. Sänk ner sakta. Upprepa 10-15 ggr. Du motverkar muskelspänningar...
4 - Abduktion av arm				Stå eller sitt. Lyft armarna rakt ut åt sidan, upp mot taket. Upprepa 10 ggr. Du får en välgörande rörlighet i axelleden...
5 - Töjning m. trapezius				Stå eller sitt. Dra in hakan, luta huvudet mot axeln. Håll 20 sekunder. Upprepa 2ggr på vardera sida. Du sträcker ut halsens sidomuskulatur...
6 - Töjning m. pectoralis major				Stöd underarmen mot en dörrkarm eller liknande. Vrid kroppen långsamt bort från armen. Håll 20 sekunder. Upprepa 2ggr på vardera sida. Du ökar din rörlighet i bröstmuskulaturen och förbättrar din hållning...

Papers

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