Maastricht University

Physiotherapy in shoulder impingement syndrome

Citation for published version (APA):

Kromer, T. O. (2014). *Physiotherapy in shoulder impingement syndrome*. [Doctoral Thesis, Maastricht University]. Datawyse / Universitaire Pers Maastricht. https://doi.org/10.26481/dis.20140213tk

Document status and date:
Published: 01/01/2014

DOI:
10.26481/dis.20140213tk

Document Version:
Publisher's PDF, also known as Version of record

Please check the document version of this publication:

• A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
• The final author version and the galley proof are versions of the publication after peer review.
• The final published version features the final layout of the paper including the volume, issue and page numbers.

Link to publication

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

• Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
• You may not further distribute the material or use it for any profit-making activity or commercial gain
• You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license above, please follow below link for the End User Agreement:

www.umlib.nl/taverne-license

Take down policy
If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

Download date: 02 Aug. 2023

PHYSIOTHERAPY IN SHOULDER IMPINGEMENT SYNDROME



THILO OLIVER KROMER

Physiotherapy in Shoulder Impingement Syndrome

© Copyright Thilo Oliver Kromer, Maastricht 2014

All rights reserved. No part of this publication may be reprinted or utilized in any form or by any electronic, mechanical or other means, now known, or hereafter invented, including photocopying and recording, or in any information storage or retrieval system, without permission from the copyright owner.

ISBN 978 94 6159 303 0
Layout and Printing by: Datawyse | Universitaire Pers Maastricht

Physiotherapy in Shoulder Impingement Syndrome

DISSERTATION

To obtain the degree of Doctor
at Maastricht University,
on the authority of the Rector Magnificus,
Prof. dr. L.L.G. Soete
in accordance with the decision of the Board of Deans,
to be defended in public on
Thursday, February 13 2014 at 14:00 hours

by

Thilo Oliver Kromer

UNIVERSITAIRE PERS MAASTRICHT

Supervisor
Prof. dr. R.A. de Bie

Co-supervisor
Dr. C.H.G. Bastiaenen

Assessment committee
Prof. dr. L.W. van Rhijn (chairman)
Prof. dr. IJ. Kant
Dr. A.J.A. Köke (Dept. Adult Revalidation, Hoensbroek)
Dr. M. Poeze
Prof. dr. J. Verbunt

The research presented in this thesis was conducted at the School for Public Health and primary Care: CAPHRI, Department of Epidemiology, of Maastricht University. CAPHRI participates in the Netherlands School for Primary Care research CaRe. CAPHRI was classified as excellent" by the external evaluation committee of leading international experts that reviewed CAPHRI in December 2010

Contents

Chapter 1	General introduction	7
Chapter 2	Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature	19
Chapter 3	Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. Study protocol.	47
Chapter 4	Physiotherapy in patients with clinical signs of shoulder impingement syndrome: a randomized controlled trial	71
Chapter 5	Effectiveness of physiotherapy and costs in patients with clinical signs of shoulder impingement syndrome: one year follow up of a randomized controlled trial.	95
Chapter 6	The influence of fear avoidance beliefs on pain and disability in patients with shoulder impingement syndrome in primary care: a secondary analysis	115
Chapter 7	General discussion	139
Addendum	Summary	162
	Zusammenfassung	166
	Acknowledgements	171
	Danksagung	173
	About the author	175
	List of publications	176

CHAPTER 1
General introduction

The central topic of this thesis focuses on the effect of manual physiotherapy in patients with shoulder impingement syndrome. This introduction gives an overview on shoulder complaints in general and on shoulder impingement syndrome (SIS) as the diagnostic sub-group of interest (1.1), outlines current treatment options for patients suffering from shoulder impingement (1.2), discusses principles of manual physiotherapy and its role in the treatment of SIS (1.3), and presents the objectives (1.4) and the outline of this thesis (1.5).

1.1. Shoulder complaints

Shoulder complaints are often seen in primary care. Incidence and prevalence data vary considerably in the literature. The incidence for different age groups ranges from 0.9 to 2.5%, point prevalence from 6.9% to 26%, 1-year-prevalence from 4.7% to 46.7%, and lifetime-prevalence from 6.7% to 66.7% (1). The annual prevalence and incidence of shoulder conditions presenting to UK primary care is given with 2.36% and 1.47% respectively (2). For the German speaking population no data are available at the moment. Only the Austrian National Health Survey (3) reports that about 6.2% of all responders reported shoulder pain during the last 12 months. All these data may to a great extent depend on the exact definition of shoulder complaints (4).

1.1.1. Definition

Shoulder complaints in general are mainly characterized by pain and functional restrictions but clinical signs and symptoms can be manyfold, depending on the anatomical structure affected and on the severity of the damage. Pain arising from affected shoulder structures is usually referred into the anterolateral arm (5). This specific pain localization is one important aspect in the diagnosis of shoulder disorders. For example pain arising from disorders of the acromioclavicular (ACJ) or sternoclavicular joints (SCJ) is usually localized locally at the affected joint itself or is referred into the trapezius muscle (5, 6) and can therefore be differentiated from shoulder pain. Pain referred from the cervical spine mimicking shoulder complaints often involves the neck itself, the trapezius region, or the scapular area, differs in quality and is usually reproduced by cervical movements quality of symptoms (7-9). Shoulder complaints seem to be recurring in nature and do not necessarily resolve over time. In a study by Croft et al. (10) only 21 % of patients reported complete recovery after 6 months and only 49% after 18 months. Van der Windt et al. (11) in another study noted that 41% of cases had symptoms persisting for longer than 1 year. My personal experience is that patients with shoulder complaints seem to wait a while longer before they visit a doctor than for example low back pain patients. They simply wait for the pain to settle maybe because shoulder pain does not have such an urgent, frightening and disabling charac-

ter in the beginning as for example low back pain (LBP) does. Possible reasons for that from my point of view are that especially in shoulder impingement complaints arise slowly over time affecting only specific activities, that the painful body part can be immobilized, controlled or compensated quite easily by using the healthy side. Furthermore the affected body part lies in the patients' visual field, can be easily touched or rubbed and has got a more peripheral location. All these aspects may modify the pain experience and makes it different from e.g. LBP.

1.1.2. "Diagnosis" subacromial impingement syndrome of the shoulder (SIS)

About 75% to 80% of patients presenting to primary care with shoulder pain show clinical signs of subacromial impingement (12-14). Subacromial impingement is caused by structures within the subacromial space that gets squeezed between the acromial arch (Fornix humeri) consisting of the acromion, the coracoid process, the coracoacromial ligament and the undersurface of the ACJ, and the humeral head. This occurs during active elevation of the arm when the humeral head and its tubercles move towards the acromial arch (15, 16), narrowing the available space. Possible structures at fault are the tendons of the rotator cuff, the long head of biceps, the subacromial bursa, and the joint capsule with its ligaments.

Symptoms arising from shoulder impingement syndrome (SIS) are pain and functional restrictions mostly during overhead activities in daily life or sporting activities (17). One typical finding during clinical examination is a painful range of motion between 60 and 120 degrees (painful arc) during active arm elevation that can be immediately reduced by passively supporting the arm in the painful position. SIS is further identified by positive impingement signs and painful resistance tests for the rotator cuff muscles. Minor passive range of motion (ROM) restrictions may be present but this is not the disabling component or main finding as it is for example in frozen shoulder. In literature the following factors are discussed potentially causing or contributing to SIS and therewith suggesting a multi-factorial aetiology: Strength, coordination and integrity of the rotator cuff (18-24) and the shoulder girdle muscles (25-29), mechanical or anatomical changes (30-32), hypo- or hypermobility of the glenohumeral joint or the scapula (22, 33-36), the cervical and upper thoracic spine, and posture (37, 38). The diagnosis of SIS is therefore mainly based on functional aspects and not necessarily on an affected anatomical structure (14, 39) and requires a thorough history and clinical examination, including aspects such as activity and participation restrictions, aggravating and easing factors, or the "patients' perspective on the situation". The last point, as a part of the yellow flag screening, tries to identify beliefs, attitudes and other circumstances that may represent an obstacle for a successful rehabilitation. In a clinical setting questions like "What do you think is the reason for your complaints?", "what can you do by yourself to ease your complaints?", "how does your fami-

ly/partner/colleagues react to your situation?" or "how do you feel because of your pain?" are helpful to get some information about it. For a more precise assessment specific questionnaires as for example the fear avoidance beliefs questionnaire (FABQ) (40) can be employed. Furthermore, other diagnoses such as frozen shoulder, gleno-humeral instability, ACJ-pathology, or referred pain from the cervical spine must be excluded. Frozen shoulder development is predominantly seen in women around the age of fifty, characterized by high and often constant pain and a marked active and passive joint restriction in external rotation and elevation; usually these complaints develop slowly without trauma. ACJ-pathology can be distinguished from SIS by pain localisation and is often caused by a direct fall on the edge of the shoulder. Gleno-humeral instability caused by a traumatic dislocation or repetitive overuse (e.g. seen in throwers or swimmers) is identified through the feeling of apprehension in shoulder abduction and external rotation, the feeling of subluxation with certain activities, with sudden stabbing pain or dead arm syndrome; in most cases patients are of younger age. Referred pain from the cervical spine can be differentiated by symptom quality and by a direct provocation of symptoms with active or passive cervical movements. These key signs help to distinguish the mentioned pathologies from SIS.

All clinical findings are finally summarized in a so called "clinical pattern", drawing a comprehensive picture of the patients' problem helping to find the important starting points for treatment. Tests used during physical examination of the patient do not only serve to identify an affected structure or a pathology but do also gain helpful information about its irritability and load capacity (e.g. with an isometric resistance test), which helps us to determine the initial dosage of the intervention. Information about the patients' perspective helps us to tailor information and education to the patients' needs and for example to adapt or to modify activities of daily living (ADL).

1.2. Treatment for SIS and its evidence base

Physiotherapeutic interventions offered for SIS can be divided into three groups: technical, active and passive. Technical interventions mainly comprise electrotherapy, ultrasound, shockwave therapy and laser therapy. Active interventions include different types of exercises, and passive treatments include therapeutic applications of e.g. massage, soft tissue or joint mobilisation techniques. These treatments are applied as single interventions or in combination with each other or even with other medical (invasive) interventions such as subacromial cortisone injections, acupuncture, or even surgery. Current evidence for the physiotherapeutic treatment of SIS, summarized in systematic reviews through the last years, supports the use of exercises in particular and the use of manual therapy as an additional treatment to exercises because it

seems to reinforce the effect of the exercise programme (41-45). According to this evidence several national treatment guidelines recommend the use of these interventions (39, 46, 47). However, evidence for manual therapy is based on only a few studies with small sample sizes and short follow up periods and is therefore deficient. Furthermore, these studies used either different types of exercises in their groups as a basic treatment, or applied a pre-defined set of manual techniques to all patients without considering the individual situation of the patient. Reasons for the selection or the combination of the exercises or the manual techniques used varied considerably between studies, were often not explained and thus remained unclear.

1.3. Manual physiotherapy

Manual physiotherapy comprises soft tissue, joint mobilization or manipulation techniques. Although the aims across different schools or concept are quite similar, techniques differ significantly in their execution, and practical application. However, they all are manually applied, leading to a more or less intensive mechanical stimulus. This stimulus is expected to relieve pain or increase mobility. The international federation of orthopaedic manipulative therapists (IFOMT) defined manual therapy as follows: *"Orthopaedic Manual Therapy is a specialized area of physiotherapy for the management of neuro-musculo-skeletal conditions, based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises"* (48).

Since this definition was made manual therapy has developed to a more holistic approach considering more and more aspects contributing to musculoskeletal pain and disability aside from hands-on techniques. This development is maybe also reflected in the name change from IFOMT into IFOMPT, the International Federation of Orthopaedic Manipulative Physical Therapists in 2009. This process is still driven by the quest for professional autonomy, a first contact policy in many countries, the growing importance of the ICF besides the ICD, and a more bio-psycho-social perspective in general. It has led to an increasing interest into superior clinical reasoning skills among practicing clinicians, helping them to make independent, accurate and appropriate decisions about diagnosis and treatment. The basic CR process can be described as a cycle of hypothesis generation, testing, and subsequent modification of hypotheses throughout the initial evaluation as well as throughout the ongoing management of a patients' problem (49) (figure 1.1). Integration of current evidence, pain sciences, the components of the ICF model leads to a more evidence based approach in clinical practice.

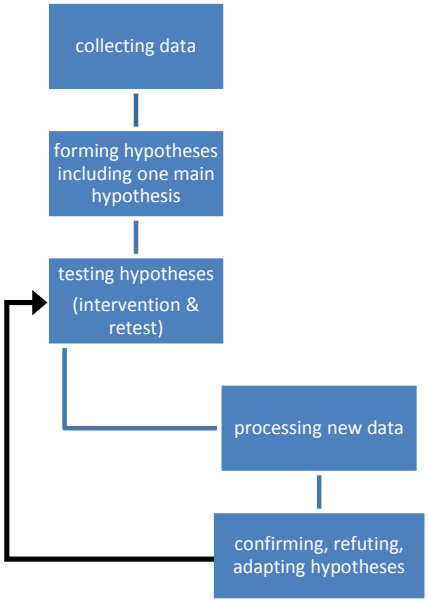


Figure 1.1 Adapted Clinical Reasoning Process – overview

1.3.1. Indications for manual physiotherapy in the treatment of SIS

Apart from the definition of manual therapy mentioned above, most of the factors causing or contributing to SIS do represent typical indications for manual mobilisation techniques. Besides local factors as for example posterior capsule tightness (36) especially the influence of the cervical and upper thoracic spine on shoulder complaints seems to be in the spotlight even if typical symptoms cannot be reproduced with active or passive movements during examination (39). And in fact, this seems to be reasonable because nearly 45% of shoulder patients do experience concurrent neck pain, which, if present, also seems to worsen prognosis (13). Further, restricted cervical and upper thoracic spine mobility may negatively influence range of motion and subacromial space width (37, 38).

1.4. Aim of this thesis

The aim of this thesis was to investigate the effect of individualized manual physiotherapy on pain and functioning in patients presenting with clinical signs and symptoms of SIS. To reflect current manual therapy with its modern principles, initially applied interventions were based on clinical examination results considering local factors, contributing factors and predictive factors (figure 1.2). Consecutive treatment deci-

sions were then based on a defined test-retest process. These aspects guarantee a progressive adaptation of the applied techniques to the development and current status of the patient and thus increase their effectiveness. Because of the current evidence for exercise therapy, manual physiotherapy was applied on top of an exercise programme. This combination also fulfils the recommendations made in literature not to test single interventions but combining different types of interventions, because this reflects current practice.

1.5. Outline of this thesis

The following chapters, except chapter 2 which is a systematic review of the literature, are based on data from a prospective randomized controlled trial about the effectiveness of manual physiotherapy and exercises in patients with SIS.

In **chapter 2** results of a systematic review are presented and discussed. This review was conducted to get a comprehensive overview about the topic and to analyse the state of current evidence at that point in time in the field of interest. The results served as a basis for planning an RCT.

In **chapter 3** the design of the randomized controlled trial is presented presenting detailed information about the background, participants, methods, and interventions.
Chapters 4 & 5 present and discuss the short and long term results of an RCT about the additional effect of individualized manual physiotherapy to exercises on pain and functioning compared to exercises alone. In chapter 5 also the direct and indirect costs are discussed.

Results about the influence of fear avoidance beliefs and catastrophizing on pain and disability at the time of inclusion are presented in **chapter 6**.
Chapter 7 reflects on the main findings of the previous chapters and discusses implications for clinical practice and further research; it closes with a personal point of view and final conclusion.

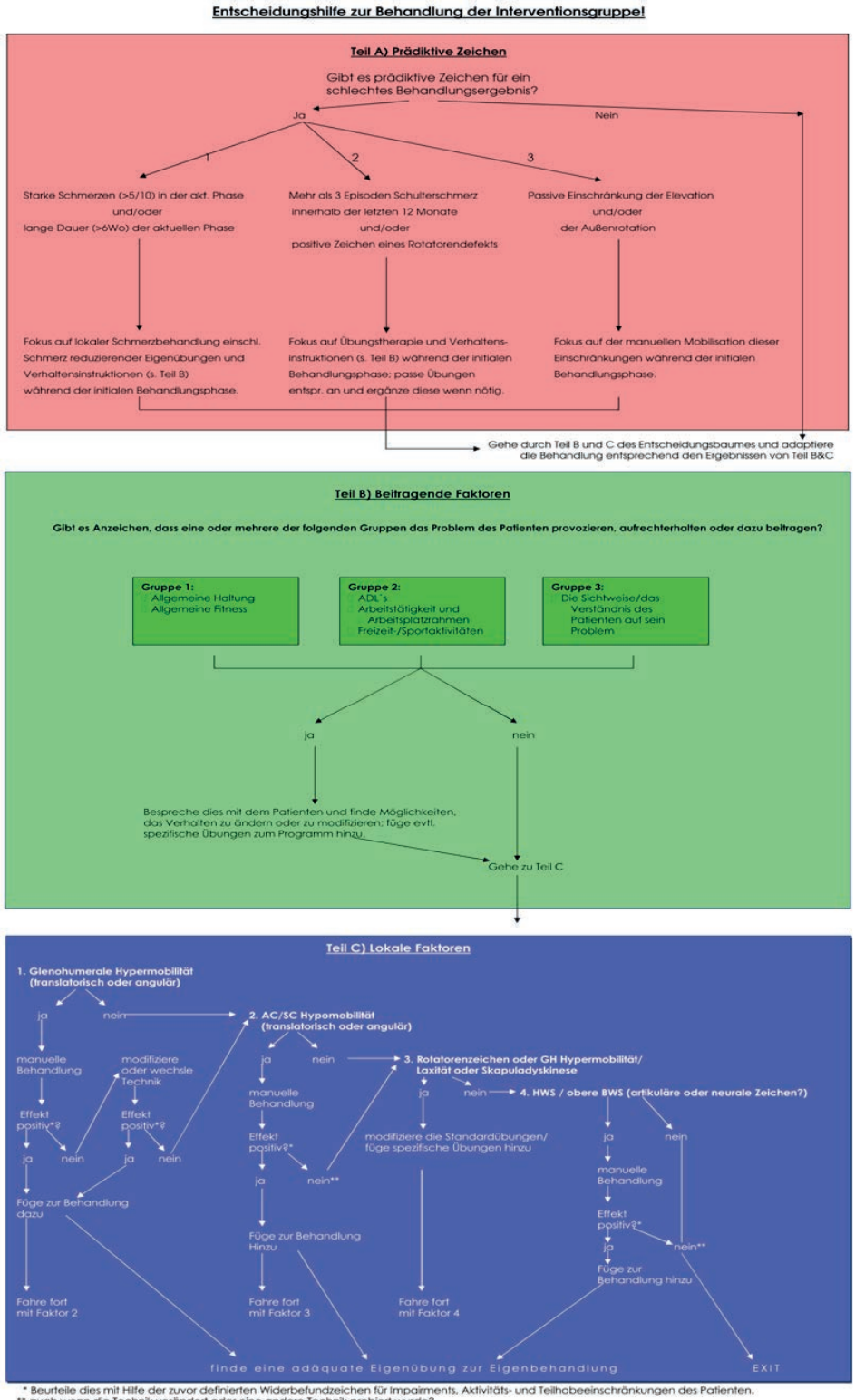


Figure 1.2 Decision aid

REFERENCES

1. Luime JJ. Shoulder complaints: the occurence, course and diagnosis [Proefschrift]. Rotterdam: Erasmus Universiteit; 2004.
2. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford) 2006; 45: 215-221.
3. Klimont J, Kytir J, Leitner B. Österreichische Gesundheitsbefragung 2006/2007 Wien: Bundesministerium für Gesundheit, Familie und Jugend2007.
4. Pope DP, Croft PR, Pritchard CM, Silman AJ. Prevalence of shoulder pain in the community: the influence of case definition. Annales of the Rheumatic Disease 1997; 56: 308-312.
5. Gerber C, Galantay RV, Hersche O. The pattern of pain produced by irritation of the acromioclavicular joint and the subacromial space. J Shoulder Elbow Surg 1998; 7: 352-355.
6. Hasset G, Barnsley L. Pain referral from the sternoclavicular joint: a study in normal volunteers. Rheumatology (Oxford) 2001; 40: 859-862.
7. Fukui S, Ohseto K, Shiotani M, Ohno K, Karasawa H, Naganuma Y, et al. Referred pain distribution of the cervical zygapophyseal joints and cervical dorsal rami. Pain 1996; 68: 79-83.
8. Gifford L. Acute low cervical nerve root pain: symptom presentations and pathobiological reasoning. Manual Therapy 2001; 6: 106-115.
9. Tanaka Y, Kokubun S, Sato T, Ozawa H. Cervical roots as origin of pain in the neck or scapular region. Spine 2006; 31: E568-E573.
10. Croft PR, Pope DP, Silman AJ. The clinical course of shoulder pain: prospective cohort study in primary care. Br Med J 1996 September 7; 313: 601-602.
11. van der Windt DAWM, Koes BW, Boeke AJP, Deville WLJM, de Jong BA, Bouter LM. Shoulder disorders in general pracitce: prognostic indicators for outcome. Br J Gen Pract 1996; 46: 519-523.
12. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. Rheumatology (Oxford) 2005; 44: 800-805.
13. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. Annals of Rheumatic Diseases 1995; 54: 959-964.
14. Winters JC, van der Windt DAWM, Spinnewijn WEM, De Jongh AC, van der Heijden GJMG, Buis PAJ, et al. NHG-Standaard Schouderklachten (Tweede herziening). Huisarts Wet 2008; 51: 555-565.
15. Graichen H, Stammberger T, Bonel H, Englmeier K-H, Reiser M, Eckstein F. Glenohumeral translation during acitve and passive elevation of the shoulder - a 3-D open MRI study. Journa of Biomechanics 2000; 33: 609-613.
16. Roberts CS, Davila JN, Hushek SG, Tillet ED, Corrigan TM. Magnetic resonance imaging analysis of the subacromial space in the impingement sign positions. J Shoulder Elbow Surg 2002; 11: 595-599.
17. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy 2001; 87: 458-469.
18. Deutsch A, Altchek DW, Schwartz E, Otis JC, Warren RF. Radiologic measurement of superior displacement of the humeral head in the impingement syndrome. J Shoulder Elbow Surg 1996; 5: 186-193.
19. Ebaugh DD, McClure PW, Karduna AR. Scapulotharacic and glenohumeral kinematics following an external rotation fatigue protocol. J Orthop Sports Phys Ther 2006; 36: 557-571.
20. Irlenbusch U, Gansen H-K. Muscle biopsy investigations on neuromuscular insufficiency of the rotator cuff: a contribution to the functional impingement of the shoulder. J Shoulder Elbow Surg 2003; 12: 422-426.

21. Leroux J-L, Codine P, Thomas E, Pocholle M, Mailhe D, Blotman F. Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. Clin Orthop 1994; 304: 108-113.
22. Meister K, Andrews JR. Classification and treatment of rotator cuff injuries in the overhead athlete. J Orthop Sports Phys Ther 1993; 18: 413-420.
23. Reddy AS, Mohr KJ, Pink MM, Jobe FW. Electromyographic analysis of the deltoid and rotator cuff muscles in persons with subacromial impingement syndrome. J Shoulder Elbow Surg 2000; 9: 519-523.
24. Sharkey NA, Marder RA. The rotator cuff opposes superior translation of the humeral head. The American Journal of Sports Medicine 1995; 23: 270-275.
25. Cools AM, Witvrouw EE, Declercq GA, Danneels LA, Cambier DC. Scapular muscle recruitment patterns: Trapezius muscle latency with and without impingement symptoms. The American Journal of Sports Medicine 2003; 31: 542-549.
26. Cools AM, Witvrouw EE, Mahieu NN, Danneels LA. Isokinetic scapular muscle performance in overhead athletes with and without impingement syndrome. Journal of Athletic Training 2005; 40: 104-110.
27. Kibler BW, Sciascia A. Current concepts: scapular dyskinesis. Br J Sports Med 2010; 44: 300-305.
28. Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. Phys Ther 2000; 80: 276-291.
29. Wadsworth DJS, Bullock-Saxton JE. Recruitment patterns of scapular rotator muscles in freestyle swimmers with subacromial impingement. Int Journal Sports Med 1997; 18: 618-624.
30. Bigliani LU, Morrison DS, April EW. Morphology of the acromion and its relationship to rotator cuff tears. Orthopaedic Trans 1986; 10: 459-460.
31. Neer CS. Anterior acromioplasty for the chronic impingement syndrome in the shoulder. J Bone Joint Surg Am 1972; 54-A: 41-50.
32. Neer CS. Impingement lesions. Clin Orthop 1983; 173: 70-77.
33. Glousman R, Jobe FW, Tibone J, Moynes D, Antonelli D, Perry J. Dynamic electromyographic analysis of the throwing shoulder with glenohumeral instability. J Bone Joint Surg Am 1988; 70A: 220-226.
34. Kibler BW. The role of the scapula in athletic shoulder function. Am J Sports Med 1998; 26: 325-337.
35. Matsen FA, Arntz CT, Lippitt SB. Rotator cuff. In: Rockwood CA, Matsen FA, editors. The Shoulder. 2 ed. Philadelphia: W.B. Saunders; 1998. p. 755-795.
36. Tyler TF, Nicholas SJ, Roy T, Gleim GW. Quantification of posterior capsule tightness and motion loss in patients with shoulder impingement. Am J Sports Med 2000; 28: 668-673.
37. Bullock MP, Foster NE, Wright CC. Shoulder impingement: the effect of sitting posture on shoulder pain and range of motion. Manual Therapy 2005; 10: 28-37.
38. Solem-Bertoft E, Thuomas K-A, Westerberg C-E. The Influence of scapular retraction and protraction on the width of the subacromial space. Clin Orthop 1993; 296: 99-103.
39. Jansen MJ, Brooijmans F, Geraets JJXR, Lenssen AF, Ottenheijm RPG, Penning LIF, et al. KNGF evidence statement subacromiale klachten. Tijdschrift voor Fysiotherapie 2011; 121: S1-14.
40. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low-back pain and disability. . Pain 1993; 52: 157–168.
41. Green SE, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD004258 2003.
42. Ho C-YC, Sole G, Munn J. The effectiveness of manual therapy in the management of musculoskeletal disorders of the shoulder: A systematic review. Manual Therapy 2009; 14: 463-474.
43. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. J Hand Ther 2004; 17: 152-164.
44. Braun C, Bularczyk M, Heintsch J, Hanchard NCA. Manual therapy and exercises for shoulder impingement revisited: a systematic review update. Physical Therapy Reviews 2013; in press.

45. Kuhn JE. Exercise in the treatment of rotator cuff impingement: A systematic review and a synthesized evidence-based rehabilitation protocol. J Shoulder Elbow Surg 2009; 18: 138-160.
46. Green S, Alexander M. Position statement on the efficacy of physiotherapy for shoulder disorders: a systematic review of the evidence. St. Kilda, Australia: Australian Physiotherapy Association; 2002.
47. AAOS. Optimizing the management of rotator cuff problems. Rosemount: American Academy of Orthopaedic Surgeons; 2010.
48. IFOMPT. OMT Definition. International Federation of Orthopaedic Manipulative Physical Therapists; 2004 [cited 2012 08 August]; Available from: http://www.ifompt.com/ReportsDocuments/-OMT+Definition.html.
49. Jones MA, Rivett DA. Clinical Reasoning for Manual Therapists. Edinburgh: Elsevier Limited; 2004.

CHAPTER 2

The effects of physiotherapy in patients with shoulder impingement syndrome: A systematic review of the literature

ABSTRACT

Objectives To critically summarize the effectiveness of physiotherapy in patients presenting clinical signs of shoulder impingement syndrome (SIS).
Design Systematic Review
Methods RCTs were searched electronically and manually from 1966 to December 2007. Study quality was independently assessed by two reviewers with the PEDro scale. If possible, relative risks (RR) and weighted mean differences were calculated for individual studies, RRs or standardized mean differences for pooled data, otherwise results were summarized in a best evidence synthesis.
Results Sixteen studies were included with a mean quality score of 6.8 points out of 10. Many different diagnostic criteria for SIS were applied. Physiotherapist-led exercises and surgery were equally effective treatments for SIS in the long term. Also home based exercises were as effective as combined physiotherapy interventions. Adding manual therapy to exercise programs may have an additional benefit on pain at three weeks follow up. Moderate evidence exist that passive treatments are not effective and cannot be justified.
Conclusion This review shows an equal effectiveness of physiotherapist-led exercises compared to surgery in the long term and of home based exercises compared to combined physiotherapy interventions in patients with SIS in the short and long term; passive treatments cannot be recommended for SIS. However, in general the samples were small and different diagnostic criteria were applied which makes a firm conclusion difficult. More high quality trials with longer follow ups are recommended.

Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CHG. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. Journal of Rehabilitation Medicine 2009;41(11):470-80

INTRODUCTION

Many primary care patients with shoulder complaints show clinical signs of subacromial impingement and rotator cuff tendinopathy (1, 2). Subacromial impingement syndrome of the shoulder (SIS) is characterized by pain and functional restrictions, mostly during overhead activities (3). Many clinicians belief that the diagnosis shoulder pain is too broad to provide sufficient information to develop specific treatment protocols in daily practice. Systematic reviews on the rehabilitation of patients with SIS included studies in which patients had received surgery beforehand, used conflicting criteria defining the same condition (4-7), and sometimes included invasive interventions not relevant for physiotherapists (8, 9). The present review aims to summarize current evidence available for the effectiveness of physiotherapy in the treatment of patients presenting with clinical signs indicative for SIS. Therefore, studies were included if shoulder patients were either diagnosed with SIS or showed one of the following positive clinical signs indicating SIS: pain aggravating with overhead activity, a painful arc, a Neer impingement test, or a Hawkins-Kennedy test. Although the diagnostic value of these tests in terms of sensitivity and specificity is not clear (10), focusing on important clinical signs guiding inclusion criteria for a review seems to correspond better with daily clinical practice. In primary care general practitioners and physiotherapists often rely solely on clinical signs and symptoms to establish a diagnosis and to determine the focus of treatment (11, 12). To further strengthen this review only randomized controlled trials of high methodological quality were included.

METHODS

Literature search / search strategy

The following databases were searched electronically: MEDLINE (from 1966 to December 2007), EMBASE (from 1988 to December 2007), CINAHL (from 1982 to December 2007), the Cochrane database of systematic reviews (to December 2007), the Cochrane Central Register of Controlled Trials (to December 2007), PEDro (to December 2007). We therefore used the following MeSH terms and keywords: `Physiotherapy`, `Physical Therapy Specialty`, `Physical Therapy Modalities`, `Musculoskeletal Manipulations`, `Shoulder Impingement Syndrome`, `Shoulder Joint`, `Shoulder Pain`, Tendinopathy`, `Rotator cuff`, `Exercise Therapy`, `Exercise Movement Technique`, `Electric Stimulation Therapy`, `Massage`. Additionally the “Cochrane optimum trial search strategy” (13) was executed in Medline. Further, reference lists from retrieved articles and systematic reviews were screened for additional relevant publications.

Inclusion criteria

To minimize bias this review contains only randomized controlled trials. Articles written in English, German and Dutch were considered eligible. All identified articles were judged for eligibility by title and abstract. If eligibility was unclear, a full text version of the article was retrieved. For the screening process a standardized eligibility form was used. Unclear articles were read by a second reviewer (UGT) and discussed until consensus was reached. For inclusion of a study, participants must demonstrate the clinical pattern of SIS. Therefore, studies in which participants have been diagnosed with SIS were included. Further, other studies were also included if the patients showed at least one of the following signs typical for SIS: pain with overhead activities, painful arc sign, Neer impingement sign, or a positive Hawkins-Kennedy sign. All subjects had to be older than sixteen years of age. Studies including subjects with adhesive capsulitis, frozen shoulder, osteoarthritis, fractures, systemic infections and systemic diseases, neoplasm or metastasis, and professional athletes were excluded. All forms of active and passive physiotherapeutic interventions including exercises, proprioceptive training, manual therapy, massage therapy, education, and electrophysical procedures were included. They could have been compared to no intervention, placebo treatment, other physiotherapeutic procedures, to each other, or even to surgical interventions. If a combination of therapies was applied, the main intervention and the co-interventions must have been clearly defined to assign the study to a specific intervention. If the main intervention was not defined or unclear, it was assigned to the group of “combined physiotherapy interventions”. Comparisons between invasive techniques as for example acupuncture, injections, or surgical interventions were not considered.

Outcome measures

The focus of this review lies on outcome measures for pain and functioning.

Quality assessment

All studies were scored with the PEDro critical appraisal tool for experimental studies in physiotherapy (http://www.pedro.fhs.usyd.edu.au). PEDro is a reliable tool (14) and contains 8 criteria for assessing internal validity of a study, and 2 criteria for assessing sufficiency of the statistical information displayed. Each criterion can be answered with `yes` or `no`. `Yes` was rated with one point, `no` with zero points. Thus, the possible maximum score is 10 points. . A detailed description of the PEDro criteria is provided in table 1. If a criterion was unclear even after discussion, no point was awarded. All

articles were independently rated by a second reviewer (UGT); inconsistency of the ratings was discussed and solved by consensus. To improve the validity of the results, only studies of a high methodological quality, defined as a minimum PEDro score of five out of ten, were included in this review.

Table 1 Criteria of the PEDro critical appraisal tool for RCTs[a]

1	subjects were randomly allocated into groups (in a crossover study, subjects were randomly allocated in order in which treatments were received)
2	allocation was concealed
3	the groups were similar at baseline regarding the most important prognostic indicators
4	there was blinding of all subjects
5	there was blinding of all therapists who administered the therapy
6	there was blinding of all assessors who measured at least one key outcome
7	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated
8	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”
9	the results of between-group statistical comparisons are reported for at least one key outcome
10	the study provides both, point measures and measures of variability for at least one key outcome

[a] Randomized controlled trial

Data extraction and analysis

Data from studies were extracted with the help of a standardized data extraction form. When sufficient data were provided, relative risks (RR) with a 95% confidence interval (CI95%) were calculated for dichotomous data, weighted mean differences (WMD) with CI95% were calculated for continuous data. When possible and appropriate, studies were pooled for meta-analytical purposes. Data were calculated with Review Manager (ver. 4.2.9) from the Cochrane Collaboration (15). When pooling was not possible a best evidence synthesis was done using the levels of evidence described by van Tulder et al. (16), provided in table 2. Consistency of results was given if more than 75% of the studies showed results in the same direction.

Table 2 Levels of evidence

Strong	consistent findings among multiple high quality RCTs[a]
Moderate	consistent findings among multiple low quality RCTs and/or CCTs[b] and/or one high quality RCT
Limited	one low quality RCT and/or CCT
Conflicting	inconsistent findings among multiple trials (RCTs and/or CCTs)
No evidence from trials	no RCTs or CCTs

[a] Randomized controlled trial [b] Controlled clinical trial

RESULTS

Search results

The initial search resulted in 3465 hits. After screening the articles by title and abstract, and after deleting duplicates 66 articles remained. Additional screening of identified systematic reviews added another two articles. The Cochrane optimum search strategy executed in Medline identified no additional papers. Therefore, 68 full text papers were retrieved for detailed evaluation with the help of a standardized eligibility form. 45 papers were excluded because of inappropriate diagnosis, study design, intervention, or participants. Another 5 studies (17-21) were excluded because of a methodological quality score below five out of ten. At last 18 articles could be included in this review, whereas 2 studies (22, 23) were follow ups of the initial studies (24, 25) so that finally 16 studies remained. A flow chart of the search process is given in figure 1.

Quality of studies

The average methodological quality of all studies included was 6.8 (range 5 to 9) out of 10; results of the methodological quality scorings for included studies are shown in table 3. Although random allocation was done in all studies, only in four studies treatment allocation was concealed (25-28) but not properly described. Subjects were blinded in six studies (29-34), therapists in four (29-32) and assessors in twelve studies (24, 27-37). In all studies except one (26) groups were comparable at baseline. Only one study (34) lost more than 15% of the patients which were initially allocated to the groups during follow-up. The median follow up time of the included studies was 11 (range 3 to 416) weeks.

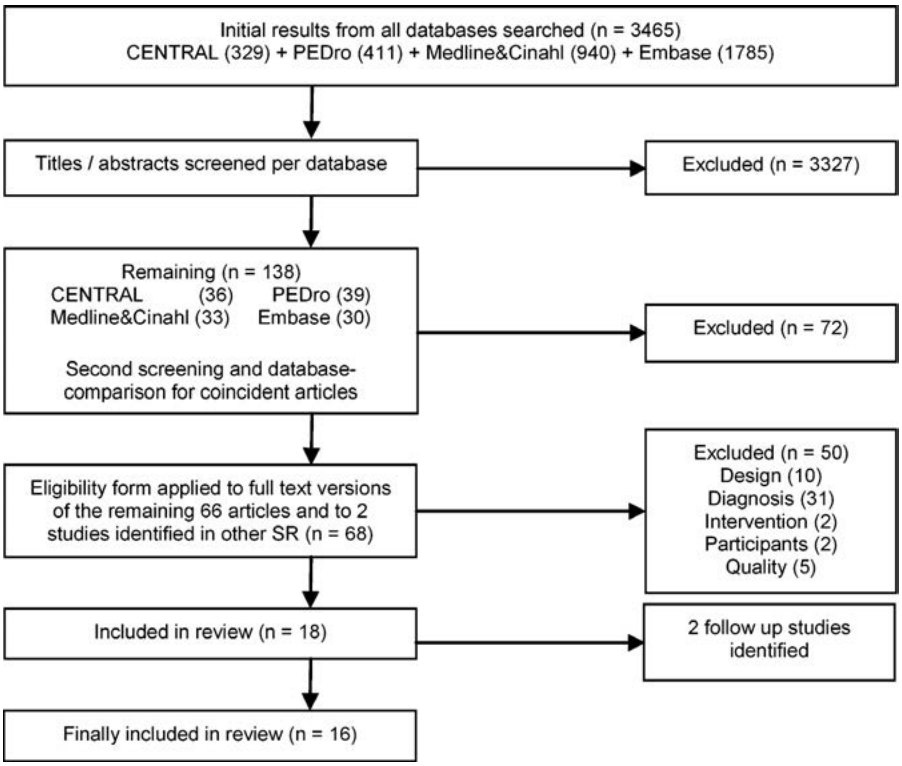


Figure 1 Search and screening process. SR: systematic reviews

Population

The median sample size of the included studies was 56 (range 14 to 138) patients. All studies except one (26) included men and women with a similar mean age. Unfortunately, information about the duration of symptoms was missing in four studies (26, 27, 29, 37). A detailed description of the population is given in table 4.

Outcome measures

All studies measured pain and functioning, but with a lot of different types of assessment methods and tools. The measurement instruments used in each study are provided and described in table 5.

Table 3 Scorings of methodological quality of included studies

Item number	1	2	3	4	5	6	7	8	9	10	
Study	random allocation	concealed allocation	baseline comparability	blinding subject	blinding therapists	blinding assessors	outcome data >85%	intention to treat	between group results	point measures/ measures of variability	Pedro score
Aktas et al. (32)	1	0	1	1	1	1	1	0	1	1	8
Bang & Deyle (36)	1	0	1	0	0	1	1	0	1	1	6
Binder et al. (33)	1	0	1	1	0	1	1	0	1	0	6
Brox et al. (22,24)	1	0	1	0	0	1	1	1	1	1	7
Chard et al. (34)	1	0	1	1	0	1	0	0	1	0	5
Conroy & Hayes (37)	1	0	1	0	0	1	1	0	1	1	6
Dickens et al. (27)	1	1	1	0	0	1	1	1	1	1	8
Ginn & Cohen (35)	1	0	1	0	0	1	1	0	1	1	6
Haahr et al. (23,25)	1	1	1	0	0	0	1	1	1	1	7
Johansson et al. (28)	1	1	1	0	0	1	1	1	1	1	8
Ludewig & Borstad (26)	1	1	0	0	0	0	1	1	1	1	6
Nykanen (29)	1	0	1	1	1	1	1	0	1	1	8
Saunders (30)	1	0	1	1	1	1	1	1	1	1	9
Vecchio et al. (31)	1	0	1	1	1	1	1	0	1	1	8
Walther et al. (38)	1	0	1	0	0	0	1	1	1	0	5
Werner et al. (39)	1	0	1	0	0	0	1	1	1	0	5

Table 4 Overview of included studies – quality, population, and intervention

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
Dickens et al. (27) 8	Sample: n=85, (37 f, 48 m) mean (range) age 55 years (27-68), all on a waiting list for surgery Duration of symptoms: NA Follow up: 6 months Drop outs: 12	Diagnosis: subacromial impingement syndrome Inclusion criteria: 1. clinical history and examination; 2. radiographic findings; 3. diagnostic local anaesthetic injections into the subacromial space and ac-joint.	Group 1 (n=45): individualized rehabilitation program based on the findings from the initial assessment; all patients received all or some of the following modalities: physiotherapy once or twice a week including mobilisation of acromioclavicular joint, cervical spine, thoracic spine, glenohumeral joint, postural advice, strapping, electrotherapy; progressive exercise therapy (for scapulothoracic and rotator cuff muscles) with theraband resistance; after sufficient instruction, exercises were performed twice a day at home. Group 2 (n=40): no intervention. Additional interventions for both groups: analgesics as necessary.
Ludewig & Borstad (26) 6	Sample: n=67, all male, mean age 49 years Duration of symptoms: NA Follow up: 10 weeks Drop outs: no	Diagnosis: impingement syndrome Inclusion criteria: 1. current pain in the glenohumeral joint region; 2. at least two positive impingement signs (Neer, Hawkins/Kennedy, Yocum, Jobe, Speeds test) and pain reproduction during two of the three categories: 1. painful arc with active abduction; 2. tenderness with palpation of the rotator cuff or biceps tendon; 3. pain with one or more glenohumeral joint movements (FLEX, ABD, IR, ER).	Group 1 (n=34): daily home based exercises for 10 weeks including pectoralis minor stretch, posterior shoulder stretch, trapezius relaxation exercise, strengthening of serratus anterior with dumbbells, and of shoulder ER with theraband resistance. Group 2 (n=33): no intervention. Group 3 (n=25, healthy controls): no intervention.
Walther et al. (38) 5	Sample: n=60, (26 f, 34 m) mean (range) age Group 1: 52 years (40-66); Group 2: 51.5 years (37-66); Group 3: 48.6 years (25-61) Duration of symptoms (mean): Group 1: 23 months;	Diagnosis: impingement syndrome Inclusion criteria: 1. clinical examination; 2. radiographs in three planes; 3. ultrasound; 4. subacromial injection of 10ml bupivacaine (Neer test).	Group 1 (n=20): exercises 5 times a week for 12 weeks including isometric strengthening of shoulder ABD, ER and EXT, and rowing with a theraband; trapezius and supraspinatus stretching, pendulum exercises with a dumbbell. Group 2 (n=20): physiotherapy for 12 weeks (mean: 30 sessions). Instructions were “centering training for the shoulder rotators and stretching”.

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
	Group 2: 32 months; Group 3: 27 months Follow up: 6, 12 weeks Drop outs: no		Group 3 (n=20): functional brace for 12 weeks during the day and night if possible. Additional interventions for both groups: NSAIDs as necessary.
Werner et al. (39) 5	Sample: n=40, (20 f, 20 m) mean (range) age Group 1: 52 years (40-66); Group 2: 51.5 years (37-66) Duration of symptoms (mean): Group 1: 23 months; Group 2: 32 months Follow up: 6, 12 weeks Drop outs: no	Diagnosis: impingement syndrome Inclusion criteria: 1. clinical examination; 2. radiological examination; 3. sonographic assessment.	Group 1 (n=20): exercises 5 times a week for 12 weeks, including isometric strengthening of shoulder ABD, ER and EXT, and rowing with a theraband; trapezius and supraspinatus stretching, pendulum exercises with a dumbbell. Group 2 (n=20): physiotherapy for 12 weeks (mean: 30 sessions); instructions were “centering training for the shoulder rotators and mobilization”. Additional interventions for both groups: NSAIDs as necessary.
Ginn & Cohen (35) 6	Sample: n=138, (56 f, 82 m) mean age (range) 55 years (22-90), subgroup impingement: n=61 Duration of symptoms (mean): Group 1: 7.4 months; Group 2: 7.3 months ; Group 3: 7.4 months Follow up: 5 weeks Drop outs: subgroup impingement: 5	Diagnosis: shoulder pain Inclusion criteria: 1. over 18 years of age; 2. unilateral shoulder pain with local mechanical origin; 3. more than 1 month duration; 5.pain exacerbated with active movements; 6. all patients in the impingement subgroup showed a painful arc of flexion and/or abduction.	Group 1 (n=48): single subacromial injection with methylprednisone acetate. Group 2 (n=48): daily home-based exercises for 5 weeks, individualized for each patient on the basis of the initial assessment, supervision once a week for progression; exercises to restore dynamic stability and co-ordination of the shoulder muscles including stretching of shortened muscles, strengthening of weak muscles, motor retraining to improve scapula-humeral rhythm and co-ordination between muscles. Group 3 (n=42): electrophysical modalities (interferential therapy, ultrasound, ice packs, hot packs) twice a week; passive joint mobilization of the glenohumeral, acromioclavicular and sternoclavicular joints twice a week based on the information from the initial examination; daily ROM exercises (ABD, FLEX, EXT, horizontal FLEX and EXT, HBB) against elastic resistance for 5 weeks

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
			to increase range of hand placement. Additional interventions for both groups: patients were requested not to commence or change medication during the study.
Bang & Deyle (36) 6	Sample: n=52, (22 f, 30 m) mean (SD) age 43 years (9.1) Duration of symptoms (mean): Group 1: 5.6 months; Group 2: 4.4 months Follow up: after treatment & 2 months Drop outs: 2	Diagnosis: impingement syndrome Inclusion criteria: one test of category 1 must be positive together with one positive test of category 2 or 3. Category 1: passive shoulder flexion with scapula stabilized, passive internal rotation at 90° shoulder flexion in the scapular plane and in progressive degrees of shoulder adduction. Category 2: active shoulder abduction. Category 3: resisted break-test in ABD, resisted break-test in ER or IR.	Group 1 (n=28): 6 sessions of physiotherapist-led exercises (see group 2) plus manual therapy within 3 weeks; application of manual therapy techniques based on information from a detailed examination of the patient aiming to restore mobility of the glenohumeral joint, shoulder girdle, thoracic spine, and cervical spine; other treatments were soft tissue massage and stretching of the pectoralis major, infraspinatus, teres minor, upper trapezius, sternocleidomastoid, and scalenus musculature; specific home exercises were given to the patient to reinforce manual treatment. Group 2 (n=23): 6 physiotherapist-led sessions of a standardized flexibility and strengthening program in 6 levels of tubing resistance within 3 weeks including shoulder FLEX, scaption, rowing, horizontal extension-external rotation, seated press up, elbow push up plus, stretches for the anterior and posterior shoulder musculature. Additional interventions for both groups: patients remained on current medication levels during the study.
Conroy & Hayes (37) 6	Sample: n=14, (6 f, 8 m) mean age 52.9 years Duration of symptoms: NA Follow up: after treatment Drop outs: 1	Diagnosis: primary impingement syndrome Inclusion criteria: 1. pain about the superolateral shoulder region and one or more of the following: a) active ROM deficits in humeral elevation; b) painful subacromial compression; c) limited functional movement patterns in an elevated position.	Group 1 (n=7): 9 sessions within 3 weeks (see group 2) plus manual mobilization of the subacromial and glenohumeral joints including inferior, posterior, and anterior glides, and long-axis traction depending on the results of the initial examination. Group 2 (n=7): 9 physiotherapist-led sessions within 3 weeks including: hot packs; stretching exercises (cane-assisted FLEX and ER, towel-assisted IR, arm-assisted horizontal adduction); strengthening exercises (chair press, IR and ER isometrics);

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
			pendulum exercises and exercises for postural correction; 10 minutes of soft tissue mobilization (effleurage, friction and kneading techniques).
Brox et al. (22,24) 7	Sample: n=125, f (%): age years (range): 18-66 Group 1: 36; Group 2: 50; Group 3: 56 Duration of symptoms ITT, n= Group 1: < 6 months: 8; 6-12 months: 8; 1-3 years: 9; > 3years: 20 Group 2: < 6 months: 5; 6-12 months: 5; 1-3 years: 5; > 3years: 14 Group 3: < 6 months: 6; 6-12 months: 6; 1-3 years: 13; > 3 years: 25 Follow up: 3, 6 months, 2.5 years. Drop outs: 25 at 3 months, 5 at 6 months, 12 at 2.5 years	Diagnosis: stage 2 impingement Inclusion criteria: 1. 18-66 years of age; 2. shoulder pain for at least three months resistant to physiotherapy and non-steroid and steroid anti-inflammatory medication; 3. dysfunction or painful arc on ABD; 4. pain (2 out of 3) with resisted or eccentric ABD in 0°, ABD in 30° or ER of the shoulder; 5. positive impingement tests; 6. normal glenohumeral ROM; diagnosis was confirmed with subacromial injection of Lignocaine (pain-free after 15min).	Group 1 (n=45): arthroscopic surgery consisting of bursectomy and resection of the lateral and anterior part of the acromion and the coracoacromial ligament followed by physiotherapy and exercises. Group 2 (n=30): 12 sessions of placebo laser within 6 weeks. Group 3 (n=50): two supervised exercise sessions per week plus home exercises on the other days for 3 to 6 months with supervision gradually being reduced; initially relaxed repetitive movements for rotation, FLEX, EXT, ABD, and ADD; then gradually added resistance to strengthen the short rotators and the scapula-stabilizing muscles; three lessons of education about shoulder anatomy and function, ergonomics, and pain management. Additional interventions for both groups: NSAIDs and analgesics were allowed.
Haahr et al. (23,25) 7	Sample: n=84, (58 f, 26 m) mean (SD) age 44,4 years (7,8) Duration of symptoms, n= Group 1: < 6 months: 3; 6-12 months: 10; >12 months 29 Group 2: < 6 months: 4; 6-12 months: 3; > 12 months 34 Follow up: 3, 6, 12 months; 4, 8 years Drop outs: 5 at 4 to 8 years-follow up	Diagnosis: subacromial impingement syndrome Inclusion criteria: 1. 18-55 years of age; 2. shoulder pain; 3. symptoms between three months and three years; 4. painful arc on ABD; 5. positive impingement sign (Hawkins sign); 6. positive impingement test.	Group 1 (n=43): 19 sessions physiotherapy (up to 60 minutes each) within 12 weeks including heat application, cold packs or soft tissue treatments; active training of the periscapular muscles; strengthening of the rotator cuff; active exercises were done at home daily for another 12 weeks, then the frequency was reduced to three times a week. Group 2 (n=41): subacromial decompression (bursectomy with partial resection of the antero-inferior part of the acromion and the coracoacromial ligament) followed by active home exercises including rotator cuff exercises for 6 to 8 weeks.

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
Nykänen (29) 8	Sample: n=73, (11 f, 62 m) mean (SD) age Group 1: 66 (6); Group 2: 67 (9) Duration of symptoms: NA Follow up: 1, 4, 12 months Drop outs: 8	Diagnosis: painful shoulder Inclusion criteria: 1. shoulder pain of at least two months duration; 2. painful arc between 40°-120° of ABD or other painful movements; 3. painful supraspinatus test.	Group 1 (n=36): 10min of ultrasound (pulse ratio 1:4, intensity 1w/cm2, frequency 1.0 mHz); 10-12 sessions within 3-4 weeks. Group 2 (n=37): sham treatment. Additional interventions for both groups: massage of neck and shoulder muscles; group gymnastics to stretch and strengthen the scapulo-humeral and cervical musculature; NSAIDs and analgesics as necessary.
Johansson et al. (28) 8	Sample: n=85, (59 f, 26 m) mean (SD) age Group 1: 49 (7); Group 2: 49 (8) Duration of symptoms, n= Group 1: 2-3 months: 13; 4-6 months: 8; 7-12 months: 10; > 12 months: 13 Group 2: 2-3 months: 11; 4-6 months: 10; 7-12 months: 11; > 12 months: 9 Follow up: 5 weeks; 3, 6, 12 months Drop outs: 21	Diagnosis: impingement syndrome Inclusion criteria: 1. 30-65 years of age; 2. pain located in the proximal lateral aspect of the upper arm, especially during arm elevation; 3. positive Neer impingement test; 4. at least two months duration.	Group1 (n=44): 10 sessions acupuncture (30minutes each) within 5 weeks; needling of 4 local and one distal point. Group 2 (n=41): 10 sessions of continuous ultrasound for 10 minutes each (intensity 1w/cm2, frequency 1.0mHz) within 5 weeks, located inferior to the anterior and lateral part of the acromion. Additional interventions for both groups: daily home exercises for 5 weeks: active/assistive FLEX; active ER; isometric FLEX, EXT, IR and ER, ABD; ER with a rubber tube; medication if necessary.
Saunders (30) 9	Sample: n=24, (12 f, 12 m) mean (SD) age 50.3 years (8.2) Duration of symptoms (mean): Group 1: 3.86 months; Group 2: 3.32 months Follow up: 3 weeks Drop outs: no	Diagnosis: supraspinatus tendinitis Inclusion criteria: 1. full passive ROM of the shoulder; 2. impingement on full elevation; 3. pain on resisted ABD in an "empty can position"; 4. tenderness on palpation of the tendon.	Group 1 (n=12): 180 sec laser treatment, 3 sessions per week for 3 weeks; intensity 40 mW, 30 J/cm2 at the surface, located at the point of maximum tenderness at the anterior shoulder and the tendon below the acromion with the patient`s hand placed behind the back. Group 2 (n=12): sham laser. Additional interventions for both groups: advice on how to use the arm with tape and written instructions.
Vecchio et al. (31) 8	Sample: n=35, (25 f, 10 m) mean (range) age 54.4 years (17 to 77)	Diagnosis: rotator cuff tendinitis Inclusion criteria: 1. painful arc between 40-120° of	Group 1 (n=19): 2 laser sessions of 10min twice a week for 8 weeks; intensity 30 mW, 1 J/3mm2; three pulses (3 J) to 5 points of

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
	Duration of symptoms (mean): 14.9 months (whole sample) Follow up: 4, 8 weeks Drop outs: no	ABD; 2. painful resisted movement of ABD, IR or ER.	maximum tenderness in the subacromial an anterior shoulder regions found on clinical examination. Group 2 (n=16): sham treatment. Additional treatment for both groups: home exercises including: pendulum exercises in FLEX and EXT, ABD and ADD, wall climbing exercises; 2mg Paracetamol daily if necessary.
Aktas et al. (32) 8	Sample: n=46, (30 f, 10 m) (without drop-outs); mean(SD) age Group 1: 48.7 (9.0); Group 2: 53.9 (11.2) Duration of symptoms (mean): Group 1: 4.8 months; Group 2: 4.8 months Follow up: 3 weeks Drop outs: 6	Diagnosis: subacromial impingement syndrome Inclusion criteria: 1. radiography and magnetic resonance imaging; 2. positive subacromial injection test; 3. positive impingement tests (Neer, Hawkins-Kennedy, painful arc).	Both groups: Codman's pendulum exercises for 3 weeks, 5 times a day and subsequent cold application for 20 minutes; meloxicam tablet 15mg daily. Group 1 (n=23): 25 minutes pulsed electromagnetic field therapy, 5 days a week for 3 weeks. Group 2 (n=23): sham treatment.
Binder et al. (33) 6	Sample: n=29, (8 f, 21 m) mean age Group 1: 54.4; Group 2: 53.2 Duration of symptoms (mean): Group 1: 9.2 months; Group 2: 9.5 months Follow up: 4, 6, 8, 16 weeks Drop outs: no	Diagnosis: rotator cuff tendinitis Inclusion criteria: 1. shoulder pain aggravated by movement against resistance in ABD, IR or ER; 2. active movements limited by pain; 3. full passive ROM; 4. painful arc on ABD.	Group 1 (n=15): daily pulsed electromagnetic field therapy for 8 weeks; patients used the coil for 5 to 9 hours with each treatment session lasting at least 1 hour. Group 2 (n=14): sham treatment (4 weeks), then real treatment (4 weeks). Additional treatment for both groups: Paracetamol as necessary.
Chard et al. (34) 5	Sample: n=49, (18 f, 25 m) (without drop-outs), mean age (without drop outs) Group 1: 50.1;	Diagnosis: rotator cuff tendinitis Inclusion criteria: 1. shoulder pain aggravated by movement against resistance in ABD, IR or ER; 2. active movements limited by pain; 3. full passive	Group 1 (n=25): low dose electromagnetic field therapy for 2 hours daily; application with a "live unit" and a coil switching off after 2 hours; patients wore the unit for 8 hours daily. Group 2 (n=24): low dose electromagnetic field therapy for 8hours

Study/Quality score	Population	Diagnosis / Inclusion criteria	Intervention
	Group 2: 52.8 Duration of symptoms (mean): Group 1: 14.6 months; Group 2: 14.2 months Follow up: 2, 4, 6, 8 weeks Drop outs: 6	ROM; 4. painful arc on ABD.	daily; application with a “live unit” 8 hours daily. Additional treatment for both groups: NSAID`s as necessary.

ABD: abduction; ADD: adduction; ER: external rotation; EXT: extension; f: female; FLEX: flexion; HBB: hand behind back; IR: internal rotation; ITT: intention to treat; m: male; NA: not available; NSAIDs: non-steroidal anti-inflammatory drugs; ROM: range of motion; SD: standard deviation.

Table 5 Overview of included studies – outcome measures and results

Study	Outcome measures (pain & function)		Results for between-groups-comparison	WMD(95%CI) (fixed effects model)	RR(95%CI) (fixed effects model)
Dickens et al. (27)	*Patients refused surgery after intervention*	6 months	+		21.93 (1.34 to 360.2)
Ludewig & Borstad (26)	*Shoulder rating questionnaire* (for function)	10 weeks	+ (G1 vs.G2) + (G3 vs.G1)	6.9 (0.6 to 13.2) 16.0 (9.1 to 22.9)	
	Work related pain (6 items scored on a 1-10-point scale)	10 weeks	+ (G1 vs.G2) + (G3 vs.G1)	1.3 (0.5 to 2.1) 1.4 (0.5 to 2.3)	
	Work related disability (4 items scored on a 1-10-point scale)	10 weeks	+ (G1 vs.G2) + (G3 vs.G1)	1.2 (0.4 to 2.0) 1.2 (0.3 to 2.1)	
Walther et al. (38)	*Constant-Murley-Score* (total score only) (ranges from 0-100 points with higher scores indicative of better function. subscales for function (60pts), pain (15pts), and strength (25pts))		0 between all groups and for all follow ups		
Werner et al. (39)	*Constant-Murley-Score* (total score only) (ranges from 0-100 points with higher scores indicative of better function. subscales for function (60pts), pain (15pts), and strength (25pts))		0 for all follow ups		
Ginn & Cohen (35)	*Pain with a standardized reaching task* (rated on a VAS 0-10)	5 weeks	0 between all groups		
	Self-reported functional limitation score (9 items scored on a 0-4 point scale)	5 weeks	0 between all groups		
Bang & Deyle (36)	*Self-reported functional assessment questionnaire* (9 items, 0-5 point scale)	AT 2 months	+ +	4.7 (1.3 to 8.6)	
	Pain composite score (active ABD, resisted ABD, IR, ER, and functional pain, all scored on a VAS)	AT	+	186.2 (55.3 to 317.2)	
	Functional pain score (9 items scored on a VAS)	AT 2 months	+ +	128.7 (39.4 to 218.0)	

Study	Outcome measures (pain & function)		Results for between-groups-comparison	WMD(95%CI) (fixed effects model)	RR(95%CI) (fixed effects model)
Conroy & Hayes (37)	*Maximum 24 hours pain* (scored on a VAS 0-10)	AT	+	33.4 (6.4 to 60.4)	
	Pain with subacromial compression (scored on a VAS 0-10)	AT	+	31.1 (4.6 to 57.6)	
	Overhead function (3 overhead activities scored on a 3-point scale)	AT	0		
Brox et al. (22,24)	*Neer shoulder score > 80 points* (ranges 10-100 points with higher scores indicative of better function. subscales for pain (35pts), function (30pts), active ROM (25pts), anatomical & radiological evaluation (10pts).	6 months (ITT)	+ (G1 vs. G2) + (G3 vs. G2) 0 (G1 vs. G3)		
	Neer shoulder score > 80 points	2.5 years (ITT)	+ (G1 vs. G2) + (G3 vs. G2) 0 (G1 vs. G3)		2.7 (1.4 to 5.4) 2.5 (1.2 to 4.9) 0.9 (0.7 to 1.2)
	Pain with activity, at rest, and at night (scored on a 1-9 point scale)	3 & 6 months	+ (G1&3 vs.G2) + (G1 vs. G3)		
		2.5 years	+ (G1&3 vs.G2) 0 (G1 vs. G3)		
	Two functional activities ("can you carry a shopping bag?", "can you take something from a wall cupboard?")	2.5 years	+ (G1&3 vs. G2) 0 (G1 vs. G3)		
Haahr et al. (23,25)	*Change in Constant score* (ranges from 0-100 points with higher scores indicative of better function. Subscales for function (20pts), ROM (40pts), pain (15pts), and strength (25pts))	3 months	0	4.6 (-3.3 to 12.5)	
		6 months	0	1.4 (-7.6 to 10.4)	
		12 months	0	4.2 (-5.1 to 13.5)	
	PRIM score (questionnaire to assess pain and dysfunction, ranges from 0-36 points with lower scores indicative of better function.)	12 months	0	0.0 (-11.8 to 11.8)	
	Change in PRIM score	4 to 8 years	0	2.3 (-2.1 to 6.7)	
	Recovered or improved in PRIM score	8 years	0		1.1 (0.8 to 1.6)
	DREAM-indices (index of marginalization, sick leave and disability pension in Denmark)	4 years	0		
Nykänen (29)	*Self-reported ADL-index*	4 weeks	0	0.1 (-0.3 to 0.5)	

Study	Outcome measures (pain & function)		Results for between-groups-comparison	WMD(95%CI) (fixed effects model)	RR(95%CI) (fixed effects model)
		4 months	0	-0.5 (-1.6 to 0.6)	
		12 months	0	-0.3 (-1.4 to 0.8)	
	Self-reported pain-index	4 weeks	0	-0.2 (-0.8 to 0.4)	
		4 months	0	0.0 (-2.2 to 2.2)	
		12 months	0	0.0 (-2.2 to 2.2)	
	Supraspinatus pain test (scored on 0-3 point scale)	4 weeks	0	0.0 (-0.3 to 0.3)	
	Arc of initial pain with active abduction (in degrees)	4 weeks	0	4.0 (-15.9 to 23.9)	
Johansson et al. (28)	*Mean of the total scores of 3 shoulder-specific assessment scales* (Constant-Murley Shoulder Score, Adolfsson-Lysholm Shoulder Score, UCLA Score)	5 weeks (ITT)	0	-3.0 (-7.3 to 1.3)	
		3 months (ITT)	0	-3.0 (-8.3 to 2.3)	
		6 months (ITT)	0	0.0 (-6.8 to 6.8)	
		12months (ITT)	0	-3.0 (-8.8 to 2.8)	
Saunders (30)	*Pain* (scored on a pain analogue scale)	3 weeks	+		5.0 (1.4 to 18.2)
	Pain diary (self-rating on a pain analogue scale)	3 weeks	+		2.0 (1.0 to 4.1)
Vecchio et al. (31)	*Painful arc score* (scored on a 0-3 point scale)	4 weeks	0	0.0 (-0.7 to 0.7)	
		8 weeks	0	0.3 (-0.6 to 1.2)	
	Change scores for night pain (scored on a VAS)	4 weeks	0	1.3 (-1.1 to 366)	
		8 weeks	0	1.2 (-1.7 to 4.1)	
	Change scores for rest pain (scored on a VAS)	4 weeks	0	0.8 (-0.9 to 2.5)	
		8 weeks	0	1.7 (-0.7 to 4.1)	
	Change scores for movement pain (scored on a VAS)	4 weeks	0	1.5 (-1.0 to 4.0)	
		8 weeks	0	1.8 (-1.1 to 4.7)	
	Change score of functional limitation of ADL (scored on a VAS)	4 weeks	0	0.9 (-1.1 to 2.9)	
		8 weeks	0	0.7 (-1.5 to 2.9)	
Aktas et al. (32)	*Rest pain* (scored on a VAS*)*	3 weeks	0	0.1 (-0.9 to 1.0)	
	Activity pain (scored on a VAS)	3 weeks	0	-0.1 (-1.5 to 1.4)	

Study	Outcome measures (pain & function)		Results for between-groups-comparison	WMD(95%CI) (fixed effects model)	RR(95%CI) (fixed effects model)
	Pain disturbing sleep (scored on a VAS)	3 weeks	0	-1.5 (-3.0 to 0.1)	
	Constant score	3 weeks	0	0.7 (-9.0 to 10.3)	
	(ranges from 0-100 points with higher scores indicative of better function. subscales for function (20pts), ROM (40pts), pain (15pts), and strength (25pts))	3 weeks			
	Shoulder disability questionnaire		0	-0.5 (-17.9 to 17.0)	
	(pain related disability questionnaire with 16 items. ranges from 0-100 with lower scores indicative for less disability)				
Binder et al. (33)	*Pain score* (sum of pain at night, movement, at rest scored on a VAS)	2 & 4 weeks	+		
		6, 8 & 16 weeks	0		
	Pain on resisted movements; painful arc score (scored on a 4 point scale)	2 & 4 weeks	+		
		6, 8 &16 weeks	0		
	Minor residual or no symptoms	16 months	0		1.1 (0.9 to 1.4)
Chard et al. (34)	*Pain scores* (at night, on movement, at rest, summated score, all scored on a VAS)		0 all follow ups		
	Pain on resisted movements (ABD, ER and IR, all scored on a 0-3 point scale)		0 all follow ups		
	Painful arc score (scored on a 0-3 point scale)		0 all follow ups		

ABD: abduction; ADL: activities of daily life; AT: after treatment; 95%CI: 95% confidence interval; ER: external rotation; G: group; IR: internal rotation; ; ITT: intention to treat; 0: no significant differences between groups as reported by the authors; PRIM: Project on Research and Intervention in Monotonous Work; RR: relative risk; VAS: visual analogue scale WMD: weighted mean difference; +: significant in favor of the intervention group as reported by the authors.

Interventions

A variety of interventions and comparisons were found throughout studies. An overview about the inclusion criteria and interventions is given in table 4; between groups results for each study are provided in table 5. The different comparisons made by the authors are now described, results are summarized and the resulting level of evidence is given.

Comparisons of interventions

Physiotherapy versus no-intervention

Dickens et al. (27) compared physiotherapy to no intervention in eighty five patients with SIS, all of them already planned for shoulder surgery. Physiotherapy treatment (n=45) included passive manual joint mobilisation, home based strengthening exercises for the rotator cuff, strapping, advice for posture, and electrotherapy once or twice a week. After six months eleven out of forty two patients refused surgery. In contrast, all patients of the control group (n=40) underwent surgery as planned. This was a significant difference in favour of the physiotherapy group. Unfortunately, there was no information available at baseline about patient expectations towards surgery or physiotherapy. Nevertheless, the authors stated that it could have influenced the outcome in favour of the physiotherapy group.

> *There is limited evidence (85 patients) that physiotherapy consisting of manual mobilisation, strengthening exercises, strapping, advice about posture, and electrotherapy effectively improves functioning at 6 months follow-up and therefore may prevent patients with SIS from undergoing shoulder surgery.*

Home based exercises versus no intervention

Ludewig & Borstad (26) investigated the effect of standardized home based exercises of ten weeks duration including six stretching and strengthening exercises in seventy six male construction workers. They found significant improvements for work related pain and disability, and the shoulder rating questionnaire assessing shoulder specific activities in the exercise group (n=34) after ten weeks compared to a control group (n=33) receiving no treatment.

> *There is limited evidence (67 patients) that home based exercises are an effective treatment for male construct workers with SIS compared to no treatment at 10 weeks follow-up.*

Physiotherapy including "centering training for the shoulder" versus home based exercises including isometric strengthening

Three studies compared physiotherapy to home based exercises (35, 38, 39). In two studies (38, 39) instructions on the prescription for physiotherapy were "centering training" and, if necessary "mobilisation". There were no further instructions or written protocols and treatment decisions were left to the physiotherapists. In contrast, the standardized exercise protocol included defined exercises aiming at centering the humeral head and included isometric strengthening on a hand-out. After instruction the patients performed the exercises at home. No difference was found between the physiotherapy groups and the exercise groups. Additionally, the study of Walther et al. (38) also included a control group wearing a functional shoulder brace for twelve weeks. This group also showed no significant differences compared to exercises or physiotherapy. Ginn & Cohen (35) compared the effect of home based exercises to a single corticosteroid injection into the subacromial space and to a group receiving "multiple physical modalities (MPM)" in shoulder pain patients including a subgroup of patients with SIS (n=61). The MPM group was taken as the physiotherapy group because of its typical physiotherapeutic content. The exercise group performed an individually planned shoulder program based on the information of the initial assessment, including strengthening and stretching exercises and exercises to gradually improve functional tasks. The program was supervised and adapted once a week. "MPM" was a combination of electrophysical means, passive joint mobilisation of the shoulder complex (twice a week), global ROM and strengthening exercises for the upper extremity to increase hand placement. After five weeks no difference between the three groups could be found. Given the restricted similarity in interventions there is only moderate evidence about the effectiveness.

There is moderate evidence (141 patients) that there is no difference in effects on functioning between a standardized shoulder-specific isometric exercise program at home and physiotherapy addressing centering of the shoulder in patients with SIS at 5-12 weeks follow up.

Physiotherapist-led exercises versus physiotherapist-led exercises plus manual therapy

In the studies by Bang & Deyle (36) (n=52) and Conroy & Hayes (37) (n=14) the groups receiving physiotherapist-led exercises plus manual therapy showed significantly better results in the short term for pain and functioning than the control groups in both trials which only received physiotherapist-led exercises. The pooled effect size (standardized mean difference (95% confidence interval)) for pain after treatment was 0.88 (0.36 to 1.40). A standardized mean difference was calculated because different measurement scales were used in the trials. The random effects model was chosen because an identical effect for both studies could not be assumed due to variations of

the manual therapy protocol and a different frequency of its application. However, the small study populations and the limited simultaneity in timing of the measures do not justify a strong evidence level.

> *There is moderate evidence (66 patients) that adding manual therapy to a standardized shoulder-specific exercise program is superior in pain improvement compared to an isolated exercise regimen at 3 and 8 weeks follow up.*

Physiotherapist-led exercises versus surgery

Brox et al. (22, 24) assigned 125 patients with SIS to three groups. Group one underwent subacromial decompression followed by physiotherapy, the second group had placebo laser and was used as the control group, and the third group received physiotherapist-led exercises. Using an intention to treat analysis the median Neer score measuring shoulder functioning reached statistical significance in favour of the active treatment groups at 6 months and 2.5 years follow up. Haahr et al. (23, 25) made the same comparison in a sample of 84 patients but without the use of a placebo group. They found no differences between groups at any follow-up point, neither for the Constant score nor for the PRIM score assessing shoulder pain and disability.

> *There is moderate to strong evidence (209 patients) that surgery is not more effective than physiotherapist-led exercises in the treatment of pain and disability in patients with SIS at 6 months, and 1, 2.5, 4, and 8 years follow up.*

Ultrasound versus sham treatment

Nykänen (29) compared ultrasound to sham treatment in 73 patients. Both groups additionally received group gymnastics and massage therapy. After four and eight months the investigators could not find any significant differences in pain and functioning between both groups.

> *There is limited evidence (73 patients) that ultrasound therapy is not more effective in improving pain and functioning than sham treatment when added to group gymnastics and massage therapy at 4 weeks, 4 or 12 months follow-up.*

Ultrasound versus acupuncture

Johansson et al. (28) compared ultrasound therapy to acupuncture. Additionally, both groups performed home based exercises on a daily basis for five weeks. Although both groups improved significantly, no differences could be seen between groups after three, six, or twelve months.

> *There is limited evidence (85 patients) that ultrasound therapy is not more effective than acupuncture in combination with home based exercises in the treatment of patients with SIS.*

Low level laser therapy (LLLT) versus sham treatment

Both, Saunders (30) and Vecchio et al. (31) compared LLLT to sham treatment. In the study of Saunders (30) real treatment had a significantly better effect on pain than sham treatment after three weeks. In contrast, Vecchio et al. (31) found no differences between the two groups after four and eight weeks.

> *There is conflicting evidence (59 patients) about the effectiveness of LLLT for the treatment of SIS.*

Electromagnetic field therapy (EMFT)

Binder et al. (33) compared eight weeks of EMFT to four weeks of sham treatment followed by four weeks of real treatment. A significant difference between groups was seen after four weeks for pain on resisted movements and the painful arc score in favour of the EMFT group, but not after six, eight, and sixteen weeks. This result could not be confirmed by Aktas et al. (32). They compared EMFT to sham treatment and found no differences between groups for pain and functioning after 3 weeks. Chard et al. (34) compared eight hours of low dose EMFT to two hours of a high dose EMFT. No difference could be seen for any outcome measure at any follow up.

> *There is conflicting evidence (124 patients) that EMFT is more effective in improving pain and function than sham treatment in the short term regardless whether high or low doses of EMFT are applied.*

DISCUSSION

This review summarized the effectiveness of physiotherapy in patients with SIS. According to our best-evidence synthesis moderate evidence was found for an equal effectiveness of physiotherapist-led exercises and surgery in patients with SIS, especially in the long term (22-25). Although the quality score of 7/10 and the number of 209 included patients suggests a stable result, certainly more high quality trials are necessary to confirm these results. These results suggest that patients should not undergo surgery before having been treated conservatively. Besides this, exercise therapy seemed to cause less costs than surgery (24). Surgery should be handled with care and clear indications for its application need to be established. Moderate evidence was also found for manual therapy combined with exercises compared to exercises alone in patients with SIS (36, 37). In both (small) studies manual treatment combined with physiotherapist-led exercises led to statistically significant improvements in pain levels compared to physiotherapist-led exercises only. However, only the protocol of Bang & Deyle (36) additionally led to a significant improvement of functional activities. The fact that Bang & Deyle (36) also included the adjacent joints in

their manual treatment, regularly rechecked and adapted their interventions, and that all patients received individually designed home exercises to reinforce the effect of manual treatment may have contributed to this. However, the moderate evidence statement was only valid for pain but not for functioning. Unfortunately both studies did not provide sufficient data to judge the minimal difference between groups in treatment effect and therefore clinical importance of the results cannot be exactly determined. Moreover both studies had short follow ups and small sample sizes and despite a quality score of 6/10, some important quality items such as allocation concealment, blinding of subjects and therapists, and intention to treat-analysis were not fulfilled. This review further revealed moderate evidence for an equal effectiveness of combined physiotherapy interventions and home based exercises on pain and functioning (35, 38, 39). Unfortunately, instructions for physiotherapy in two studies (38, 39) were quite similar to the protocol of the exercise groups and therefore similar results could be expected. The fact that in the study of Werner et al. (39) participants were significantly more satisfied with home based exercises questions the quality of the thirty physiotherapy sessions. Even Ginn & Cohen (35) could not reveal any differences between both interventions, perhaps because the study was highly likely to be underpowered (n = 61) to detect any difference. Their treatment for the exercise group was individualized for each patient and covered exercises to improve strength, flexibility, co-ordination, posture, and motor control. Unfortunately, this exercise program was withheld from the MPM group, replaced with standardized ROM exercises and only manual joint mobilisation was individualized. Therefore, the benefit of manual mobilisation and electrophysical means in addition to an individualized home based exercise program remained unclear. Although Dickens et al. (27) found that combined physiotherapy interventions are significantly more effective than no intervention, this was also true for home based exercises (26) and thus the application of this more complex intervention must be justified in future studies. Both, the combinations of the exercises used in the exercise protocols (24-26) and the combinations of physiotherapy interventions (27, 35, 38, 39) varied considerably between studies. Reasons for their selection were often not explained and remained therefore unclear. This suggests that no clear criteria exist for determining the content of an exercise protocol or the combination of physiotherapy interventions which might also have limited the effect. A detailed description of the interventions is provided in table 4.

The results for a passive treatment were that ultrasound (29) was not more effective than sham application and evidence for the effect of LLLT (30, 31) or EMFT (32, 33) was conflicting. Thus, moderate evidence exists that passive treatment modalities are not more effective than sham application and their use can therefore not be recommended.

METHODOLOGICAL LIMITATIONS OF THIS REVIEW

There are some methodological limitations of this review. Although only studies were included where subjects presented typical clinical signs and symptoms for SIS, more than thirty different inclusion criteria and more than forty different exclusion criteria were used across all studies. This may reflect the need for a valid and practical classification system for patients with shoulder complaints in general. Considerable clinical heterogeneity regarding interventions and outcome measures, and missing or incomplete data made it often impossible to pool study results or to calculate any effect size. Furthermore, only few studies could be summarized per comparison.

The cut-off point chosen for the definition of a high quality study (5/10) was based on the impossibility of blinding therapists and participants with most active physiotherapeutic interventions but remains to some extent subjective. This may have affected the resultant level of evidence statements and in combination with the average methodological quality of included studies of 6.8/10 (range 5 to 9) the stability of the review results must be questioned. When applying the CONSORT (Consolidated Standards of Reporting Trials) statement for trials assessing non-pharmacological treatments (40, 41) to the included studies it becomes obvious, that conclusions of this systematic review are limited by missing quality aspects such as sequence generation, allocation concealment, blinding, intention to treat-analysis, or incomplete outcome data. Together with the small number of studies found for each comparison, small sample sizes (median 56) and short follow up periods (median 11 weeks), these aspects may have contributed to an overestimation of treatment effects.

IMPLICATIONS FOR FURTHER RESEARCH

A major concern for further studies is that defined interventions based on a structured decision making process should be applied to clearly defined clinical patterns. To do so, a valid and practical classification system for shoulder disorders is needed. The use of similar shoulder specific outcome measures for pain, activity and participation restrictions is recommended to facilitate future pooling of data. To enable the reader to judge the clinical value of statistically significant study results and to allow a transfer of study results into daily practice, sufficient statistical data for within- and between-group results and a detailed description of treatment modalities tested should be provided. There is an urgent need for more high quality randomized controlled trials in this field.

REFERENCES

1. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. Rheumatology 2005; 44: 800-805.
2. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristic, and management. Ann Rheum Dis 1995; 54: 959-964.
3. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy 2001; 87: 458-469.
4. Green SE, Buchbinder R, Forbes A, Glazier R. Interventions for shoulder pain. The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD001156 1999
5. Green SE, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD004258 2003.
6. Desmeules F, Cote CH, Fremont P. Therapeutic exercise and orthopaedic manual therapy for impingement syndrome: a systematic review. Clin J Sports Med 2003; 13: 176-182.
7. van der Heijden GJ. Shoulder disorders: a state of the art review. Baillieres Best Pract Res Clin Rheumatol 1999; 13: 287-309.
8. Faber E, Kuiper JI, Burdorf A, Miedema HS, Verhaar JAN. Treatment of impingement syndrome: a systematic review of the effects on functional limitations and return to work. J Occup Rehabil 2006; 16: 7-25.
9. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. J Hand Ther 2004; 17: 152-164.
10. Hughes PC, Taylor NF, Green RA. Most clinical tests cannot accurately diagnose rotator cuff pathology: a systematic review. Aust J Physiother 2008; 54: 159-170.
11. Burnett J, Grimmer K, Saravana K. Development of a generic critical appraisal tool by consensus: presentation of first round Delphi survey results. IJAHSP 2005; 3: available from http://ijahsp.nova.edu/articles/vol3num1/burnett.htm.
12. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care: patterns of diagnosis and referral. Rheumatology 2006; 45: 215-221.
13. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 [updated May 2005]. Chichester, UK: John Wiley & Sons, Ltd.; 2005.
14. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther 2003; 83: 713-721.
15. The Cochrane Collaboration. Review Manager (RevMan) [Computer program]. Version 4.2 for Windows. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2003.
16. van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. Spine 2003; 28: 1290-1299.
17. Citaker S, Taskiran H, Akdur H, Arabaci UO, Ekici C. Comparison of the mobilization and proprioceptive neuromuscular facilitation methods in the treatment of shoulder impingement syndrome. Pain Clinic 2005; 17: 197-202.
18. Munday SL, Jones A, J.W. B, Globe G, Jensen M, Price JL. A randomized, single-blinded, placebo-controlled clinical trial to evaluate the efficacy of chiropractic shoulder girdle adjustment in the treatment of shoulder impingement syndrome. JACA-Journal of the American Chiropractic Association 2007; 44: 6-15.
19. Peters G, Kohn D. Mittelfristige klinische Resultate nach operativer versus konservativer Behandlung des subakromialen Impingementsyndroms [Medium-term clinical results after operative and non-operative treatment of subacromial impingement]. Unfallchirurg 1997; 100: 623-629 (in German).

20. Rahme H, Solem-Bertoft E, Westerberg C-E, Lundberg E, Sörensen S, Hilding S. The subacromial impingement syndrome. Scand J Rehab Med 1998; 30: 253-262.
21. Senbursa G, Baltaci G, Atay A. Comparison of conservative treatment with and without manual physical therapy for patients with shoulder impingement syndrome: a prospective, randomized clinical trial. Knee Surg Sports Traumatol Arthrosc 2007; 15: 915-921.
22. Brox JI, Gjengedal E, Uppheim G, Bohmer AS, Brevik JI, Ljunggren AE, et al. Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): A prospective, randomized, controlled study in 125 patients with a 2.5-year follow up. J Shoulder Elbow Surg 1999; 8: 102-111.
23. Haahr JP, Andersen JH. Exercises may be as efficient as subacromial decompression in patients with subacromial stage II impingement: 4 to 8 years follow up in a prospective randomized trial. Scand J Rheumatol 2006; 35: 224-228.
24. Brox JI, Brevik JI, Ljunggren AE, Staff PH. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome). BMJ 1993; 307: 899-903.
25. Haahr JP, Ostergaard S, Dalsgaard J, Norup K, Frost P, Lausen S, et al. Exercise versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. Ann Rheum Dis 2005; 64: 760-764.
26. Ludewig PM, Borstad JD. Effects of a home exercise programme on shoulder pain and functional status in construction workers. Occup Environ Med 2003; 60: 841-849.
27. Dickens VA, Williams JL, Bahmra MS. Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. Physiotherapy 2005; 91: 159-164.
28. Johansson KM, Adolfsson LE, Foldevi MOM. Effects of acupuncture versus ultrasound in patients with impingement syndrome: randomized clinical trial. Phys Ther 2005; 85: 490-501.
29. Nykänen M. Pulsed ultrasound treatment of the painful shoulder a randomized, double-blind, placebo-controlled study. Scand J Rehab Med 1995; 27: 105-108.
30. Saunders L. The efficacy of low-level laser therapy in supraspinatus tendinitis. Clin Rehab 1995; 9: 126-134.
31. Vecchio P, Cave M, King V, Adebajo AO, Smith M, Hazleman BL. A double-blind study of the effectiveness of low level laser treatment of rotator cuff tendinitis. Br J Rheumatol 1993; 32: 740-742.
32. Aktas I, Akgun K, Cakmak B. Therapeutic effect of pulsed electromagnetic field in conservative treatment of subacromial impingement syndrome. Clin Rheumatol 2007; 26: 1234-1239.
33. Binder A, Parr G, Hazelman BL. Pulsed electromagnetic field therapy of persistent rotator cuff tendinitis. Lancet 1984; 1: 695-698.
34. Chard MD, Hazelman BL, Devereaux MD. Controlled study to investigate dose-response patterns to portable pulsed electromagnetic fields in the treatment of rotator cuff tendinitis. J Orthop Rheumatol 1988; 1: 33-40.
35. Ginn KA, Cohen M. Exercise therapy for shoulder pain aimed at restoring neuromuscular control: a randomized comparative clinical trial. J Rehab Med 2005; 37: 115-122.
36. Bang MD, Deyle GD. Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. J Orthop Sports Phys Ther 2000; 30: 126-137.
37. Conroy DE, Hayes KW. The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. J Orthop Sports Phys Ther 1998; 28: 3-14.
38. Walther M, Werner A, Stahlschmitt T, Woelfel R, Gohlke F. The subacromial impingement syndrome of the shoulder treated by conventional physiotherapy, self-training, and a shoulder brace: results of a prospective randomized study. J Shoulder Elbow Surg 2004; 13: 417-423.
39. Werner A, Walther M, Ilg A, Stahlschmitt T, Gohlke F. Zentrierende Kräftigungstherapie beim einfachen subakromialen Schmerzsyndrom: Eigentraining versus Krankengymnastik [Self-training versus conventional physiotherapy in subacromial impingement syndrome]. Z Orthop 2002; 140: 375-380 (in German).

40. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Methods and processes of the CONSORT group: examples of an extension for trials assessing nonpharmacological treatments. Ann Intern Med 2008; 148: W-60-W-66.
41. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357: 1191-1194.

CHAPTER 3

Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome:

A randomized controlled trial

ABSTRACT

Background Shoulder impingement syndrome is a common musculoskeletal complaint leading to significant reduction of health and disability. Physiotherapy is often the first choice of treatment although its effectiveness is still under debate. Systematic reviews in this field highlight the need for more high quality trials to investigate the effectiveness of physiotherapy interventions in patients with subacromial impingement syndrome.

Methods/Design This randomized controlled trial will investigate the effectiveness of individualized physiotherapy in patients presenting with clinical signs and symptoms of subacromial impingement, involving 90 participants aged 18-75. Participants are recruited from outpatient physiotherapy clinics, general practitioners, and orthopaedic surgeons in Germany. Eligible participants will be randomly allocated to either individualized physiotherapy or to a standard exercise protocol using central randomization. The control group will perform the standard exercise protocol aiming to restore muscular deficits in strength, mobility, and coordination of the rotator cuff and the shoulder girdle muscles to unload the subacromial space during active movements. Participants of the intervention group will perform the standard exercise protocol as a home program, and will additionally be treated with individualized physiotherapy based on clinical examination results, and guided by a decision tree. After the intervention phase both groups will continue their home program for another 7 weeks. Outcome will be measured at 5 weeks and at 3 and 12 months after inclusion using the shoulder pain and disability index and patients` global impression of change, the generic patient-specific scale, the average weekly pain score, and patient satisfaction with treatment. Additionally, the fear avoidance beliefs questionnaire, the pain catastrophizing scale, and patients` expectancies of treatment effect are assessed. Participants' adherence to the protocol, use of additional treatments for the shoulder, direct and indirect costs, and sick leave due to shoulder complaints will be recorded in a shoulder log-book.

Discussion To our knowledge this is the first trial comparing individualized physiotherapy based on a defined decision making process to a standardized exercise protocol. Using high-quality methodologies, this trial will add evidence to the limited body of knowledge about the effect of physiotherapy in patients with SIS.

Trial registration Current Controlled Trials ISRCTN86900354

Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskeletal Disorders 2010;11:114

BACKGROUND

Shoulder complaints are one of the most common musculoskeletal complaints seen by health professionals [1-5] with an incidence of 9.5 per 1000 patients presenting to primary care [6] and varying data for point prevalence (6.9% to 26%) [7]. They can lead to a significant reduction of health [6, 8], seem to be recurring in nature and do not necessarily resolve over time [9-12]. Thus, shoulder complaints represent a relevant health problem for clinicians, employers and health insurance companies. Although no standardized diagnostic classification for shoulder complaints exists, most shoulder patients presenting to primary care show clinical signs of subacromial impingement [5, 6]. Subacromial impingement syndrome of the shoulder (SIS) occurs due to a mechanical disturbance within the subacromial space and is characterized by pain and functional restrictions mostly during overhead activities in daily life or sporting activities [13]. Potential factors causing or contributing to SIS such as strength, coordination and integrity of the rotator cuff [14-21] and the shoulder girdle muscles [22-26], mechanical or anatomical changes [27-29], hypomobility or instability of the glenohumeral joint or the scapula [16, 26, 30-33], and the influence of posture [34, 35] are discussed in the literature and suggest a multi-factorial aetiology of SIS. Besides the biomedical aspects of SIS, psychological factors such as kinesiophobia or catastrophizing may negatively influence recovery and thus leading to chronic pain and disability [36-41]. The specific diagnosis of SIS is often based on a thorough history and clinical examination; technical examination methods such as MRI or ultrasonography are often not used in first instance [10], also because their diagnostic accuracy is still limited [42-47].

Physiotherapy is often the first choice of treatment for SIS. Between 10 to 30% of all shoulder patients seen in primary care are referred to physiotherapy after initial presentation [5, 10, 48]. However, the effectiveness of physiotherapy in patients with SIS is still under debate. Conclusions from systematic reviews suggest that physiotherapy-led interventions, combining different methods or techniques, are not more effective than exercises alone except adding manual mobilization to exercises, which seems to be of additional benefit. Most technical treatments such as ultrasound or laser therapy cannot be recommended. However evidence is limited by poor methodological quality, short follow ups and small sample sizes [49-52]. Thus nearly all current systematic reviews emphasize the need for more high quality trials of physiotherapy interventions, especially of combination of treatment techniques.

This trial compares individualized physiotherapy (IP), considering the patients' individual situation, bio-psycho-social aspects, and the WHO-classification of functioning and disability [53] to a standardized exercise protocol (SEP). Physiotherapeutic management is based on clinical examination results and guided by

a defined clinical reasoning process, which belongs to one of the basic skills in muscu-musculoskeletal physiotherapy [54].

Aims of the study

a) To investigate the effect of individually planned physiotherapy (IP) on pain and functioning compared to a standard exercise protocol (SEP) in patients presenting with clinical signs of SIS.
b) To compare direct and indirect costs between both interventions.

METHODS

Study design

To answer the questions a randomized controlled trial design will be used over a 12 months period. Patients will be randomized after providing informed consent. Randomization and all communication about it is executed and controlled by the Department of Epidemiology, Maastricht University. A flow chart of the trial profile is provided in figure 1.

Ethics

Ethical approval for this trial has been granted by the Medical Ethics Committee of the Munich University Hospital, Ludwig-Maximilians-University Munich, Germany.

Eligibility criteria

Patients presenting to primary care with clinical signs and symptoms indicating SIS will be included in the trial. This concept of focusing on important clinical signs for setting up inclusion criteria for a RCT corresponds well with daily clinical practice.

Inclusion criteria: (1) age between 18 and 75 years, (2) symptoms for more than four weeks, (3) main complaints in the glenohumeral joint region or the proximal arm, (4) presence of one of the following signs indicating SIS: Neer impingement test, Hawkins-Kennedy impingement test, painful arc with active abduction or flexion, (5) pain with one of the following resistance tests: external rotation, internal rotation, abduction, or flexion.

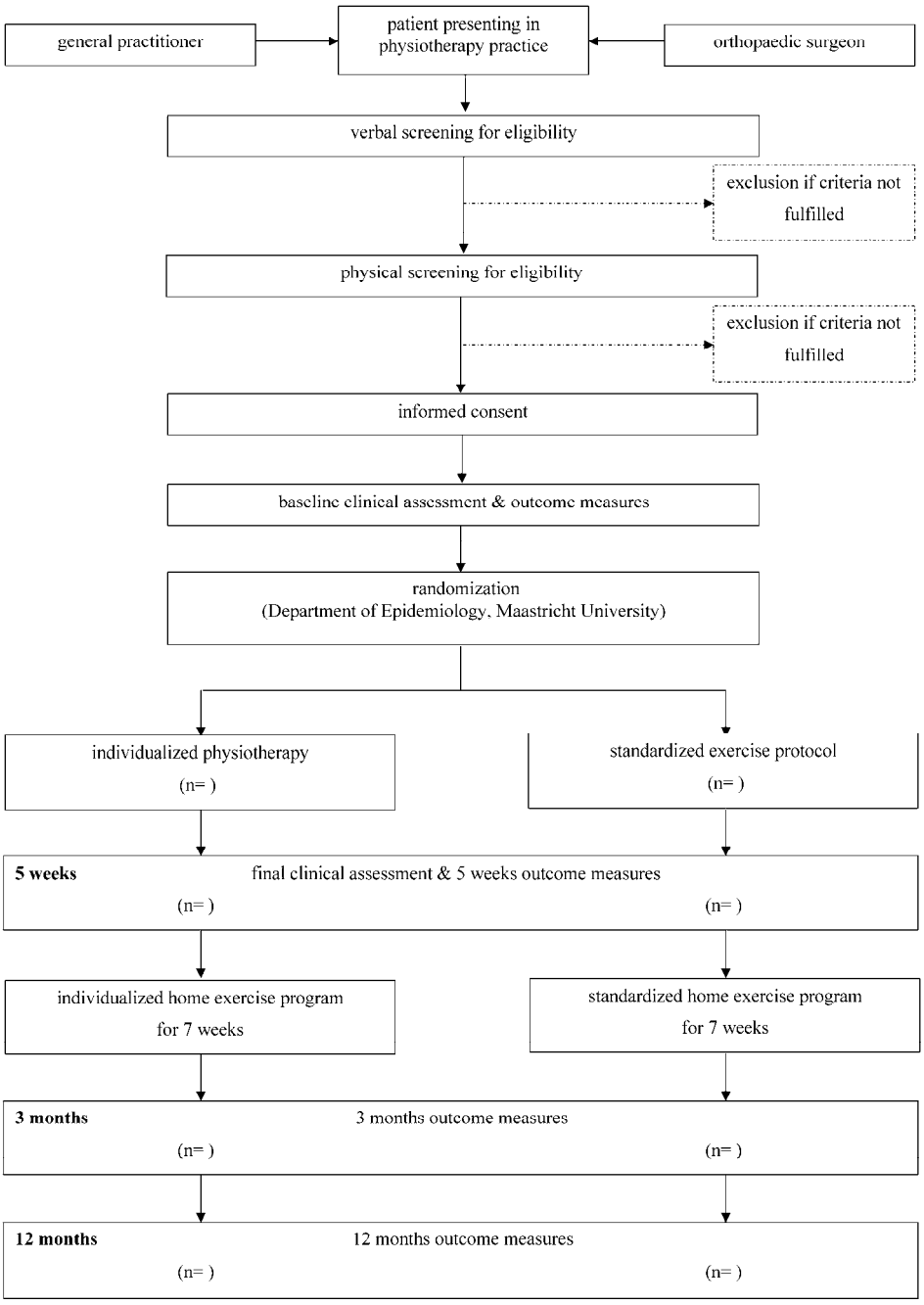


Figure 1 Trial profile

Exclusion criteria: (1) average 24-hours pain of 8/10 or more on a visual numeric rating scale (VNRS), (2) primary scapulothoracic dysfunction due to paresis, (3) diagnosed instability or previous history of dislocation, (4) adhesive capsulitis (frozen shoulder), (5) more than 1/3 restriction of elevation compared to the unaffected side, (6) substantial shoulder weakness or loss of active shoulder function, (7) shoulder surgery in the last 12 months on the involved side, (8) reproduction of symptoms with active or passive cervical movements, (9) neurological involvement with sensory and muscular deficit, (10) inflammatory joint disease (e.g. rheumatoid arthritis), (11) diabetes mellitus, (12) intake of psychotherapeutic drugs, (13) compensation claims, (14) inability to understand written or spoken German.

Recruitment of participants

The proposed trial will be embedded in the normal daily process of selected physiotherapy clinics in Germany. Participants will be identified by physiotherapy referrals and by research physiotherapists. If a patient agrees to participate, the research therapist will check eligibility criteria. If eligibility is confirmed, informed consent will be asked. Participants will then undergo baseline assessment including some questionnaires and a standardized clinical examination protocol for the shoulder complex, the cervical and upper thoracic spine.

An inclusion period of eighteen months is thought to be sufficient to recruit the number of participants needed for this study.

Randomization and allocation concealment

After informed consent and baseline assessment participants will be randomized to either SEP or IP using block allocation of six. To guarantee allocation concealment, therapists will be informed about allocation after the participant completed all baseline measurements and gave informed consent, prior to first treatment by the Department of Epidemiology, Maastricht University.

Interventions

Both groups

All participants will undergo a clinical examination process starting with a thorough history taking, followed by a physical examination of the cervical spine, the shoulder girdle, and the shoulder joints. All joints are manually assessed with passive, active,

and combined angular movements, and with translatory tests according to the description of Kaltenborn [55], Evjenth and Hamberg [56] or Maitland [57]. Isometric resistance tests are used to judge shoulder strength and pain. Integrity of the rotator cuff is assessed with the external rotation lag sign [58], the lift off test [59], and the hornblowers' sign [60]; involvement of the neural system with upper limb tension tests described by Butler [61]. Contributing factors such as a slouched posture, forward head position, thoracic kyphosis, or protracted shoulders are noted and if necessary also assessed in detail. Results serve as basis for the treatment of participants allocated to the group receiving individualized physiotherapy.

All participants will attend two 20-30 minute contact sessions per week over a 5 week period. Afterwards participants will continue with their home exercises for another 7 weeks. At the beginning of treatment all participants will receive an information booklet containing basic information about anatomy and biomechanics of the shoulder complex, a short description of the aetiology of SIS and the pathology itself, and a brief overview about possible contributing factors to their shoulder pain. The booklet also explains the goals to be achieved with treatment, and it provides general guidelines for behaviour through daily living. Participants will also receive a shoulder log book for documentation of their weekly pain levels, additional treatments or medication, sick leave, and the completion of the home exercise during the intervention phase and during the follow up period. Participants will be requested not to make use of other treatment options and not to change their medication intake during the intervention phase. However, due to ethical considerations the use of analgesics and non-steroidal anti-inflammatory drugs will be permitted and will be recorded in the shoulder log-book.

Treatment will be administered by experienced physiotherapists with an international qualification for manual therapy (IFOMPT standard). All physiotherapists will be trained prior to commencement of the study to guarantee a uniform background and treatment application. A written manual with detailed and comprehensive instructions is given to the therapists. Thoroughness of the application is supported by structured recording forms and check lists, monthly team meetings and audits. The two groups are as follows:

Control group

Participants assigned to the control group will perform a standard exercise protocol (SEP) aiming at restoring muscular deficits in strength, mobility, or coordination of the rotator cuff and the shoulder girdle, unloading the subacromial space, and centering the humeral head in the glenoid fossa during active movements. Thus, the SEP contains mainly strengthening exercises, stretching and mobility exercises, but also exercises to control pain. To set up a high quality protocol, exercises are taken from papers

investigating exercises for shoulder rehabilitation [62-79], and exercises specifically addressing deficits in strength, mobility, or coordination revealed in patients with SIS [19, 23-25, 31, 80, 81]. Another important criterion for the selection of the exercises was their practicability, their potential for pain provocation, and the possibility to perform all exercises at home with a rubber band. Exercises are subdivided in a "core program" and "additional exercises". A short description of the exercises is provided in table 1&2.

Table 1 Exercises of the core program

No.	Exercise	Material	Description
C1a	Low row	Pinoband or pulley apparatus with 2 handles	Subject is sitting in front of pinoband, shoulders in 80° forward flexion and neutral rotation; subject performs shoulder extension with elbows flexed.
C1b	High row	Pinoband or pulley apparatus with 2 handles	Subject is sitting in front of pinoband, shoulders in 100° forward flexion and neutral rotation; subject performs shoulder extension with elbows extended.
C2	Shoulder adduction in scapular plane	Pinoband or pulley apparatus with 1 handle	Subject is standing, shoulder in 80° abduction in scapular plane; subject performs shoulder adduction with elbow extended.
C3a	Shoulder external rotation in 0° abduction	Pinoband or pulley apparatus with 1 handle	Subject is standing, with towel between arm and trunk to prevent compensatory shoulder movements, elbow flexed to 90°; subject performs shoulder external rotation.
C3b	Shoulder external rotation in side-lying	Dumbbell	Subject is side-lying, with towel between arm and trunk to prevent compensatory shoulder movements, elbow flexed to 90°; subject performs shoulder external rotation.
C4a	Shoulder internal rotation in 0° abduction	Pinoband or pulley apparatus with 1 handle	Subject is standing, with towel between arm and trunk to prevent compensatory shoulder movements, elbow flexed to 90°; subject performs shoulder internal rotation.
C4b	Shoulder internal rotation in side-lying	Dumbbell	Subject is side-lying, elbow flexed to 90°; subject performs shoulder internal rotation.
C5	Elbow flexion with forearm supination	Pinoband or dumbbell	Subject standing arm at the side, neutral rotation; subject performs elbow flexion/forearm supination.
C6a	Horizontal scapular protraction	Pinoband or pulley apparatus with 2 handles	Subject is standing, elbows flexed to 90°; subject performs shoulder flexion to 80° and elbow extension, then scapular protraction.
C6b	Vertical scapular protraction	Pinoband or dumbbells	Subject lying supine, elbows flexed to 90°; subject performs shoulder flexion to 90° and elbow extension, then scapular protraction.

No.	Exercise	Material	Description
C7	4-point kneeling scapular protraction	-	Subject in 4-point kneeling position, hands underneath shoulders performs dynamic scapular protraction.
C8	Scapular setting	-	Subject lying prone with arms held by the side in external rotation; subject holds scapulae in depressed and retracted position.
C9	Posterior shoulder stretch	-	Subject is standing, pulling the elbow passively across the body into horizontal adduction with the opposite arm.
C10	Lateral neck stretch	-	Subject is standing, pulling the head into lateral flexion with the opposite arm and is adding the shoulder depression to stretch the ipsilateral neck.
C11	Thoracic spine extension	-	Supine on the floor, hips and knees flexed to 90 degrees, hands supporting the neck, with thoracic kyphosis lying on a towel roll.

Table 2 Additional exercises

No.	Exercise	Material	Description
A1a	Shoulder abduction in scapular plane (scaption)	Pinoband or dumbbell	Subject is standing with feet on the pinoband; subject performs 80° of scaption with elbows slightly flexed and external rotation of the shoulder (thumb up).
A1b	Shoulder flexion	Pinoband or dumbbell	Subject is standing with feet on the pinoband; subject performs 80° of shoulder flexion with elbows slightly flexed and external rotation of the shoulder (thumb up).
A2a	Shoulder press via flexion	Pinoband or dumbbell	Subject is sitting with back supported. Upper arms are in contact with the trunk, elbows are maximally flexed and hands in front of shoulders; subject performs full shoulder flexion and elbow extension.
A2b	Shoulder press via abduction	Pinoband	Subject is sitting with back supported. Upper arms are in contact with the trunk, elbows are maximally flexed and hands next to shoulders; subject performs full shoulder abduction and elbow extension.
A3	Horizontal abduction	Pinoband or pulley apparatus with 1 handle	Subject is sitting in front of pinoband attached in shoulder height, shoulders in 80° forward flexion and external rotation; subject performs horizontal shoulder abduction with nearly extended elbows.
A4	External rotation in supported 80° shoulder flexion	Pinoband or pulley apparatus with 1 handle	Subject is sitting with elbow supported on a table in 80° of shoulder flexion and 90° elbow flexion. Pinoband fixed on the table with other hand; subject performs 90° of external rotation.

No.	Exercise	Material	Description
A5	Internal rotation in supported 80° shoulder flexion	Pinoband or pulley apparatus with 1 handle	Subject is sitting with elbow supported with the other hand in 80° of shoulder flexion, pinoband fixed in waste height; subject performs 90° of internal rotation.
A6a	Shoulder protraction in kneeling push up position	-	Subject in kneeling push up position, hands underneath shoulders and knees behind hips; subject performs dynamic scapular protraction.
A6b	Shoulder protraction in push up position	-	Subject in push up position; subject performs dynamic scapular protraction.
A6c	Half way push up plus	-	Subject in push up position; subject performs a half way push up with a dynamic scapular protraction at the end of arm extension.
AM1	Internal rotation positioning	-	Subject is placing the hand on the buttock or lower back in a pain-free manner, supported by the other hand.
AP1	Pendulum exercises	Dumbbell or bottle	Subject is standing leaning on a chair or table with the good arm and bending forward at the waist. Relax the shoulder blade and let it drop. Subject performs relaxed forward-backward swings and circle swings using body motion.
AP2	Longitudinal shoulder traction	Pinoband	Subject is standing and slightly side bent with pinoband is wrapped around the wrist and fixed with the feet on the bottom with tension. Subject is relaxing the shoulder to allow for longitudinal traction.

Exercises of the “core program” are introduced and instructed to the patient in detail first, and if patients show good progression, exercises from the pool of “additional exercises” can be added. At home exercises are realized with the help of a PINOFIT rubber band (Pino GmbH, Hamburg, Germany) which allows dynamic resistance and is easy to use. It is available from very light resistance to heavy resistance and allows the therapist to progressively adapt resistance to the physical capacity of the patient. Patients are supervised during their contact sessions; their exercise program is monitored, controlled and adapted if necessary. Physiotherapists are allowed to adapt the SEP individually to each patient with respect to the situation of the patient. Therapists who deliver the treatment for the control group remain blinded to the clinical examination results to prevent inadvertent contamination of the SEP.

Intervention group

Participants assigned to the intervention group will perform the SEP as a home program. Additionally this group will receive six to ten session of individualized physiotherapy (IP), based on the findings of the clinical examination and the individual main

complaints of the patient. To guarantee a uniform decision making process and to deliver a defined and repeatable way of treatment application a decision tree was developed. The decision tree was previously tested in patients with SIS to improve weaknesses and to test its practicability. It consists of three parts and directs initial treatment applications. The first part of the decision tree addresses predictive signs for a poor treatment outcome such as recurrent episodes of shoulder pain in the past [7, 9, 11, 12], severe pain or long duration of the current episode [82-84], signs indicating a tear of the rotator cuff [85, 86], and restriction of external rotation and/or elevation of the shoulder [9, 87].

The second part leads the therapist through factors maintaining or contributing to the patients' problem such as general posture, ADL`s, working activities and work place setting, leisure and sports activities, and patients' understanding of his problem. The third part guides through the positive findings of the physical examination of the upper quarter (cervical and upper thoracic spine, shoulder and shoulder girdle). Local factors will be treated according to the manual therapy concepts of Maitland [57], Kaltenborn [88], Evjenth and Hamberg [56], or Butler [61]. For further treatment decisions and as an important part of treatment application a defined clinical reassessment process is implemented, adapted from Jones and Rivett [89]. The reassessment process, based on the test-retest-principle, delivers important information about the effect of an applied intervention or technique and thus assists the therapist in further decision making.

Main contrast between both groups

The main difference between both groups is that the intervention group additionally receives individualized physiotherapy considering all predictive, local or contributing factors that may maintain or contribute to the patients' problem, identified through clinical examination. Therefore this intervention, combining a shoulder specific exercise programme with a defined decision making process and clinical experience, represents a best practice approach.

Outcome measures

Selection criteria for the outcome measures used in this study were their reliability and validity in relation to the study population, and also their sensitivity to detect change statistically, whether it is relevant to the patient or clinician or not. Another important criterion was their practical applicability in a clinical setting. The main focus is on pain and functioning. Primary outcome measures will be as follows:

1. Shoulder Pain and Disability Index (SPADI)

The SPADI is a shoulder specific self-reported questionnaire measuring pain and disability in patients with shoulder pain of musculoskeletal origin [90]. It contains 5 items assessing pain and 8 items assessing shoulder function and is easily applicable in daily practice. Each item is scored on a 100mm visual analogue scale (VAS); the right end of the VAS is defined as "worst pain imaginable/ so difficult required help", the left end as "no pain/no difficulty". A score is then calculated out of 100 with higher scores reflecting higher pain/disability levels. The SPADI has shown to be valid and highly responsive in assessing shoulder pain and function [90, 91]; it is therefore highly recommended for the use in patients with SIS [92]. The German version of the SPADI also showed an excellent reliability and internal consistency for both, total score and sub-scores. A minimum improvement in the total SPADI score of 11points will be considered as a minimum clinically important change [93].

2. Patients' global impression of change (PGIC)

Measuring PGIC is a clinically relevant and stable concept for interpreting truly meaningful improvements in pain from the individual perspective [94, 95]. It is measured with the help of an ordinal scale with 1-much worsened, 2-slightly worsened, 3-unchanged, 4-slightly better, 5-much better, whereas a rating of "slightly better" will be defined a priori as a clinically important and meaningful difference and therefore as a successful result. According to this definition, the scale is then dichotomized. To test stability of this dichotomization a sensitivity analysis will be conducted.

Secondary outcome measures will be:

1. Generic Patient-Specific Scale (GPSS)

The GPSS is published by Stratford et al. [96] and assesses individual complaints and restrictions in a short and efficient way. It is based on the patient-centred approach, identifying the most problematic areas of functioning.

The GPSS is a reliable and valid tool and also sensitive to detect change over time [97]. Although it is a generic outcome measure, its validity, reliability and sensitivity has been established for different patient groups [96, 98, 99]. For this study, patients will chose 3 activities they got difficulties with and rate the ability to perform them on an 11-point visual numeric rating scale (VNRS). 10 at the right end of the VNRS is defined as "I can do the chosen function without difficulty", 0 at the left end as "I am unable to do the chosen function". An average score across all activities is calculated. Because the expected change of severely restricted activities is less than the expected change of only mild restrictions, a minimum change of 30% will be considered as a clinically important improvement [95, 100].

2. Average weekly pain score

Patients will rate their average weekly pain intensity on an 11-point VNRS. The VNRS is a one-dimensional measure to assess pain intensity. The distance between each number is 10 millimetres; 0 on the left end of the VNRS is defined as "no pain at all", 10 at the right end as "as much pain as I can imagine". An improvement in pain level of 2 points or more was defined as a clinically important and meaningful difference [95, 100].

3. Patient satisfaction with treatment

After 5 weeks all patients will rate their satisfaction with treatment on an 11-point visual numeric rating scale (VNRS). 10 at the right end of the VNRS is defined as "completely satisfied", 0 at the left end as "completely dissatisfied".

4. Fear Avoidance Beliefs Questionnaire (FABQ)

It has been shown that fear of movement is an important obstacle to a successful rehabilitation in patients suffering from low back pain. To be able to analyze the influence of fear of movement on treatment outcome in patients with SIS, a modified version of the FABQ is used in this study. The FABQ was developed by Waddell et al. [101] to assess the influence of patients' beliefs about physical activity and work on low back pain. The German version of the FABQ shows good psychometric properties and is therefore used in this study [102-105]. The FABQ is a 16-items questionnaire. Each item is scored on a seven-point Likert scale (0 = strongly disagree, 6 = strongly agree). A total score is calculated by summing up the resultant scores. Sub-scores for physical activity and work are calculated, with 7 items assessing beliefs about work (item 6, 7, 9, 10, 11, 12, 15) and 4 items assessing beliefs about physical activity (item 2, 3, 4, 5). Higher scores reflect a higher presence of fear avoidance believes.

5. Pain Catastrophizing Scale (PCS)

Besides fear of movement, catastrophizing may also play an important role in mediating responses to pain, leading to perception of higher pain intensities and therefore influencing treatment outcome negatively [106-108]. The PCS is a multidimensional, reliable and valid 13-item self-report measurement tool with a strong association to pain and emotional distress [106, 107, 109, 110]. The PCS has been validated for the German population [111]. It comprises three subscales for rumination (item 8 to 11), magnification (item 6 to 7, 13), and helplessness (item 1 to 5, 12). Each item is rated on a 5-point scale from 0 (not at all) to 4 (all the time). A total score and sub-scores for each subscale are calculated by summing up the ratings for each item within a subscale. In a sample of 86 patients with sustained soft tissue injuries to the neck, shoulders or back including shoulder patients, Sullivan et al. [112] found that catastrophizing

was significantly correlated with patients' reported pain intensity, disability and employment status. The rumination subscale was the strongest predictor of pain and disability. Due to sufficient test-retest stability even over a longer period of time the PCS is an appropriate screening tool for pain catastrophizing [113].

6. Patients` expectancies of treatment outcome
Patients` beliefs about the success of a given treatment may influence treatment outcome; this has been shown by Goossens et al. [114] and Smeets et al. [115] in low back pain patients. For this trial a modified question of the Credibility/Expectancy Questionnaire (CEQ), developed by Deviliya and Borkovecb [116], to measure patients` expectancies is used. The CEQ shows high internal consistency and good test-retest reliability. The question is: "By the end of the therapy period, how much improvement in your limitations due to shoulder pain do you think will occur?"

The question is scored on an 11-point visual numeric rating scale (VNRS) from 0 (no improvement) to 10 (completely recovered). A higher score will reflect more positive expectancies.

7. Compliance with treatment, direct (health care) and indirect (non-health care) costs
A shoulder log book will be used to obtain the following data: i) Compliance of participants with treatment including the attended treatment visits out of a maximum of ten and the performance of the given home exercises; ii) direct health care costs including physiotherapy, other health provider visits, diagnostic tests, prescriptions and over the counter medication due to shoulder complaints; iii) indirect health care costs including days of sick leave and paid help. The log book is presented in booklet form containing instructions and explanations about the objective of the log book. Log-books will be posted back to the assessor and checked for completion every two months.

Demographic information will also be collected including age, sex, height, weight, profession, sports and leisure activities, medical history, and medication intake. Information about severity and duration of symptoms and previous episodes of shoulder pain are also documented.

Follow-up evaluation

Patients are assessed at baseline, after completion of the intervention period at 5 weeks, and at 3 and 12 months after inclusion to assess the long term outcome of the intervention. An overview of the outcome measures is given in table 3.

Table 3 Primary and secondary outcome measures

Primary Outcomes	Measurement	Follow up
Shoulder pain and disability index (SPADI)	13 items (5 for pain, 8 for function) scored on a 100mm visual analogue scale	baseline; 5 weeks; 3, 12 months
Patients` global impression of change	Ordinal scale (1-much worse, 2-slightly worse, 3-no change, 4-slightly better, 5-much better)	5 weeks; 3, 12 months
Secondary Outcomes	**Measurement**	**Follow up**
Generic patient-specific scale	11 point visual numeric rating scale (end descriptors of 0 = impossible to do, 10 = no difficulties at all)	baseline; 5 weeks; 3, 12 months
Average weekly pain score	11 point visual numeric rating scale (end descriptors of 0 = no pain, 10 = worst pain possible)	baseline; 5 weeks; 3 months
Patients` satisfaction with treatment	11 point visual numeric rating scale (end descriptors of 0 = completely dissatisfied, 10 = completely satisfied)	5 weeks
Kinesiophobia/Fear avoidance beliefs	Modified fear avoidance beliefs questionnaire (FABQ)	baseline
Catastrophizing	Pain catastrophizing scale (PCS)	baseline
Patients` expectancies of treatment effect	One modified question from the Credibility/Expectancy Questionnaire (CEQ)	baseline
Compliance	Shoulder log book: Attention of treatment sessions and completion and frequency of home exercises	5 weeks; 3, 12 months
Costs	Cost diary: Disease specific healthcare utilization, days of sick leave, drug use, paid help	5 weeks; 3, 12 months

Sample size

Sample size for this trial is based on an expected difference between groups of a 13 points reduction of the SPADI score. The statistical level of significance was set to alpha = 0.05, statistical power to 80%, and a 15% drop out rate was expected. The assumed standard deviation was set to 20 points based on the results of other studies [117-120]. Power calculations resulted in an estimated sample size of 90 participants (45 per group) to detect a 13 points difference in SPADI score. The minimum clinically important change is set to an 11 points improvement in total SPADI score [93].

Data analysis

First, descriptive statistics for demographical characteristics of the whole group will be used. Second, descriptive statistics for demographical and clinical characteristics, for baseline results of outcome measures and other potential confounding variables for the intervention group and control group will be used. Differences will be calculated for within-groups results and between-groups comparisons. Results will be calculated according to the "intention-to-treat principle". Between groups-analysis will include differences between baseline and follow up measurements for each clinical outcome measure used, their standard deviations and 95% confidence intervals. Additionally mixed models for the long term follow ups will be used. Influence of baseline differences for outcome measures will be assessed in a multivariable linear regression analysis. Statistical significance is set to $p \leq 0.05$, clinical importance will be judged by the lower 95% confidence interval which equals the minimum effect size.

An economic evaluation will compare costs of both treatment options from a societal perspective.

Resources recorded in the shoulder log book will be valued using published prices for medical costs. Costs for over the counter drugs, aids, and paid help will be reported directly by the participants in their log-books.

Productivity costs resulting from loss of paid labor will also be calculated by applying the friction costs method, which limits the period of production loss to the time during the work of the person is not replaced.

Between-group differences in outcomes of mean total costs were analyzed by Student's *t*-tests for unpaired observations.

RESULTS

Inclusion of participants has started in April 2010. First results are expected in 2012, long term results in 2013.

DISCUSSION

In order to compare the effectiveness of individualized physiotherapy to a standard exercise protocol a randomized controlled trial design will be used. Our diagnostic and eligibility criteria are purely based on clinical signs and symptoms which correspond very well with clinical practice, and the population usually seen in primary care is well reflected.

Exercises, as a quite simple form of physiotherapeutic treatment, has been shown to be as effective as other physiotherapy-led interventions in the treatment of SIS and are therefore often recommended. However, most investigated forms of physiotherapy-led interventions have been applied as standard protocols without considering individual needs and may be therefore limited in their effect. In this study, treatment of the intervention group, guided by a defined decision making process will address the individual activity and participation restrictions of each patient, predictive signs for a poor outcome, contributing and local factors. To reveal the additional benefit of this intervention, participants of the intervention group will also perform the SEP as a home program.

To strengthen the validity of the trial results, important qualitative methodological factors have been considered in the planning stage of this trial. To prevent selection bias, participants will be randomly allocated to groups via concealed allocation sequence, implemented by a remote clinical trial centre. To minimize performance bias, physiotherapists treating the active control group remain blinded to the results of the clinical examination to prevent contamination of the SEP. Further the statistician remains blinded to group assignment of the participants. Outcome measures used in this trial are easy to apply in daily practice.

To our knowledge this is the first trial comparing individualized physiotherapy led by a defined decision making process to a standard exercise protocol. Results from this trial will add evidence to the limited body of knowledge about the effect of physiotherapy in patients with SIS.

ACKNOWLEDGEMENTS

We are grateful to Prof. Dr. Ernst Wiedemann from the OCM Munich (Germany) for his help with submitting the study protocol to the Ethical Committee of the LMU Munich.

We also give thanks to the Pino GmbH Hamburg (Germany) for providing the Pinofit-elastic band.

REFERENCES

1. Huisstede BMA, Bierma-Zeinstra SMA, Koes BW, Verhaar JAN: Incidence and prevalence of upper-extremity musculoskeletal disorders. a systematic appraisal of the literature. *BMC Musculoskeletal Disorders* 2006, 7.
2. Rekola KE, Keinanen-Kiukaanniemi S, Takala J: Use of primary health services in sparsely populated country districts by patients with musculoskeletal symptoms: consultations with a physician. *Journal of Epidemiology and Community Health* 1993, 47.

3. Luime JJ: Shoulder complaints: the occurrence, course and diagnosis. *Proefschrift.* Erasmus Universiteit, 2004.
4. van der Heijden GJ: Shoulder disorders: a state of the art review. *Baillieres Clinical Rheumatology* 1999, 13:287-309.
5. van der Windt DA, Koes BW, de Jong BA, Bouter LM: Shoulder disorders in general practice: incidence, patient characteristics, and management. *Annals of Rheumatic Diseases* 1995, 54:959-964.
6. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL: Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology* 2005, 44:800-805.
7. Luime JJ, Hendriksen IJM, Burdorf A, Verhagen AP, Miedema HS, Verhaar JAN: Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scandinavian Journal of Rheumatology* 2004, 33:73-81.
8. Gartsman GM, Brinker MR, Khan M, Karahan M: Self-assessment of general health status in patients with five common shoulder complaints. *Journal of Shoulder and Elbow Surgery* 1998, 7:228-237.
9. Croft PR, Pope DP, Silman AJ: The clinical course of shoulder pain: prospective cohort study in primary care. *British Medical Journal* 1996, 313:601-602.
10. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A: Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology* 2006, 45:215-221.
11. Winters JC, Sobel JS, Groenier KH, Arendzen JH, Meyboom-de Jong B: The long-term course of shoulder complaints: a prospective study in general practice. *Rheumatology* 1999, 38:160-163.
12. Bot SDM, van der Waal JM, Terwee CB, van der Windt DAWM, Scholten RJPM, Bouter LM, Dekker J: Predictors of outcome in neck and shoulder symptoms. *Spine* 2005, 30:E459-E470.
13. Lewis JS, Green AS, Dekel S: The aetiology of subacromial impingement syndrome. *Physiotherapy* 2001, 87:458-469.
14. Deutsch A, Altchek DW, Schwartz E, Otis JC, Warren RF: Radiologic measurement of superior displacement of the humeral head in the impingement syndrome. *Journal of Shoulder and Elbow Surgery* 1996, 5:186-193.
15. Ebaugh DD, McClure PW, Karduna AR: Scapulotharacic and glenohumeral kinematics following an external rotation fatigue protocol. *Journal of Orthopaedic and Sports Physical Therapy* 2006, 36:557-571.
16. Meister K, Andrews JR: Classification and treatment of rotator cuff injuries in the overhead athlete. *Journal of Orthopaedic and Sports Physical Therapy* 1993, 18:413-420.
17. Sharkey NA, Marder RA: The rotator cuff opposes superior translation of the humeral head. *The American Journal of Sports Medicine* 1995, 23:270-275.
18. Leroux J-L, Codine P, Thomas E, Pocholle M, Mailhe D, Blotman F: Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. *Clinical Orthopaedics and Related Research* 1994, 304:108-113.
19. Reddy AS, Mohr KJ, Pink MM, Jobe FW: Electromyographic analysis of the deltoid and rotator cuff muscles in persons with subacromial impingement syndrome. *Journal of Shoulder and Elbow Surgery* 2000, 9:519-523.
20. Warner JJP, Micheli LJ, Arslanian LE, Kennedy J, Kennedy R: Pattern of flexibility, laxity, and strength in normal shoulders and shoulders with instability and impingement. *American Journal of Sports Medicine* 1990, 18:366-375.
21. Irlenbusch U, Gansen H-K: Muscle biopsy investigations on neuromuscular insufficiency of the rotator cuff: a contribution to the functional impingement syndrome of the shoulder. *Journal of Shoulder and Elbow Surgery* 2003, 12:422-426.
22. Wadsworth DJS, Bullock-Saxton JE: Recruitment patterns of scapular rotator muscles in freestyle swimmers with subacromial impingement. *Int Journal Sports Med* 1997, 18:618-624.

23. Ludewig PM, Cook TM: Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. *Physical Therapy* 2000, 80:276-291.
24. Cools AM, Witvrouw EE, Declercq GA, Danneels LA, Cambier DC: Scapular muscle recruitment patterns: Trapezius muscle latency with and without impingement symptoms. *The American Journal of Sports Medicine* 2003, 31:542-549.
25. Cools AM, Witvrouw EE, Mahieu NN, Danneels LA: Isokinetic scapular muscle performance in overhead athletes with and without impingement syndrome. *Journal of Athletic Training* 2005, 40:104-110.
26. Kibler BW: The Role of the Scapula in Athletic Shoulder Function. *American Journal of Sports Medicine* 1998, 26:325-337.
27. Neer CS: Impingement syndrome in the shoulder. *Journal of Bone and Joint Surgery* 1972, 54-A:41-50.
28. Neer CS: Impingement lesions. *Clinical Orthopaedics and Related Research* 1983, 173:70-77.
29. Bigliani LU, Morrison DS, April EW: Morphology of the acromion and its relationship to rotator cuff tears. *Orthopaedic Trans* 1986, 10:459-460.
30. Glousman R, Jobe FW, Tibone J, Moynes D, Antonelli D, Perry J: Dynamic electromyographic analysis of the throwing shoulder with glenohumeral instability. *Journal of Bone and Joint Surgery* 1988, 70A:220-226.
31. Tyler TF, Nicholas SJ, Roy T, Gleim GW: Quantification of posterior capsule tightness and motion loss in patients with shoulder impingement. *American Journal of Sports Medicine* 2000, 28:668-673.
32. Matsen FA, Arntz CT, Lippitt SB: Rotator cuff. In *The Shoulder. Volume* 1. 2 edition. Edited by Rockwood CA, Matsen FA. Philadelphia: W.B. Saunders; 1998: 755-795
33. Harryman DT, Slides JA, Clark JM, McQuade KJ, Gibb TD, Matsen III FA: Translation of the humeral head on the glenoid with passive glenohumeral motion. *Journal of Bone and Joint Surgery* 1990, 72A:1334-1343.
34. Bullock MP, Foster NE, Wright CC: Shoulder impingement: the effect of sitting posture on shoulder pain and range of motion. *Manual Therapy* 2005:28-37.
35. Solem-Bertoft E, Thuomas K-A, Westerberg C-E: The Influence of scapular retraction and protraction on the width of the subacromial space. *Clinical Orthopaedics and Related Research* 1993, 296:99-103.
36. Vlaeyen JWS, Linton SJ: Fear-avoidance and its consequences in chronic musculoskeletal pain:a state of the art. *Pain* 2000, 85:317-332.
37. Feleus A, van Dalen T, Bierma-Zeinstra SMA, Bernsen RMD, Verhaar JAN, Koes BW, Miedema HS: Kinesiophobia in patients with non-traumatic arm, neck and shoulder complaints: a prospective cohort study in general practice. *BMC Musculosceletal Disorders* 2007, 8:117.
38. Karels CH, Bierma-Zeinstra SMA, Burdorf A, Verhagen AP, Nauta AP, Koes BW: Social and psychological factors influenced the course of arm, neck and shoulder complaints. *Journal of Clinical Epidemiology* 2007, 60:839-848.
39. Lundberg M, Larsson M, Östlund H, Styf J: Kinesiophobia among patients with musculoskeletal pain in primary healthcare. *Journal of Rehabilitation Medicine* 2006, 38:37-43.
40. van der Windt DAM, Kuijpers T, Jellema P, van der Heijden GJMG, Bouter LM: Do psychological factors predict outcome in both low-back pain and shoulder pain? *Annals of the Rheumatic Diseases* 2007, 66:313-319.
41. De Bruijn C, de Bie R, Gereats J, Goossens M, van der Heuvel W, Van der Heijden GJ, Candel M, Dinant G-J: Effect of an education and activation programme on functional limitations and patient-perceived recovery in acute and sub-acute shoulder complaints – a randomised clinical trial. *BMC Musculoskeletal Disorders* 2007, 8.
42. Dinnes J, Lovemann E, McIntyre L, Waugh N: The effectiveness of diagnostic tests of the assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health Technology Assessment* 2003, 7:1-175.
43. Read JW, Perko M: Shoulder ultrasound: Diagnostic accuracy for impingement syndrome, rotator cuff tear, and biceps tendon pathology. *Journal of Shoulder and Elbow Surgery* 1998, 7:264-271.

44. Sher JS, Iannotti JP, Williams GR, Herzog RJ, Kneeland JB, Llisser S, Patel N: The effect of shoulder magnetic resonance imaging on clinical decision making. *Journal of Shoulder and Elbow Surgery* 1998, 7:205-209.
45. Awerbuch MS: The clinical utility of ultrasonography for rotator cuff disease, shoulder impingement syndrome and subacromial bursitis. *Medical Journal of Australia* 2008, 188:50-53.
46. Ardic F, Kahraman Y, Kacar M, Kahraman MC, Findikoglu G, Yorgancioglu ZR: Shoulder impingement syndrome: relationships between clinical, functional, and radiologic findings. *American Journal of Physical Medicine & Rehabilitation* 2006, 85:53-60.
47. Teefey SA, Rubin DA, Middleton WD, Hildebolt CF, Leibold RA, Yamaguchi K: Detection and quantification of rotator cuff tears. comparison of ultrasonographic, magnetic resonance imaging, and arthroscopic findings in seventy-one consecutive cases. *Journal of Bone and Joint Surgery* 2004, 86:708-716.
48. Peters D, Davies P, Pietroni P: Musculoskeletal clinic in general practice: study of one year's referrals. *British Journal of Gneral Practice* 1994, 44:25-29.
49. Faber E, Kuiper JI, Burdorf A, Miedema HS, Verhaar JAN: Treatment of impingement syndrome: a systematic review of the effects on functional limitations and return to work. *Journal of Occupational Rehabilitation* 2006, 16:7-25.
50. Green SE, Buchbinder R, Hetrick S: Physiotherapy interventions for shoulder pain. *The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD004258* 2003a.
51. Michener LA, Walsworth MK, Burnet EN: Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. *Journal of Hand Therapy* 2004, 17:152-164.
52. Kuhn JE: Exercise in the treatment of rotator cuff impingement: A systematic review and a synthesized evidence-based rehabilitation protocol. *Journal of Shoulder and Elbow Surgery* 2009, 18:138-160.
53. WHO: *ICF - Internationale Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit.* Köln: Deutsches Institut für Medizinische Dokumentation und Information (DIMDI); 2005.
54. Jones M, Edwards I, Grimmer K, Higgs J, Tede F: Challenges of applying best evidence to physiotherapy: Part 2 - health and clinical reasoning models to facilitate evidence-based practice. *Internet Journal of Allied Health Sciences and Practice* 2006, 4:1-8.
55. Kaltenborn F: Wirbelsäule - Manuelle Untersuchung und Mobilisation. Oslo: Olaf Noris Bokhandel; 1992.
56. Evjenth O, Hamberg J: *Muscle stretching in manual therapy.* Alfta: Alfta Rehab; 1998.
57. Maitland GD: *Manipulation der Wirbelsäule.* 2nd edn. Berlin: Springer Verlag; 1994.
58. Hertel R, Ballmer FT, Lombert SM, Gerber C: Lag signs in the diagnosis of rotator cuff rupture. *Journal of Shoulder and Elbow Surgery* 1996, 5:307-313.
59. Gerber C, Krushell RJ: Isolated rupture of the tendon of the subscapularis muscle. Clinical features in 16 cases. *Journal of Bone and Joint Surgery* 1991, 73B:389-394.
60. Walch G, Boulahia A, Calderone S, Robinson AHN: The 'dropping' and 'hornblower's' signs in evaluation of rotator-cuff tears. *Journal of Bone and Joint Surgery Br* 1998, 80:624-628.
61. Butler DS: *Mobilisation des Nervensystems.* Berlin: Springer Verlag; 1995.
62. Hintermeister RA, Lange GW, Schultheis JM, Bey MJ, Hawkins RJ: Electromyographic activity and applied load during shoulder rehabilitation exercises using elastic resistance. *The American Journal of Sports Medicine* 1998, 26:210-220.
63. Decker MJ, Hintermeister RA, Faber KJ, Hawkins RJ: Serratus anterior muscle activity during selected rehabilitation exercises. *The American Journal of Sports Medicine* 1999, 27:784-791.
64. Alpert SW, Pink MM, Jobe FW, McMahon PJ, Mathiyakom W: Electromyographic analysis of deltoid and rotator cuff function under varying loads and speeds. *Journal of Shoulder and Elbow Surgery* 2000, 9:47-58.
65. Jenp Y-N, Malanga GA, Growney ES, An K-N: Activation of the rotator cuff in generating isometric shoulder rotation torque. *The American Journal of Sports Medicine* 1996, 24:477-485.

66. Kelly BT, Kadrmas WR, Speer KP: The manual muscle examination for rotator cuff strength. *The American Journal of Sports Medicine* 1996, 24:581-587.
67. Kronberg M, Broström L-A: Electromyographic recordings in shoulder muscles during eccentric movements. *Clinical Orthopaedics and Related Research* 1995, 314:143-151.
68. Lear LJ, Gross MT: An electromyographical analysis of the scapular stabilizing synergists during a push up progression. *Journal of Orthopaedic and Sports Physical Therapy* 1998, 28:146-157.
69. Levy AS, Kelly BT, Lintner SA, Osbahr DC, Speer KP: Function of the long head of the biceps at the shoulder: Electromyographic analysis. *Journal of Shoulder and Elbow Surgery* 2001, 10:250-255.
70. Swanik KA, Lephart SM, Swanik B, Lephart SP, Stone DA, Fu FH: The effects of shoulder plyometric training on proprioception and selected muscle performance characteristics. *Journal of Shoulder and Elbow Surgery* 2002, 11:579-586.
71. Reinold MM, Wilk KE, Fleisig GS, Zheng N, Barrentine SW, Chmielewski T, Cody RC, Jamerson GG, Andrews JR: Electromyographic analyses of the rotator cuff and deltoid musculature during common shoulder external rotation exercises. *Journal of Orthopaedic and Sports Physical Therapy* 2004, 34:385-394.
72. Uhl TL, Carver TJ, Mattacola CG, Mair SD, Nitz, J. A: Shoulder musculature activation during upper extremity weight bearing exercise. *Journal of Orthopaedic and Sports Physical Therapy* 2003, 33:109-117.
73. Moseley BJ, Jobe FW, Pink MM, Perry J, Tibone J: EMG analysis of the scapular muscles during a shoulder rehabilitation program. *American Journal of Sports Medicine* 1992, 20:128-134.
74. Lintner D, Mayol M, Uzodinma O, Jones R, Labossiere D: Glenohumeral Internal Rotation Deficits in Professional Pitchers Enrolled in an Internal Rotation Stretching Program. *American Journal of Sports Medicine* 2007, 35:617-621.
75. Reinold MM, Escamilla R, Wilk KE: Current concepts in the scientific and clinical rationale behind exercises for glenohumeral and scapulothoracic musculature. *Journal of Orthopaedic & Sports Physical Therapy* 2009, 39:106-117.
76. Reinold MM, Macrina LC, Wilk KE, Fleisig GS, Dun S, Barrentine SW, Ellerbusch MT, Andrews JR: Electromyographic analysis of the supraspinatus and deltoid muscles during 3 common rehabilitation exercises. *Journal of Athletic Training* 2007, 42:464-469.
77. Townsend H, Jobe FW, Pink M, Perry J: Electromyographic analysis of the glenohumeral muscles during a baseball rehabilitation programme. *The American Journal of Sports Medicine* 1991, 19:264-272.
78. McClure P, Balaicuis J, Heiland D, Broersmsma ME, Thorndike CK, Wood A: A randomized controlled comparison of stretching procedures for posterior shoulder tightness. *Journal of Orthopaedic and Sports Physical Therapy* 2007, 37:108-113.
79. Cools AM, Dewitte V, Lanszweert F, Notebaert D, Roets A, Soetens B, Cagnie B, Witvrouw EE: Rehabilitation of scapular muscle balance: which exercises to prescribe? *American Journal of Sports Medicine* 2007, 35:1744-1750.
80. Leroux J-L, Codine P, Thomas E, Pocholle M, Mailhe D, Blotman F: Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. *Clinical Orthopaedics and Related Research* 1994, 304:108-115.
81. Warner JJP, Micheli LJ, Arslanian LE, Kennedy J, Kennedy R: Pattern of flexibility, laxity, and strength in normal shoulders and shoulders with instabilityand impingement. *American Journal of Sports Medicine* 1990, 18:366-375.
82. TaheriAzam A, Sadatsafavi M, Moayyeri A: Outcome predictors in nonoperative management of newly diagnosed subacromial impingmeent syndrome: a longitudinal study. *Medscape General Medicine* 2005, 7:63.
83. Kuijpers T, van der Windt DAWM, van der Heijden GJMG, Bouter LM: Systematic review of prognostic cohort studies on shoulder disorders. *Pain* 2004, 109:420-431.

84. Kuijpers T, van der Windt DAWM, Boeke AJP, Twisk JWR, Vergouwe Y, Bouter LM, van der Heijden GJMG: Clincal presentation for the prognosis of shoulder pain in general practice. *Pain* 2006, 120:276-285.
85. Habermayer P, Lehmann L, Lichtenberg S: Rotatorenmanschetten-Ruptur. *Orthopäde* 2000, 29:196-208.
86. Smith KL, Harryman II DT, Antonlou J, Campbell B, Sidles JA, Matsen III FA: A prospective, multipractice study of shoulder function and health status in patients with documented rotator cuff tears. *Journal of Shoulder and Elbow Surgery* 2000, 9:395-402.
87. Pope DP, Croft PR, Pritchard CM, McFarlane GJ, Silman AJ: The frequency of restricted range of movement in individuals with self-reported shoulder pain: results from a population-based survey. *British Journal of Rheumatology* 1996, 35:1137-1141.
88. Kaltenborn F: *Manuelle Mobilisation der Extremitätengelenke.* Oslo: Olaf Noris Bokhandel; 1992.
89. Jones MA, Rivett DA: *Clinical Reasoning for Manual Therapists.* Butterworth-Heinemann; 2004.
90. MacDermid J, Solomon P, Prkachin K: The shoulder pain and disability index dmonstrates factor, construct and longitudinal validity. *BMC Musculoskeletal Disorders* 2006, 7:12.
91. Beaton DE, Richards RR: Measuring function of the shoulder. A cross-sectional comparison of five questionnaires. *Journal of Bone and Joint Surgery* 1996, 78A:882-890.
92. Cloke DJ, Lynn SE, Watson H, Steen IN, Purdy S, Williams JR: A comparison of functional, patient-based scores in subacromial impingement. *Journal of Shoulder and Elbow Surgery* 2005, 14:380-384.
93. Williams JW, Holleman DR, Simel DL: Measuring shoulder function with the shoulder pain and disability index. *Journal of Rheumatology* 1995, 22:727-732.
94. ten Klooster PM, Drossaers-Bakker KW, Taal E, van de Laar MAFJ: Patient-perceived satisfactory improvement (PPSI): Interpreting meaningful change in pain from the patient's perspective. *Pain* 2006, 121:151-157.
95. Farrar JT, Young Jr. JP, LaMoreaux L, Werth JL, Poole RM: Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001, 94:149-158.
96. Stratford PW, Gill C, Westaway MD, Binkley JM: Assessing disability and change on individual patients: a report of a patient specific measure. *Physiotherapy Canada* 1995, 47:258-263.
97. Donnelly C, Carswell A: Individualized outcome measures: a review of the literature. *Revue Canadienne D`Ergothèrapie* 2002:84-94.
98. Chatman AB, Hyams SP, Neel JM, Binkley JM, Stratford PW, Schomberg A, Stabler M: The Patient-Specific Functional Scale: Measurement properties in patients with knee function. *Physical Therapy* 1997, 77:820-829.
99. Westaway MD, Stratford PW, Binkley JM: The patient-specific functional scale: validation of its use in persons with neck dysfunction. *Journal of Orthopaedic and Sports Physical Therapy* 1998, 27:331-338.
100. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W: Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *European Journal of Pain* 2004, 8:283-291.
101. Waddell G, Newton M, Henderson I, Somerville D, Main CJ: A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low-back pain and disability. . *Pain* 1993, 52:157–168.
102. Pfingsten M, Kröner-Herwig B, Leibing E, Kronshage U, Hildebrandt J: Validation of the German version of the Fear-Avoidance Beliefs Questionnaire (FABQ). *European Journal of Pain* 2000, 4259-266.
103. Staerkle R, Mannion AF, Elfering A, Junge A, Semmer NK, Jacobshagen N, Grob D, Dvorak J, Boos N: Longitudinal validation of the Fear-Avoidance Beliefs Questionnaire (FABQ) in a Swiss-German sample of low back pain patients. *European Spine Journal* 2004, 13:332-340.
104. Crombez G, Vlaeyen JWS, Heuts PHTG, Lysens R: Pain-related fear is more disabling than pain itself: evidence on the role of pain-related fear in chronic back pain disability. *Pain* 1999, 80:329-339.

105. Swinkels-Meewisse EJCM, Swinkels RAHM, Verbeek ALM, Vlaeyenz JWS, Oostendorp RAB: Psychometric properties of the Tampa scale for kinesiophobia and the fear-avoidance beliefs questionnaire in acute low back pain. *Manual Therapy* 2003, 8:29-36.
106. Osman A, Barrios FX, Kopper BA, Hauptmann W, Jones J, O'Neill E: Factor structure, reliability, and validity of the pain catastrophizing scale. *Journal of Behavioral Medicine* 1997, 20:589-605.
107. Weissman-Fogel I, Sprecher E, Pud D: Effects of catastrophizing on pain perception and pain modulation. *Eperimental Brain Research* 2008, 186:79-85.
108. Block CK, Brock J: The relationship of pain catastrophizing to heightened feelings of distress. *Pain Management Nursing* 2008, 9:73-80.
109. Osman A, Barrios FX, Guittierrez PM, Kopper BA, Merrifield T, Grittmann L: The pain catastrophizing Ssale: further psychometric evaluation with adult samples. *Journal of Behavioral Medicine* 2000, 23:351-365.
110. Sullivan MJ, Bishop SR, Pivik J: The pain catastrophizing scale: development and validation. *Psychological Assessment* 1995, 7:524-532.
111. Meyer K, Sprott H, Mannion AF: Cross-cultural adaptation, reliability, and validity of the German version of the pain catastrophizing scale. *Journal of Psychosomatic Research* 2008, 64:469-478.
112. Sullivan MJ, Stanish W, Waite H, Sullivan M, Tripp DA: Catastrophizing, pain, and disability in patients with soft-tissue injuries. *Pain* 1998, 77:253-260.
113. Lame I, Peters ML, Kessels AG, van Kleef M, Patijn J: Test-retest stability of the pain catastrophizing scale and the tampa scale for kinesiophobia in chronic pain patients over a longer period of time. *Journal of Health Psychology* 2008, 13:820-826.
114. Goossens MEJB, Vlaeyen JWS, Hidding A, Kole-Snijders A, Evers SMAA: Treatment expectancy affects the outcome of cognitive-behavioral interventions in chronic pain. *Clinical Journal of Pain* 2005, 21:18-26.
115. Smeets RJEM, Beelen S, Goossens MEJB, Schouten EGWJ, Knottnerus A, Vlaeyen JWS: Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clinical Journal of Pain* 2008, 24:305-315.
116. Deviliya GJ, Borkovecb TD: Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy & Experimental Psychatry* 2000, 31:73-86.
117. Carette S, Moffet H, Tardif J, Bessette L, Morin F, Fremont P, Bykerk V, Thorne C, Bell M, Bensen W, Blanchette C: Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder. *Arhtitis & Rheumatism* 2003, 48:829-838.
118. Chen JF, Ginn KA, Herbert RD: Passive mobilisation of shoulder region joints plus advice and exercise does not reduce pain and disability more than advice and exercise alone: a randomised trial. *Australian Journal of Physiotherapy* 2009, 55:17-23.
119. Dogru H, Basaran S, Tunay S: Effectiveness of therapeutic ultrasound in adhesive capsulitis. *Joint Bone Spine* 2008, 75:445-450.
120. Tveita EK, Tariq R, Sesseng S, Juel NG, Bautz-Holter E: Hydrodilatation, cortocosteroids and adhesive capsulitis: a randomized controlled trial. *BMC Musculoskeletal Disorders* 2008, 9:53.

CHAPTER 4

Physiotherapy in patients with clinical signs of shoulder impingement syndrome:

A randomized controlled trial

ABSTRACT

Objective To investigate the effect of individualized manual physiotherapy and exercises compared to individualized exercises alone in patients with shoulder impingement syndrome.
Design Randomized controlled trial.
Subjects Patients with shoulder impingement of more than 4 weeks' duration.
Methods Patients in the intervention group were treated with individually adapted exercises and examination-based physiotherapy. Controls were treated with individually adapted exercises only. Both groups had 10 treatment sessions over a period of 5 weeks and subsequently continued their exercises at home for another 7 weeks.
Results were analyzed at 5 and 12 weeks after the start of the study. Primary outcome measures were: Shoulder Pain and Disability Index, and Patient's Global Impression of Change. Secondary outcome measures were: mean weekly pain score; Generic Patient-Specific Scale; and Patient's Satisfaction with Treatment.
Results A total of 46 patients were randomized to the intervention group and 44 to the control group. Although both groups showed significant improvements, there was no difference between groups for the primary and secondary outcomes at any time. Only results for mean pain differed at 5 weeks in favor of the intervention group.
Conclusion Individually adapted exercises were effective in the treatment of patients with shoulder impingement syndrome. Individualized manual physiotherapy contributed only a minor amount to the improvement in pain intensity. However, further research is necessary to confirm these results before definite recommendations can be made.

Kromer TO, de Bie RA, Bastiaenen CHG. Physiotherapy in patients with clinical signs of shoulder impingement syndrome: a randomized controlled trial. Journal of Rehabilitation Medicine 2013;45:488- 97

INTRODUCTION

Shoulder pain is a common complaint seen by health professionals (1, 2) with an incidence of 9.5 per 1000 patients presenting to primary care and a point prevalence of 7% to 26% (3, 4). Shoulder pain considerably affects health (4, 5), seems to be recurrent in nature with only low recovery rates even after 3 years since onset (1, 6, 7). Although no standardized classification for shoulder complaints exists, most shoulder patients show clinical signs of subacromial impingement (2, 4). Subacromial impingement syndrome (SIS) occurs due to a mechanical disturbance within the subacromial space. It is characterized by pain and functional restrictions mostly during overhead activities (8).

Physiotherapy is an often prescribed measure for the treatment of shoulder disorders (2, 9). Particularly for SIS the use of exercise therapy to improve muscle strength, flexibility and coordination of the rotator cuff and the shoulder girdle muscles have been reported in several studies (10-15). Combining exercises with manual therapy to specifically influence structural components on the shoulder complex and the spine seems to be even more effective and is therefore recommended in secondary literature (16, 17).However, the available evidence for the effect of these interventions is still limited due to small sample sizes and other methodological flaws and recent systematic reviews on this topic emphasize the need for more high quality trials, especially of combination of modalities to reflect common practice (16, 18-20).

This randomized controlled trial investigated the effect of individualized manual physiotherapy combined with an individualized exercise program on pain and functioning compared to individualized exercises alone in patients with SIS. The study design has been published in BMC Musculoskeletal Disorders (21). To our knowledge this is the first trial of this type for the German population.

METHODS

Participants

Participants were recruited by referral from general practitioners or orthopaedic surgeons to physiotherapy because of shoulder complaints. They were screened for the clinical presentation of SIS by trained physiotherapists considering the following eligibility criteria:

Inclusion criteria: (1) age between 18 and 75 years, (2) symptoms for at least four weeks, (3) main complaints in the glenohumeral joint region or the proximal arm, (4) presence of one of the following signs indicating SIS: Neer impingement sign, Kennedy-

Hawkins impingement test, painful arc with active abduction or flexion, (5) pain during one of the following resistance tests: external rotation, internal rotation, abduction, or flexion.

Exclusion criteria: (1) average 24-hours pain of 8/10 or more on a visual numeric rating scale (VNRS), (2) primary scapulothoracic dysfunction due to paresis, (3) diagnosed instability or previous history of dislocation, (4) adhesive capsulitis (frozen shoulder), (5) more than 1/3 restriction of elevation compared to the unaffected side, (6) substantial shoulder weakness or loss of active shoulder function, (7) shoulder surgery in the last 12 months on the involved side, (8) reproduction of symptoms with active or passive cervical movements, (9) neurological involvement with sensory and muscular deficit, (10) inflammatory joint disease (e.g. rheumatoid arthritis), (11) diabetes mellitus, (12) intake of psychotherapeutic drugs, (13) compensation claims, (14) inability to understand written or spoken German.

Inclusion process and randomisation

After signing informed consent and baseline assessment eligible participants were randomly allocated to treatment groups in blocks of six using central blinded randomization. To guarantee allocation concealment, therapists received the information about patient allocation immediately before the first treatment by the Department of Epidemiology, Maastricht University.

Interventions

The intervention group received individually adapted exercises (IAEX) plus individualized manual physiotherapy (IMPT), the control group received individually adapted exercises (IAEX) only. A detailed description of the interventions is provided in the published protocol for this study (21) and in Appendix 1. Treatment was provided in six outpatient physiotherapy clinics by 12 experienced and trained physiotherapists with an international qualification for manual therapy according to IFOMPT standard and an average post-qualification experience of more than 23 years (range 18 to 28). Participants received ten treatment sessions within 5 weeks. To guarantee an equal instruction of the exercise program in both groups and to be able to identify the additional effect of the IMPT the time frame for treatment was 15 to 20 minutes for the control group and 20 to 30 minutes for the intervention group. Afterwards both groups continued their exercise program three times a week for another 7 weeks.

Therapists' compliance with the protocol

Compliance of therapists with the treatment guidelines was monitored with the help of the examination and treatment records, group meetings and regular interviews.

Outcome measures

Patients were assessed at baseline, after the intervention period at 5 weeks and at 12 weeks. Primary outcome measures were the Shoulder Pain and Disability Index (SPADI) (22) and Patient's Global Impression of Change (PGIC). An improvement of 11 points in the total SPADI score (23) and a statement of "slightly better" in the PGIC were considered as the minimum clinically important changes. As secondary outcome measures we used the Generic Patient-Specific Scale (GPSS) (24), the average weekly pain score and Patient's Satisfaction with Treatment (PST). For the GPSS an average score across all activities was calculated. A minimum change of 30% was considered as a clinically important improvement (25, 26). For average pain an improvement of 2 points or more on a visual numeric rating scale (VNRS) was defined as a clinically important difference (25, 26). Satisfaction with treatment was also rated on an 11 point VNRS with 10 defined as "completely satisfied" and 0 as "completely dissatisfied". A more detailed description of all outcome measures is given in the study protocol. To be able to analyze the possible influence of other important factors on our main outcome all patients filled in a modified version of the Fear Avoidance Beliefs Questionnaire (FABQ), the Pain Catastrophizing Scale (PCS), and answered a question about their expectancies of treatment outcome at baseline also scored on a VNRS with higher scores reflecting more positive expectancies.

Compliance with treatment was assessed with the shoulder logbook. Treatment compliance included the number of attended treatment visits out of a maximum of ten and the frequency of the home exercises. Demographic data including age, sex, height, weight, profession, sports activities, information about medication intake, sick leave, severity and duration of symptoms and previous episodes of shoulder pain were also documented.

Sample size calculation

Power calculation resulted in an estimated sample size of 90 participants (45 per group) to detect a 13 points difference in SPADI score. The assumed standard deviation (SD) was set to 20 points based on the results of other studies (27-30). Alpha was set to 0.05; statistical power to 80% given an expected drop-out rate of 15%.

Data analysis

Descriptive statistics for demographical and clinical characteristics, for baseline results of outcome measures and other potentially confounding variables for both groups and the total group were used. Data for work classification, working hours per week, and sick leave were only analyzed for patients who were in work. Work was classified according to the estimated physical load for the upper extremity of the patient's profession. Examples for class 1 professions are accountants, secretaries, or school teachers; for class 2 housewives, nurses, or retail dealers, and for class 3 manual workers such as carpenters, gardeners, or mechanics. Differences after 5 and 12 weeks were calculated for between-group comparisons and within-group results according to the "intention-to-treat principle". For between-group analysis mean differences between groups, their SDs and 95% confidence intervals (95%CI) were calculated for each clinical outcome measure. Within-group results were calculated by subtracting the 5-week results from baseline values and the 12-week from the 5-week values. Influence of baseline differences and other potentially influencing factors based on literature on the main outcome measure were assessed in a multivariable linear regression analysis. Statistical significance was set to $p \leq 0.05$. Due to the nature of the intervention it was impossible to blind therapist and participants. However, we blinded therapists of the control group to all clinical information of their patients. Measurements of outcome were also blinded because therapists were not involved in this process and we kept patients naive to their allocation. Statistical analyses were performed using IBM SPSS Statistics 19.

RESULTS

Recruitment process

188 patients were assessed for eligibility over an 18 month period. Some 55 patients did not fulfil the eligibility criteria, 33 refused participation. 10 patients were not included due to other reasons (3 moved, 4 didn't get a prescription for physiotherapy, 3 couldn`t guaranty a continuous treatment due to frequent business travels abroad). Finally, 90 participants were randomly allocated with 44 patients in the control group (IAEX) and 46 patients in the intervention group (IAEX+IMPT). At 5 weeks all patients were analyzed with no loss to follow up, at 12 weeks 2 patients in the intervention group discontinued treatment, one without giving reasons, the other because of too much effort. The recruitment process is summarized in figure 1.

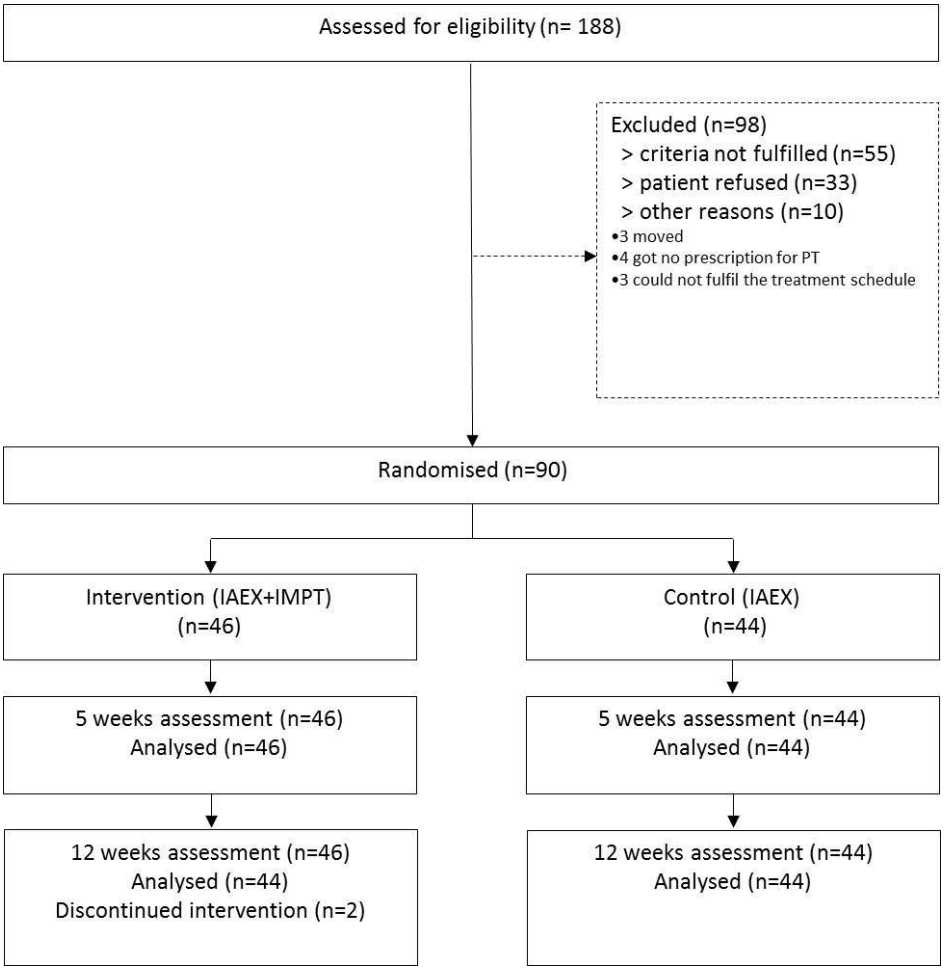


Figure 1 Inclusion process

No significant differences for demographic and clinical baseline characteristics between groups were found except for sports hours per week, overall duration of symptoms, total FABQ, and the FABQ activity subscale. Baseline characteristics for the total group, the intervention and control group are displayed in table 1 and table 2.

Table 1 Baseline demographic data and baseline results of the questionnaires

	Intervention (n=46)	Control (n=44)	Total group (n=90)
Age, years (mean; SD)	50.1 (12.2)	53.7 (9.9)	51.8 (11.2)
18-29 years, *n* (%)	2 (4.3)	0 (0.0)	2 (2.2)
30-44 years, *n* (%)	13 (28.3)	8 (18.2)	21 (23.4)
45-59 years, *n* (%)	21 (45.7)	20 (45.4)	41 (45.5)
>60 years, *n* (%)	10 (21.7)	16 (36.4)	26 (28.9)
Gender (female), *n* (%)	22 (47.8)	24 (54.5)	46 (51.1)
BMI, mean (SD)	25.3 (3.7)	26.8 (4.3)	26.0 (4.1)
Classification of physical work load*, *n* (%)	(n=40)	(n=38)	(n=78)
Low	16 (40.0)	19 (50.0)	35 (44.9)
Medium	18 (45.0)	13 (34.2)	31 (39.7)
High	6 (15.0)	6 (15.8)	12 (15.4)
Working hours per week*, mean (SD)	32.2 (13.8)	37.2 (10.7)	34.6 (12.6)
Days of sick leave*, mean (SD)	0.1 (0.6)	1.1 (4.1)	0.6 (2.9)
Sports hours per week, *n* (%)			
0-2	13 (28.3)	21 (47.4)	34 (37.8)
3-5	33 (71.7)	23 (52.6)	56 (62.2)
Duration of the current episode in weeks, mean (SD)	27.4 (28.4)	40.8 (53.4)	33.9 (42.8)
Overall duration of shoulder pain in weeks, mean (SD)	136.9 (198.5)	71.3 (68.7)	104.8 (152.6)
Number of episodes during the last 12 months, *n* (%)			
1-3 (including the current one)	37 (80.4)	38 (86.4)	75 (83.3)
>3	9 (19.6)	6 (13.6)	15 (16.7)
Average pain score, mean (SD)	5.2 (1.8)	5.0 (1.8)	5.1 (1.8)
SPADI total score, mean (SD)	39.7 (17.2)	41.3 (17.0)	40.4 (17.0)
SPADI sub-score for pain, mean (SD)	47.8 (18.8)	49.6 (17.3)	48.7 (18.0)
SPADI sub-score for function, mean (SD)	31.5 (18.6)	32.9 (19.3)	32.2 (18.9)
GPSS average score, mean (SD)	4.1 (1.8)	4.0 (1.7)	4.0 (1.7)
FABQ total score, mean (SD)	36.4 (17.4)	28.7 (16.7)	32.7 (17.4)
FABQ sub-score for physical activity, mean (SD)	15.9 (4.1)	13.3 (5.3)	14.6 (4.9)
FABQ sub-score for work, mean (SD)	13.4 (10.3)	10.8 (9.5)	12.1 (9.9)
PCS total score, mean (SD)	12.4 (9.7)	10.4 (7.1)	11.4 (8.5)
PCS sub-score for rumination, mean (SD)	4.6 (3.9)	3.8 (3.0)	4.2 (3.5)
PCS sub-score for magnification, mean (SD)	3.1 (2.6)	2.5 (1.9)	2.8 (2.3)
PCS sub-score for helplessness, mean (SD)	4.7 (4.2)	4.1 (3.3)	4.4 (3.8)
PET, mean (SD)	8.4 (1.6)	8.7 (1.3)	8.5 (1.5)

BMI: Body Mass Index; FABQ: Fear Avoidance Beliefs Questionnaire; GPSS: Generic Patient Specific Scale; PCS: Pain Catastrophizing Scale; PET: Patients Expectancies of Treatment Outcome; SD: standard deviation; SPADI: Shoulder Pain and Disability Index; *: Only participants who are in work; 40 and 38, respectively.

Table 2 Baseline clinical test results

Clinical tests (positive results)	Intervention (n=46)	Control (n=44)	Total group (n=90)
	n (%)	*n* (%)	*n* (%)
Painful arc	44 (95.7)	43 (97.7)	87 (96.7)
Hawkins-Kennedy test	34 (73.9)	33 (75.0)	67 (74.4)
Neer compression test	38 (82.6)	42 (95.5)	80 (88.9)
ER lag sign	0 (0.0)	1 (2.3)	1 (1.1)
Lift off test	0 (0.0)	1 (2.3)	1 (1.1)
Hornblower's sign	0 (0.0)	0 (0.0)	0 (0.0)
Restriction of caudal glide	39 (84.8)	38 (86.4)	77 (85.6)
Restriction of posterior glide	35 (76.1)	38 (86.4)	73 (81.1)
Restriction of passive elevation (up to 20°)	14 (30.4)	14 (31.8)	28 (31.1)
Restriction of passive ER (up to 15°)	11 (23.9)	13 (29.5)	24 (26.7)
Comparable signs of the cervical spine	27 (58.7)	23 (52.3)	50 (55.6)

ER: external rotation

Power of study results

Our power calculation was based on a 13 points difference in SPADI score and an estimated standard deviation of 20 points. With a mean (SD) improvement of 14.9 (18.5) points on the SPADI for the total group and no drop-outs, this study has sufficient power.

Shoulder log books

From a total of 90 participants 89 (98.9%) returned a complete logbook after 5 weeks and 85 (94.4%) after 12 weeks from which 3 were incomplete for analysis.

Sick leave

7.7 percent (n=6) of patients who were at work (n=78) were responsible for all days of sick leave during the 5 weeks treatment period. Only one patient from the intervention group had 12 sick days compared to 5 patients from the control group with a total of 58 days. During the home exercise period data were available for 73 participants.

Again, 1 patient in the intervention group was responsible for 4 sick days compared to 3 patients with 41 sick days in the control group.

Exercise frequency

Mean (SD) exercise frequency per week including the two supervised sessions for both groups was 5.5 (1.3) and during the home exercise period 3.8 (1.6) for the intervention and 3.9 (1.8) for the control group.

Additional diagnostics, medication, and co-interventions

Baseline to week five: 5 patients in the intervention and 7 in the control group received additionally NSAIDs from their general practitioner. 5 in the intervention and nobody in the control group had an injection with cortisone. One patient in the intervention and two in the control group had self-paid massages for their back during the 5 weeks, one patient in each group made use of a soothing ointment containing dimethyl sulfoxide and heparin (Dolobene®). One patient in the intervention group had 5 treatments with electrotherapy. For further diagnosis one in the control group but three patients of the intervention group had an MRI with one of them having additionally two x-rays.

Week 6 to 12: In the intervention group 2 had a cortisone injection, 4 received NSAIDs and 2 participants had a combination of both. 11 patients received a total of 39 additional physiotherapy treatments and one had a diagnostic MRI. In the control group, 3 had a cortisone injection, 4 NSAIDs and 1 participant a combination of both; only 2 patients had a total of 12 additional treatments.

Therapists' compliance with the protocol

All patients in the intervention group were examined and treated according to the initial instructions. They received passive manual mobilization techniques for the shoulder complex, the cervical or thoracic spine, and self-mobilization exercises to intensify the effect of the passive techniques. Patients were informed about the influence of their daily activities on symptoms and healing, instructed on how to avoid, modify or compensate their most provocative activities at work and during leisure time, and focused on an upright posture. Patients in the intervention group also performed specific exercises to improve scapular setting, control and scapulohumeral rhythm. Therapists of the control group remained blinded to the clinical examination

results. However, due to illness of one of the therapists, two patients in the control group were supervised by the therapist of the intervention group for half of their contact sessions. During the first three treatment sessions it was difficult for therapists of the intervention group to instruct the exercises besides the individualized manual treatments within the given average time frame of about 25 minutes. They estimated their time for the exercise instructions with about 35 to 40% (9 to 10 minutes). Therefore they were allowed to extend the exercise instruction time if necessary to guarantee a sufficient instruction of the exercises comparable to the control group for the first three sessions. Therapists of the control group felt uneasy to start treatment without having any clinical baseline information although clear instructions were given.

Efficacy analysis

Total SPADI score and sub-scores

Both groups improved significantly after 5 and 12 weeks in total SPADI score and its sub-scores (table 3). No difference between groups in any of the SPADI scores could be detected (table 4). Due to baseline differences between groups overall duration of symptoms, total FABQ, the FABQ activity sub-score and other potentially influencing baseline covariates identified from the literature were entered into a univariate linear regression analysis to check their influence on group differences in SPADI. Significant relevant covariates ($p < 0.05$) were then combined in a multivariable regression analysis, which had a certain influence but did not change group difference to a significant level.

Table 3 Results after 5 and 12 weeks for within-groups comparison

	Groups									
	Week 0		Week 5		Week 12		Difference within groups at 5 weeks		Difference within groups between 5 and 12 weeks	
Outcomes	Mean (SD)		Mean (SD)		Mean (SD)		Mean (SD) (CI95%)		Mean (SD) (CI95%)	
	Intervention (n= 46)	Control (n= 44)	Intervention (n= 46)	Control (n= 44)	Intervention (n= 44)	Control (n= 44)	Intervention (n= 46)	Control (n= 44)	Intervention (n= 44)	Control (n= 44)
SPADI (0-100)	39.7 (17.2)	41.3 (17.0)	23.5 (17.5)	26.8 (17.8)	16.1 (17.2)	19.8 (19.5)	16.2 (18.2)*** (10.8 – 21.6)	14.4 (17.1)*** (9.2 – 19.6)	7.5 (12.3)*** (3.7 – 11.2)	7.0 (13.8)** (2.8 – 11.2)
Pain SPADI (0-100)	47.8 (18.8)	49.6 (17.3)	29.8 (21.1)	31.5 (18.8)	20.1 (19.7)	24.1 (21.7)	18.0 (20.2)*** (12.0 – 24.0)	18.0 (21.4)*** (11.5 – 24.5)	9.8 (15.2)*** (5.2 – 14.4)	7.4 (16.6)** (2.4 – 12.5)
Function SPADI (0-100)	31.5 (18.6)	32.9 (19.3)	17.1 (15.0)	22.1 (18.1)	12.1 (15.4)	15.5 (18.1)	14.4 (18.8)*** (8.8 – 20.0)	10.8 (15.8)*** (6.0 – 15.6)	5.1 (10.8)** (1.9 – 8.4)	6.7 (12.6)*** (2.8 – 10.5)
Pain (0-10)	5.2 (1.8)	5.0 (1.8)	2.9 (1.6)	3.3 (1.6)	2.3 (1.8)	2.3 (1.8)	2.3 (1.8)*** (1.7 – 2.8)	1.6 (2.3)*** (1.0 – 2.3)	0.6 (1.5)* (0.1 – 1.0)	1.0 (1.7)*** (0.5 – 1.5)
GPSS (0-10)	4.1 (1.8)	4.0 (1.7)	7.1 (2.0)	6.3 (2.0)	7.3 (2.5)	7.4 (2.0)	3.0 (2.3)*** (2.3 – 3.7)	2.3 (2.2)*** (1.6 – 3.0)	0.3 (1.8) (-0.27– 0.81)	1.1 (2.0)*** (0.5 – 1.7)

*: significant at p=0.05; **: significant at p=0.01; ***: significant at p=0.001; SPADI: Shoulder Pain and Disability Index; GPSS: Generic Patient Specific Scale; SD: standard deviation.

Table 4 Results after 5 & 12 weeks for between-groups comparison

	Difference between groups at 5 weeks (change scores 0 to 5 weeks)		Difference between groups at 12 weeks (change scores 6 to 12 weeks)	
Outcomes	Mean (CI95%)	p-value	Mean (CI95%)	p-value
SPADI (0-100)	1.8 (-5.7 – 9.2)	0.64	0.4 (-5.1 – 6.0)	0.88
SPADI adjusted	3.6 (-2.8 – 10.0)	0.27	0.4 (-5.1 – 6.0)	0.88
Pain SPADI (0-100)	-0.1 (-8.8 – 8.6)	0.99	2.4 (-4.3 – 9.1)	0.48
Function SPADI (0-100)	3.6 (-3.7 – 10.9)	0.34	-1.5 (-6.5 – 3.5)	0.54
Pain (0-10)	0.6 (-0.2 – 1.5)	0.15	-0-4 (-1.1 – 0.2)	0.20
GPSS (0-10)	0.7 (-0.3 – 1.6)	0.16	-0.8 (-1.6 – 0.0)	0.05

SPADI: Shoulder Pain and Disability Index; GPSS: Generic Patient Specific Scale; 95%CI: confidence interval.

Average pain score and the GPSS

Both groups improved significantly in pain levels (p=0.000) and in the GPSS scores (p=0.000) within the first 5 weeks, but only the control group showed further improvement up to week 12 (table 3). However, the difference between groups was not significant (table 4). An overview about the activities chosen by the participants for the GPSS is given in appendix 2. Upwards directed activities are clearly the most disabled, followed by lying on the affected side, sports activities and dressing. Between-groups results and additional within-groups comparisons are displayed in table 3 and 4.

PGIC and PST after 5 weeks

No significant difference could be found for either PGIC or PST at any follow up (table 5). To test the robustness of the result for PGIC, the cut off was changed from “slightly better” to “much better” leading to a RR (CI95%) of 1.05 (0.68 to 1.64) after 5 weeks and 0.96 (0.66 – 1.39) at 12 weeks respectively. High satisfaction was defined as a score of 8 or higher on the VNRS and was more present in the intervention (87%) than in the control group (75%), but also this difference was not statistically significant (table 5).

Results for patients with a MCID

Looking at the absolute number of patients with a clinically significant change score in the outcome measures as defined a priori, no significant difference in any outcome could be found at any follow up. A minor advantage for the intervention group was found for average pain with a RR (CI95%) of 1.46 (1.01 to 2.10), NNT=5 at 5 but not after 12 weeks. The 5 weeks results are shown in table 5.

Table 5 Numbers (percentages) of patients with a clinically important difference for every outcome measures at 5 weeks with relative risk (RR) (95%CI).

Outcomes	Total group (n= 90) *n* (%)	Intervention (n= 46) *n* (%)	Control (n= 44) *n* (%)	Relative Risk (CI 95%)
Total SPADI Score (>10)	51 (56.7)	25 (54.4)	26 (59.1)	0.92 (0.64 – 1.32)
GPSS (>2)	39 (43.3)	21 (45.7)	18 (40.9)	1.12 (0.69 – 1.79)
Average Pain Score (>1)	53 (58.9)	32 (69.6)	21 (47.7)	1.46 (1.01 – 2.10)
PGIC (slightly & much better)	79 (87,8)	42 (91.3)	37 (84.1)	1.06 (0.93 – 1.27)
PGIC (much better)	42 (46.7)	22 (47.8)	20 (45.5)	1.05 (0.68 – 1.64)
PST (>7)	73 (81.1)	40 (87.0)	33 (75.0)	1.16 (0.95 – 1.42)

95%CI: confidence interval; SPADI: Shoulder Pain and Disability Index; GPSS: Generic Patient Specific Scale; PGIC: Patient's Global Impression of Change; PST: Patients' Satisfaction with Treatment.

DISCUSSION

This randomized controlled trial investigated the short term effect of individualized manual physiotherapy combined with an individualized exercise program in comparison to individualized exercises alone on pain and functioning in patients with a clinical presentation of shoulder impingement syndrome. Both groups improved significantly in all outcomes measures. A minor additional benefit of individualized manual physiotherapy could only be found for average weekly pain at 5 weeks.

Baseline findings

Total SPADI score at baseline was similar to the scores found in other studies investigating shoulder complaints. However, the pain sub-score was markedly higher than the value for functional restriction which became more obvious in the GPSS scores. This, together with small numbers of sick days, high activity levels, and low scores for fear avoidance and catastrophizing despite an average mean duration of 105 weeks, would in our opinion be indicative for a dominant nociceptive pain mechanism at that timeframe in the course of the disorder. Table 2 summarizes the clinical baseline findings. Interestingly, all employed rotator cuff tests were negative in 89 cases. These tests do not have a discriminative ability in this population and therefore we doubt their clinical usefulness in this patient group. However, over 80% of the total group showed translatory restrictions of the shoulder and over 55% showed comparable signs of the cervical spine, which are definite indications for individualized manual therapy. We would have expect, that the possibility to manually treat these contrib-

uting factors is an advantage and would contribute to a better physical improvement of the intervention group compared to the controls.

Influence of relevant covariates, additional medication and injection on SPADI
We identified average pain, SPADI baseline scores, and the number of previous episodes as significant covariates. Combining them in a multivariable regression analysis for both follow ups decreased the p-value for between group differences to a certain degree but did not change it to a significant level. Also the influence of medication or injection in our study on between group results for the SPADI was not significant. For example patients who received an injection in the first 5 weeks had a mean (SD) improvement of 10.7 (12.4) on SPADI (total group 15.3 (17.6)) which is contradictory to the results of Crawshaw et al (31) who concluded that a combination of cortisone injection, manual therapy and exercises would lead to better short term results than manual therapy and exercises alone.

Therapists' expectations of outcome and obstacles with treatment application
Four out of six research therapists treating the intervention group believed in a better result for a combination of manual therapy and exercises in the short term. Three out of five therapists from the control group, although blinded to the content of the IMPT and to all the examination results, favored additional manual therapy over exercises alone. Reasons given for that were the ability to mobilize restricted joints, a more individualized care with a better placebo effect, the ability to address contributing factors individually and to give more precise instructions for the adaptation of daily activities. For the long term prognosis three therapists from the intervention and two from the control group still favored additional manual therapy. One control therapist expected a better result for only exercises in the long term. However, results of this trial raise the question, to what degree the time frame and the number of supervised session in the control group could be reduced without losing effect.

Comparison with other studies

Few studies used the same exercise protocol as the basic intervention for both groups, on which the additional effect of individualized physiotherapy has been investigated. In the study of Bang and Deyle (32) 52 participants had 6 sessions of supervised flexibility and strengthening exercises. Only two out of 8 exercises were performed at home on a daily basis. The intervention group (n=28) received manual physical therapy and specific home exercises to reinforce its effect. The intervention group showed better results for pain, strength and function after treatment and at 8 weeks. Conroy and Hayes (33) applied 9 sessions of hot packs, soft tissue mobilization, stretching,

strengthening and pendulum exercises to 14 patients. Seven patients also received manual mobilization of the subacromial and glenohumeral joints. After treatment the manual therapy group had better results for pain but not for function or range of motion. Senbursa et al. (34) randomized 77 participants to supervised exercises, supervised exercises combined with joint and soft tissue mobilization, and to a group performing the exercises at home. There were no differences for pain, range of motion, strength, or the rate of positive tests after 4 and 12 weeks except for function in favor of the manual therapy group at 4 weeks.

We also found a slightly better effect on pain in our intervention group at 5 weeks but not for function or disability scores. The significant results of Conroy and Hayes (33) for pain improvement in favor of the intervention group may be an over-interpretation due to a type 1 error. Moreover we do not support the statement of Senbursa et al. (34) that the "best results were seen in the manual therapy group" because both groups showed significant improvements with no statistically significant between-groups differences. Interestingly, both of their exercise groups seemed to be equally effective. This raises the question about the number of supervised sessions needed or in this case how supervision was done.

Differences between our results and the results of Bang and Deyle (32) can be explained by the differences in the exercises used. We started with a progressive non-provocative, pain free and high dose/low resistance program. In contrast, Bang and Deyle (32) used a low dose program and the chosen exercises, from our experience, were all highly pain provocative in SIS patients. This may have prevented progression and significant improvement in the exercise group of Bang & Deyle (32). Therefore the results in favor of manual therapy may have rather been influenced by an ineffective exercise program than by the manual therapy intervention itself.

Why did IMPT not result in a stronger additional effect?

The additional effect of IMPT after 5 weeks is still questionable even if a minor effect on pain level was detected and may be depending on the quality of the applied exercise program too. Exercises in general do show a comparable effect with (mixed) physiotherapy interventions (11, 35) and seem to be more effective than no intervention (13, 14, 36). The exercise protocol used in our study was designed to reach a maximum effect. Beside the shoulder joint muscles it also addressed the shoulder girdle muscles, posture, and mobility of the thoracic spine as important aspects (37-39). It was progressively organized with focus on a pain-free performance. Dosage was targeted to increase endurance and load capacity of the affected tissues and muscles, to achieve a maximum number of repetitions per training session, and an optimal dose-response

relationship; the advantages of a high-dose compared to a low-dose exercise program was shown by Osteras et al (40). We also combined supervised and home exercises sessions supported by pictures and detailed written instructions. All these aspects may not have only improved effectiveness of the program but seemed to reduce the possibility for IMPT to make a significant contribution. However, it might have accelerated improvement during the first 5 weeks but this effect was lost after 12 weeks. One could also argue that the longer treatment time in the intervention group could also have influenced the effect on outcomes, but, if so, this did not significantly influence the results. The comparison of the number needed to treat to benefit for the intervention group (NNT=21) with the NNT for the total group receiving IAEX (NNT=2) for the first measurement point supports our assumption, that SIS, even if long lasting or episodic, is a dominantly mechanical and nociceptive driven event.

Limitations

This trial was conducted in an outpatient physiotherapy setting under common conditions of the German health system. It provides detailed baseline information, well-described interventions, and results based on sufficient power which allows the clinician to replicate and apply this information appropriately. We blinded therapists of the control group to all clinical information about their patients. Measurements of outcome were also blinded because therapists were not involved in this process. We couldn't blind patients but they were kept naive to their allocation. The outcome measures we used were valid and easy to use in daily practice. The offer to participate in the study was solely based on clinical examination results without the use of diagnostic imaging which reflected clinical practice and saved resources. Our experience was that patients, after being informed about the study, were willing to participate on this basis even if they had a recommendation for surgery from a general practitioner or orthopaedic surgeon. Because of ethical standards we did not include a placebo or passive control group in our study, so we could not estimate the contribution of a placebo effect to the results. However, results from other studies have shown that exercises are superior to wait-and-see policy in the short-term (13, 14) and placebo treatment (41, 42). We involved only 6 outpatient physiotherapy clinics with 12 research therapists in our trial so this may, to some degree, limit the external validity of the study results.

CONCLUSION

Results of this study show that individually adapted exercises are effective in the treatment of patients with SIS, and that IMPT had only a minor additional effect on pain intensity after 5 weeks. However, further research is necessary to confirm these results before definite recommendations can be made. Further research should also explore the components and parameters needed for an exercise program to achieve maximum effect.

ACKNOWLEDGEMENTS

We acknowledge the contributions of Cornelis Admiraal, Robert Blaser-Sziede, Isabella Knoecklein, Horst Baumgarten, Nils Jansen and their colleagues to this study as research therapists.

REFERENCES

1. Rekola KE, Keinanen-Kiukaanniemi S, Takala J. Use of primary health services in sparsely populated country districts by patients with musculoskeletal symptoms: consultations with a physician. J Epidemiol Community Health 1993; 47: 153-157.
2. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. Ann Rheum Dis 1995; 54: 959-964.
3. Luime JJ, Hendriksen IJM, Burdorf A, Verhagen AP, Miedema HS, Verhaar JAN. Prevalence and incidence of shoulder pain in the general population; a systematic review. Scand J Rheumatol 2004; 33: 73-81.
4. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. Rheumatology (Oxford) 2005; 44: 800-805.
5. Gartsman GM, Brinker MR, Khan M, Karahan M. Self-assessment of general health status in patients with five common shoulder complaints. J Shoulder Elbow Surg 1998; 7: 228-237.
6. Croft PR, Pope DP, Silman AJ. The clinical course of shoulder pain: prospective cohort study in primary care. Br Med J 1996 September 7; 313: 601-602.
7. Winters JC, Sobel JS, Groenier KH, Arendzen JH, Meyboom-de Jong B. The long-term course of shoulder complaints: a prospective study in general practice. Rheumatology (Oxford) 1999; 38: 160-163.
8. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy 2001; 87: 458-469.
9. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford) 2006; 45: 215-221.
10. Citaker S, Taskiran H, Akdur H, Arabaci UO, Ekici C. Comparison of the mobilization and proprioceptive neuromuscular facilitation methods in the treatment of shoulder impingement syndrome. Pain Clinic 2005; 17: 197-202.
11. Ginn KA, Cohen M. Exercise therapy for shoulder pain aimed at restoring neuromuscular control: a randomized comparative clinical trial. J Rehabil Med 2005; 37: 115-122.

12. Haahr JP, Ostergaard S, Dalsgaard J, Norup K, Frost P, Lausen S, et al. Exercise versus arthroscopic decompression in patients with subacromial impingement: a randomised, controlled study in 90 cases with a one year follow up. Ann Rheum Dis 2005; 64: 760-764.
13. Lombardi I, Magri AG, Fleury AM, Da Silva AC, Natour J. Progressive resistance training in patients with shoulder impingement syndrome: a randomized controlled trial. Arthritis Rheum 2008; 59: 615-622.
14. Ludewig PM, Borstad JD. Effects of a home exercise programme on shoulder pain and functional status in construction workers. Occup Environ Med 2003; 60: 841-849.
15. Tyler TF, Nicholas SJ, Roy T, Gleim GW. Quantification of posterior capsule tightness and motion loss in patients with shoulder impingement. Am J Sports Med 2000; 28: 668-673.
16. Green SE, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD004258 2003.
17. Kuhn JE. Exercise in the treatment of rotator cuff impingement: A systematic review and a synthesized evidence-based rehabilitation protocol. J Shoulder Elbow Surg 2009; 18: 138-160.
18. Kelly SM, Wrightson PA, Meads CA. Clinical outcomes of exercise in the management of subacromial impingement syndrome: a systematic review. Clin Rehabil 2010; 24: 99-109.
19. Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CHG. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. J Rehabil Med 2009; 41: 470-480.
20. Ho C-YC, Sole G, Munn J. The effectiveness of manual therapy in the management of musculoskeletal disorders of the shoulder: A systematic review. Man Ther 2009; 14: 463-474.
21. Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskelet Disord 2010; 11:114.
22. MacDermid J, Solomon P, Prkachin K. The shoulder pain and disability index demonstrates factor, construct and longitudinal validity. BMC Musculoskelet Disord 2006; 7: 12.
23. Williams JW, Holleman DR, Simel DL. Measuring shoulder function with the shoulder pain and disability index. J Rheumatol 1995; 22: 727-732.
24. Stratford PW, Gill C, Westaway MD, Binkley JM. Assessing disability and change on individual patients: a report of a patient specific measure. Physiother Can 1995; 47: 258-263.
25. Farrar JT, Young Jr. JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94: 149-158.
26. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J Pain 2004; 8: 283-291.
27. Carette S, Moffet H, Tardif J, Bessette L, Morin F, Fremont P, et al. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder. Arthritis Rheum 2003; 48: 829-838.
28. Chen JF, Ginn KA, Herbert RD. Passive mobilisation of shoulder region joints plus advice and exercise does not reduce pain and disability more than advice and exercise alone: a randomised trial. Aust J Physiother 2009; 55: 17-23.
29. Dogru H, Basaran S, Tunay S. Effectiveness of therapeutic ultrasound in adhesive capsulitis. Joint Bone Spine 2008; 75: 445-450.
30. Tveita EK, Tariq R, Sesseng S, Juel NG, Bautz-Holter E. Hydrodilatation, cortocosteroids and adhesive capsulitis: a randomized controlled trial. BMC Musculoskelet Disord 2008; 9: 53.
31. Crawshaw DP, Helliwell PS, Hensor EM, Hay EM, Aldous SJ, Conaghan PG. Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial. BMJ 2010; 340: c3037.
32. Bang MD, Deyle GD. Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. J Orthop Sports Phys Ther 2000; 30: 126-137.

33. Conroy DE, Hayes KW. The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. J Orthop Sports Phys Ther 1998; 28: 3-14.
34. Senbursa G, Baltaci G, Atay AÖ. The effectiveness of manual therapy in supraspinatus tendinopathy. Acta Orthop Traumat Turc 2011; 45: 162-167.
35. Walther M, Werner A, Stahlschmitt T, Woelfel R, Gohlke F. The subacromial impingement syndrome of the shoulder treated by conventional physiotherapy, self-training, and a shoulder brace: Results of a prospective randomized study. J Shoulder Elbow Surg 2004; 13: 417-423.
36. Dickens VA, Williams JL, Bahmra MS. Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. Physiotherapy 2005; 91: 159-164.
37. Baskurt Z, Baskurt F, Gelecek N, Özkan MH. The effectiveness of scapular stabilisation exercise in the patients with subacromial impingement syndrome. J Back Musculoskelet Rehabil 2011; 24: 173-179.
38. Bullock MP, Foster NE, Wright CC. Shoulder impingement: the effect of sitting posture on shoulder pain and range of motion. Man Ther 2005; 10: 28-37.
39. Solem-Bertoft E, Thuomas K-A, Westerberg C-E. The Influence of scapular retraction and protraction on the width of the subacromial space. Clin Orthop 1993; 296: 99-103.
40. Osteras H, Torstensen TA, Osteras B. High-dosage medical exercise therapy in patients with long-term subacromial shoulder pain: a randomized controlled trial. Physiother Res Int 2010; 15: 232-242.
41. Brox JI, Brevik JI, Ljunggren AE, Staff PH. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome). Br Med J 1993; 307: 899-903.
42. Brox JI, Gjengedal E, Uppheim G, Bohmer AS, Brevik JI, Ljunggren AE, et al. Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): A prospective, randomized, controlled study in 125 patients with a 2.5-year follow up. J Shoulder Elbow Surg 1999; 8: 102-111.
43. Kaltenborn FM. Manuelle Therapie nach Kaltenborn, Untersuchung und Behandlung, Teil I – Extremtitäten. 12th ed. Oslo: Norli; 2005
44. Evjenth O, Hamberg J. Muscle Stretching in Manual Therapy, a clinical manual, Vol. I and II. Alfta: Alfta Rehab Förlag; 1984.
45. Butler DS. Mobilisation des Nervensystems. 2nd ed. Heidelberg: Springer Verlag; 2004.
46. Maitland GD. Manipulation der peripheren Gelenke. 3rd ed. Heidelberg: Springer Verlag; 2004.

APPENDIX 1. ADDITIONAL INTERVENTION DESCRIPTION

Individually adapted exercises (IAEX) for both groups

Procedure:

- The "core program" was instructed during the first 3-4 treatment sessions.
- Patients were monitored twice a week during their contact sessions.

Frequency and dosage:

- Patients performed the exercises twice a day for the first week, then once daily.
- Minimum exercises frequency during the week was 4, maximum 7.
- Dynamic exercises started with 2 sets of 10 repetitions and with low resistance (yellow rubber band).
- Shoulder and neck stretches were held for 10 seconds and repeated twice.
- Isometric scapular training positions were held for 10 seconds and repeated twice.

Progression if patients performed the core program without problems:

- Sets were increased from 2 to 3.
- Repetitions (respectively seconds for the static exercises) were increased from 10 to 20.
- In a last step, resistance was increased from the yellow to the red and to the green rubber band.
- Exercises from an "additional program" could be added if the patient could still perform the core program without problems, whereas exercise C3 was replaced by exercise A4, C4 by A5, and C6 by A7.

Patient instructions and stopping rules:

- Patients were instructed on how to perform each single exercise.
- They received a booklet with pictures and descriptions of the exercises and the individually defined dosage.
- Patients had to stop an exercise if they had pain of more than 3 out of 10 on a VNRS during the exercises or longer than about 30 seconds after they had stopped an exercise.
- Patients recorded performance and difficulties with the program in their logbooks which enabled the therapist to check the 24-h effect of the program and to make adaptations.

Therapists' measures for adapting exercises to upcoming pain:

- Reduction of resistance, sets, repetitions, or the range of movement.
- If the total load of the program was too provocative, patients were allowed to split the program into 2 parts performing them at different times during the day.
- For some exercises an alternative version could be used (e.g. exercises C6b instead of C6a).
- If an exercise could not be performed due to pain, it was left out for the next two training sessions and was replaced by exercises AP1 and AP2.

Contact time for the control group was 15-20 minutes.

Intervention group: Individualized manual physiotherapy (IMPT)

IMPT was based on clinical examination results and individual main complaints.
Therapists were guided by a defined tripartite decision process to achieve a uniform and repeatable way of initial decision-making.

- Part 1 addressed signs which may predict a poor treatment outcome such as:
  ≥3 episodes of shoulder pain in the last 12 months; pain >5/10 on a VNRS.
  Duration of the current episode of >6 weeks; signs indicating a rotator cuff tear.
  Restrictions of external rotation and/or elevation of the shoulder.

➢ Positive results led the therapist to focus initially on:
  Local manual pain treatment, pain-reducing exercises (AP1 and AP2), improving patients' understanding about the pathology, and instructions for the most provocative ADLs to reduce pain events during the day.
  Behavioural instructions for painful ADLs and on manually assisted exercises to facilitate rotator cuff contraction.
  Manual mobilization of the identified restrictions.

- Part 2 summarized information about possible contributing factors such as general posture, patients' main restricted activities identified through the GPSS, and other aggravating components, work place setting, leisure and sports activities.

➢ Ways of improving these factors and compensation strategies were then discussed.

- Part 3 defined the manual assessment of the glenohumeral and shoulder girdle joints, the cervical and upper thoracic spine.

➢ Initial treatment for positive findings:
  Painful and angular and/or translatory restricted peripheral joints were treated with manual glide techniques according to the concept of Kaltenborn (43).

Comparable signs of the spine segments were treated with posterior-anterior glides or coupled movements.

Shortened muscles were stretched according to the description of Evjenth and Hamberg (44).

Neural tissue was treated according to Butler (45).

- Dosage for interventions of part 3:
  - Treatment intensity was limited by pain of >4/10.
  - Initial duration of the glide techniques and the stretches was 20 to 30 seconds. Further dosage was based on reassessment results.
  - Subsequent treatment decisions were made with the help of an adapted clinical reassessment process based on the test-retest-principle described by Maitland (46).
  - In addition to the general information in the shoulder booklet, this group received detailed information about the assessment results and therapy interventions.

Contact time for the intervention group was 20-30 minutes.

APPENDIX 2: RESTRICTED ACTIVITIES FROM THE GPSS

Activity	Frequency
Activities in an upward direction	89
Reaching overhead / upwards	18
Working overhead	19
Lifting above shoulder height	17
Drying / combing or washing hair	11
Getting something down from a cupboard	9
Holding something in front of the body	15
Lying on the affected shoulder	33
Sports activities	24
Playing tennis	2
Swimming	2
Fitness training	4
Other	16
Getting dressed	23
Putting on a jacket	6
Pushing forward with the affected arm	21
Cleaning windows	7
Housework	16
Activities with hand behind back	16
Steering a car	12
Carrying	10
Computer work (with/without a mouse)	10
Body care	5
Leaning on/Stemming	5
To buckle up in the car	3
Other	3
Total	270

CHAPTER 5

Effectiveness of physiotherapy and costs in patients with clinical signs of shoulder impingement syndrome:

One year follow up of a randomized controlled trial

ABSTRACT

Objectives To investigate the long-term effect of manual physiotherapy and exercises compared to exercises alone in patients with shoulder impingement syndrome.
Design Randomized controlled trial.
Subjects Patients with shoulder impingement of more than 4 weeks.
Methods The intervention group received individualized manual physiotherapy plus individualized exercises; the control group had individualized exercises only. Both groups had ten treatments over a period of 5 weeks and subsequently continued their exercises at home for another 7 weeks.
Primary outcomes were: Shoulder Pain and Disability Index; and Patients' Global Impression of Change. The Generic Patient-Specific Scale was used as secondary outcome. Costs were recorded in a log book.
Results 90 patients were included in the study and 87 could be analyzed one year after inclusion. Both groups showed significant improvements in all outcome measures but no difference was detected between the groups. Only costs differed significantly in favor of the control group (p=0.03) after 5 weeks.
Conclusion Individualized exercises show a significant effect on pain and functioning within the whole group after 1 year. Exercises are therefore recommended as a basic treatment. Due to the progressive improvement we also suggest to wait with further treatments for about a year afterwards.

Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of physiotherapy and costs in patients with clinical signs of shoulder impingement syndrome: one year follow up of a randomized controlled trial. Submitted to the Journal of Rehabilitation Medicine on 6 August 2013

INTRODUCTION

Shoulder complaints are one of the most common musculoskeletal complaints seen by health professionals (1-4) with an incidence of 9.5 per 1000 patients. They seem to be recurring in nature and do not necessarily resolve over time thus leading to a significant reduction of health (5, 6). Most shoulder patients presenting to primary care show clinical signs of subacromial impingement (4, 6), which are indicative for mechanical problems within the subacromial space causing pain and functional restrictions mostly during overhead activities (7).

Physiotherapy is therefore often prescribed for the treatment of subacromial shoulder pain (4, 8, 9). In the literature a positive short-term effect of physiotherapist-led exercises and manual physiotherapy on pain and functioning is suggested, but study results are inconsistent and often limited by poor methodological quality and small sample sizes (10-12). However, long-term results are scarce and therefore evidence for a sustained effect of these physiotherapeutic interventions seen in the short-term follow up is even more limited.

This trial compared the effectiveness of individualized manual physiotherapy (IMPT) compared to an individualized standard exercise protocol (SEP) on pain and functioning in patients with clinical signs of shoulder impingement syndrome (SIS) and presents the results 1 year after inclusion.

METHODS

Participants

Participants were recruited by referral from general practitioners or orthopaedic surgeons to physiotherapy because of shoulder complaints. They were then screened by trained physiotherapists for eligibility. Patient who fulfilled the eligibility criteria were asked to sign informed consent, they underwent baseline assessment and were subsequently allocated to treatment groups in blocks of six using central randomization. The eligibility criteria set for this trial are described in detail in the published study protocol for this paper (13).

Interventions

The intervention group received examination-based, individualized manual physiotherapy (IMPT) plus an individualized standard exercise program (SEP); the control

group had SEP only. Treatment was provided in 6 outpatient physiotherapy clinics by 12 trained physiotherapists with an international qualification for manual therapy according to the standard of the International Federation of Manipulative Physical Therapists (IFOMPT). Participants received ten treatment sessions within 5 weeks. Shoulder logbooks were used to record sick leave, exercise frequency, additionally prescribed medication intake, co-interventions, further diagnostic measures, costs for paid help, and over the counter medication. Due to ethical considerations the use of analgesics and non-steroidal anti-inflammatory drugs was permitted and was also recorded in the logbook. A detailed description of the interventions is provided in the published protocol for this study (13) and the published short term results of this trial (14).

Outcome measures

Primary outcome measures for the one year follow up were the Shoulder Pain and Disability Index (SPADI) and Patient's Global Impression of Change (PGIC). The SPADI is a shoulder specific self-reported questionnaire measuring pain and disability (15). Subscales for pain and function are scored from 0 to 100 with higher scores reflecting higher pain/disability levels. The total SPADI score was calculated by averaging the score of the two sub-scales. The minimum clinically important change was considered 11 points in the total SPADI score (16). PGIC was measured with an ordinal scale from 1 (much worsened) to 5 (much better). A rating of "slightly or much better" was defined as a successful result.

As a secondary outcome measure we used the Generic Patient-Specific Scale (GPSS) which assesses individual complaints and restrictions in a short and efficient way (17). Patients chose their 3 most difficult activities and rated the ability to perform them on an 11-point visual numeric rating scale (VNRS). 10 at the right end of the VNRS was defined as "I can perform the chosen function without difficulty", 0 at the left end as "I am unable to perform the chosen function". An average score across all activities was calculated and a minimum change of 3 points was considered as a clinically important improvement (18, 19). Additionally, all patients filled in a modified version of the Fear Avoidance Beliefs Questionnaire (FABQ) and the Pain Catastrophizing Scale (PCS), two factors possibly influencing our main outcome measure.

Direct and indirect health care costs were assessed with the shoulder logbook. Direct costs included all diagnostic and therapeutic measures paid by the German health system due to the patient's shoulder complaints. Indirect costs included days of sick leave and paid help. Demographic data including age, sex, height, weight, profession, sports activities, severity and duration of symptoms, and previous episodes of

shoulder pain were also documented. Patients were assessed at baseline, at 5, 12, and 52 weeks after inclusion in the trial.

Sample size and recruitment

Power calculation resulted in an estimated sample size of 90 participants (45 per group) to detect a 13 points difference in SPADI score. The assumed standard deviation was set to 20 points based on the results of other studies (20-23). Alpha was set to 0.05, statistical power to 80%, and a dropout rate of 15% was expected.

Data Analysis

Descriptive statistics for demographic and clinical characteristics for both groups and the total group were used. Working hours per week, and sick leave were only analysed for patients who were at work.

Differences after 5 and 12 weeks were calculated for between-groups comparisons and within-groups results according to the “intention-to-treat principle”. These results have been published previously (14).

Because of the unbalanced structure of our repeated-measures design and the assumed correlation of observations in longitudinal data sets we used a linear mixed models approach for calculating differences between baseline and our final follow up at 52 weeks. This method uses both, fixed and random effects in the same analysis. It handles naturally unbalanced data as e.g. uneven spacing of repeated measures and allows analysing the relationship of predictor covariates with the dependent variable. It also accounts successfully for the observed pattern of dependences in those measurements. Appropriate covariates were identified in a univariable regression analysis and from literature. Before starting the analysis, the baseline SPADI score and all identified covariates were centred by subtracting the group mean.

In a first step a fixed effects model was run and in a second step random effects were added. Insignificant covariates were then stepwise removed from the model. Model fit was assessed with the help of the Bayesian Information Criterion (BIC) and the -2Log likelihood.

Costs recorded in the shoulder log book were valued using published prices for medical costs. Productivity costs were calculated by applying the friction costs method. Depending on data distribution between-group differences in outcomes of total costs were analyzed by Student's *t*-tests for unpaired observations or the Mann-Whitney-U test.

RESULTS

Recruitment process

188 patients were assessed for eligibility over an 18 month period in which finally 90 participants were randomly assigned to either IMPT or SEP. After one year data were available for 87 patients with 44 patients in the IMPT group and 43 patients in the SEP group. This process is summarized in figure 1. No significant differences for baseline characteristics between groups were found except for sports hours per week, overall duration of symptoms, total FABQ, and the FABQ activity subscale. Baseline data are shown in table 1.

Table 1 Baseline demographic data and baseline results of the questionnaires

	Intervention (n=46)	Control (n=44)	Total group (n=90)
Age, years (mean; SD)	50.1 (12.2)	53.7 (9.9)	51.8 (11.2)
18-29 years, *n* (%)	2 (4.3)	0 (0.0)	2 (2.2)
30-44 years, *n* (%)	13 (28.3)	8 (18.2)	21 (23.4)
45-59 years, *n* (%)	21 (45.7)	20 (45.4)	41 (45.5)
>60 years, *n* (%)	10 (21.7)	16 (36.4)	26 (28.9)
Gender (female), *n* (%)	22 (47.8)	24 (54.5)	46 (51.1)
BMI, mean (SD)	25.3 (3.7)	26.8 (4.3)	26.0 (4.1)
Classification of physical work load*, *n* (%)	(n=40)	(n=38)	(n=78)
Low	16 (40.0)	19 (50.0)	35 (44.9)
Medium	18 (45.0)	13 (34.2)	31 (39.7)
High	6 (15.0)	6 (15.8)	12 (15.4)
Working hours per week*, mean (SD)	32.2 (13.8)	37.2 (10.7)	34.6 (12.6)
Days of sick leave*, mean (SD)	0.1 (0.6)	1.1 (4.1)	0.6 (2.9)
Sports hours per week, *n* (%)			
0-2	13 (28.3)	21 (47.4)	34 (37.8)
3-5	33 (71.7)	23 (52.6)	56 (62.2)
Duration of the current episode in weeks, mean (SD)	27.4 (28.4)	40.8 (53.4)	33.9 (42.8)
Overall duration of shoulder pain in weeks, mean (SD)	136.9 (198.5)	71.3 (68.7)	104.8 (152.6)
Number of episodes during the last 12 months, *n* (%)			
1-3 (including the current one)	37 (80.4)	38 (86.4)	75 (83.3)
>3	9 (19.6)	6 (13.6)	15 (16.7)
Average pain score, mean (SD)	5.2 (1.8)	5.0 (1.8)	5.1 (1.8)
SPADI total score, mean (SD)	39.7 (17.2)	41.3 (17.0)	40.4 (17.0)
SPADI sub-score for pain, mean (SD)	47.8 (18.8)	49.6 (17.3)	48.7 (18.0)
SPADI sub-score for function, mean (SD)	31.5 (18.6)	32.9 (19.3)	32.2 (18.9)
GPSS average score, mean (SD)	4.1 (1.8)	4.0 (1.7)	4.0 (1.7)
FABQ total score, mean (SD)	36.4 (17.4)	28.7 (16.7)	32.7 (17.4)
FABQ sub-score for physical activity, mean (SD)	15.9 (4.1)	13.3 (5.3)	14.6 (4.9)
FABQ sub-score for work, mean (SD)	13.4 (10.3)	10.8 (9.5)	12.1 (9.9)
PCS total score, mean (SD)	12.4 (9.7)	10.4 (7.1)	11.4 (8.5)
PCS sub-score for rumination, mean (SD)	4.6 (3.9)	3.8 (3.0)	4.2 (3.5)
PCS sub-score for magnification, mean (SD)	3.1 (2.6)	2.5 (1.9)	2.8 (2.3)
PCS sub-score for helplessness, mean (SD)	4.7 (4.2)	4.1 (3.3)	4.4 (3.8)
PET, mean (SD)	8.4 (1.6)	8.7 (1.3)	8.5 (1.5)

BMI: Body Mass Index; FABQ: Fear Avoidance Beliefs Questionnaire; GPSS: Generic Patient Specific Scale; PCS: Pain Catastrophizing Scale; PET: Patients Expectancies of Treatment Outcome; SD: standard deviation; SPADI: Shoulder Pain and Disability Index; *: Only participants who are in work; 40 and 38, respectively.

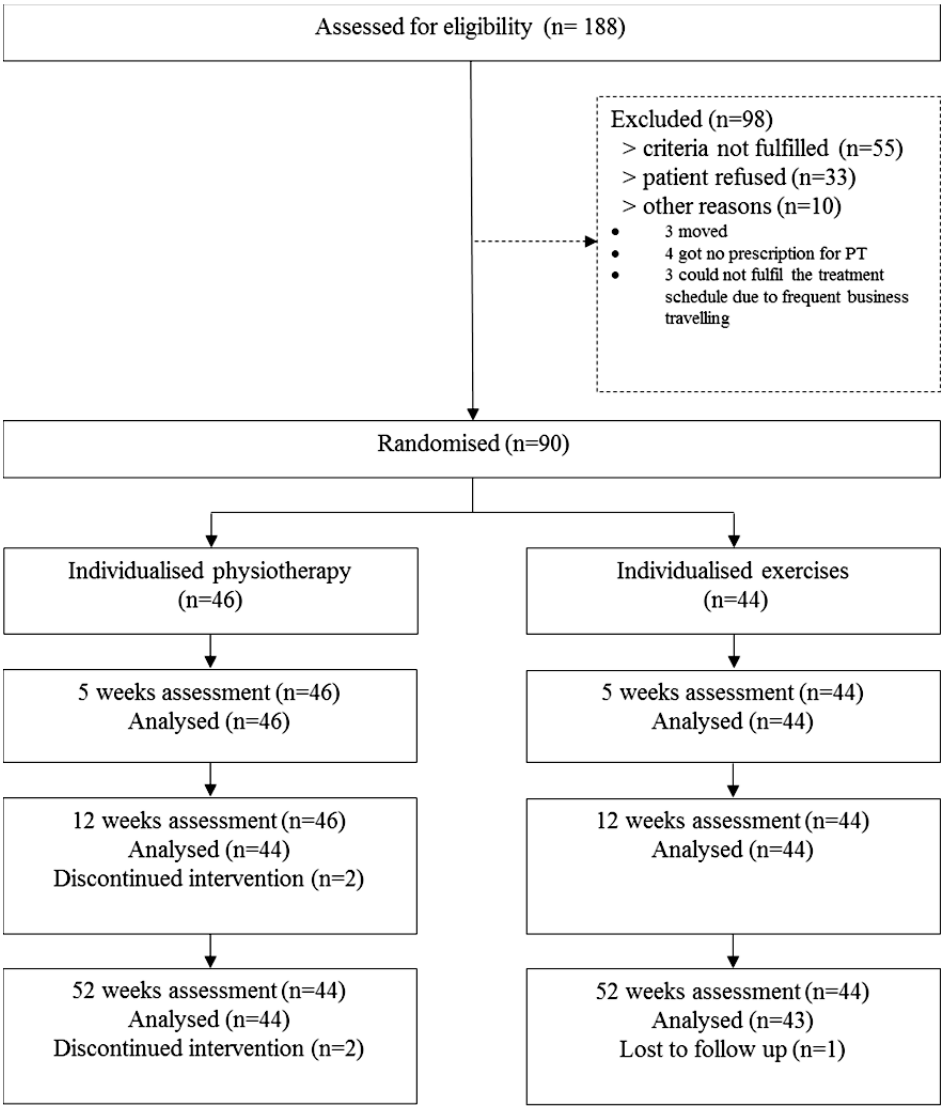


Figure 1 Inclusion process

Shoulder log books

From a total of 90 participants 89 (98.9%) returned a complete logbook after 5 weeks and 85 (94.4%) after 12 weeks from which 3 were incomplete. Within the follow up period (week 13 to 52) 87 (96.7%) participants returned their log-books from which another 4 in the intervention group were incomplete for analysis.

Additional medication, co-interventions, and diagnostics

During the first twelve weeks more patients in the intervention group had additional treatments and diagnostic measures compared to the control group. However, co-interventions, especially the cortisone injections had no significant influence on between group comparisons (14).

After 1 year similar figures for additional interventions and diagnostics in both groups were found. However, 2 patients in the intervention group but only 1 in the control group underwent surgery. An overview about additional treatments and diagnostics is provided in table 2.

Table 2 Number of patients receiving additional medication, co-interventions, and diagnostic

	Week 0 to 5 (n=89)		Week 6 to 12 (n=85)		Week 13 to 52 (n=87)	
Additional Interventions	Intervention (n=46)	Control (n=43)	Intervention (n=45)	Control (n=40)	Intervention (n=44)	Control (n=43)
Cortisone injection	5	0	2	3	7	2
NSAIDs	5	7	4	4	3	4
C. injection +NSAID'S	0	0	2	1	0	2
Physiotherapy (*n*=)	0	0	11 (39)	2 (12)	10 (118)	7 (150)
Surgery (SAD) followed by rehabilitation	0	0	0	0	2	1
Massage (*n*=)	1 (1)	2 (12)	0	1 (3)	0	2 (18)
Soothing ointment	1	1	1	2	0	2
Electrotherapy (*n*=)	1 (5)	0	0	0	0	0
X-ray	1	0	0	0	0	0
MRI	3	1	1	0	4	4
GP clinical assessment (*n*=)	0	0	1	0	3 (9)	1
Ultrasound	0	0	0	1	1	1

GP: general practitioner; MRI: magnetic resonance imaging; NSAIDs: non-steroidal anti-inflammatory drugs; *n* = number of treatments/visits; SAD: subacromial decompression.

Direct costs

During the first 5 weeks basic costs for the prescribed physiotherapy interventions differed between groups (intervention group: 188€ per patient for a prescription of

manual therapy; control group: 171€ for a prescription of physiotherapy exercises). A total of only 21 (26.9%) patients were responsible for all additional costs, with 13 (16.7%) being in the intervention group. Total direct costs differed significantly (p = 0.03) in favour of the control group at 5 weeks. However, no differences were found after 12 and 52 weeks, or for overall directs costs between groups. These results are displayed in table 3.

Table 3 Results for direct costs in Euro (SD) and between group differences

	Week 0 to 5 (n=89)		Week 6 to 12 (n=84)		Week 13 to 52 (n=87)		Week 0 to 52 (n=84)	
	Interv (n=46)	Contr (n=43)	Interv (n=44)	Contr (n=40)	Interv (n=44)	Contr (n=43)	Interv (n=44)	Contr (n=40)
Mean (SD)	209.3 (49.6)	185.7 (50.4)	30.4 (68.2)	14.0 (28.3)	167.9 (518.7)	127.2 (447.0)	408.5 (545.8)	332.7 (472.2)
p-value	0.03		0.15		0.70		0.5	

Contr: control group; Interv: intervention group; SD = standard deviation; p = 0.05.

Indirect costs

Indirect costs were only analysed for patients who were at work and could be calculated for 78 patients after 5 weeks, for 73 patients after 12 weeks, and for 75 patients after 1 year. Cost calculations for sick leave were based on the average daily working hours of the patient and the average hourly labour costs in Germany (24). Only a few patients were responsible for all days of sick leave (n=10; female = 5, male = 5; mean (SD) age in years 54.2 (11.0)) and most of the costs during the evaluation period. Only one patient of the intervention group made use of paid help.

During the 5 weeks treatment period 7.7 percent (n=6) of patients who were at work (n=78) were responsible for all days of sick leave. Only one patient from the intervention group had 12 sick days compared to 5 patients from the control group with a total of 58 days. Similar results were found from week 7 to 12. During the one year follow up 2 patients in the intervention and 3 in the control group were on sick leave. Between-groups differences for sick leave and indirect costs were analysed with the Mann-Whitney-U test for non-normally distributed data (tested with the Kolmogorov-Smirnov Z). However, neither days of sick leave nor indirect costs were differed significantly between groups at any time. These results are displayed in table 4.

Table 4 Days of sick leave and indirect costs in Euro (SD) for patients who were in work

	Week 0 to 5 (n=78)		Week 6 to 12 (n=73)		Week 13 to 52 (n=75)		Week 0 to 52 (n=73)	
	Interv (n=40)	Contr (n=38)	Interv (n=38)	Contr (n=35)	Interv (n=38)	Contr (n=37)	Interv (n=38)	Contr (n=35)
No. of days (*n* =)	12 (1)	58 (5)	4 (1)	41 (3)	30 (2)	66 (3)	46 (3)	165 (3)
Total costs (*n* =)	838 (1)	5400 (5)	571 (2)	4205 (3)	2954 (2)	7109 (3)	4363 (4)	16714 (7)
Average costs mean (SD)	20.9 (132.4)	142.1 (528.0)	15.0 (69.1)	120.1 (401.0)	77.7 (444.3)	192.1 (741.5)	114.8 (521.4)	477.5 (1292.0)
p-value	0.18		0.14		0.42		0.13	

Contr: control group; Interv: intervention group; p = 0.05; No.: number; *n* = number of patients; SD: standard deviation.

Efficacy analysis

SPADI total score

Over the one year period both groups improved significantly in total SPADI score, its sub-scores for pain and for function and the GPSS. These results are displayed in table 5a and 5b.

Table 5a Results after 5, 12, and 52 weeks

	Groups							
	Week 0		Week 5		Week 12		Week 52	
Outcomes	Mean (SD)		Mean (SD)		Mean (SD)		Mean (SD)	
	Intervention (n= 46)	Control (n= 44)	Intervention (n= 46)	Control (n= 44)	Intervention (n= 44)	Control (n= 44)	Intervention (n= 44)	Control (n= 43)
SPADI (0-100)	39.7 (17.2)	41.3 (17.0)	23.5 (17.5)	26.8 (17.8)	16.1 (17.2)	19.8 (19.5)	15.3 (20.3)	10.2 (15.2)
Pain SPADI (0-100)	47.8 (18.8)	49.6 (17.3)	29.8 (21.1)	31.5 (18.8)	20.1 (19.7)	24.1 (21.7)	17.7 (21.8)	12.4 (16.9)
Function SPADI (0-100)	31.5 (18.6)	32.9 (19.3)	17.1 (15.0)	22.1 (18.1)	12.1 (15.4)	15.5 (18.1)	12.9 (19.4)	7.7 (14.1)
GPSS (0-10)	4.1 (1.8)	4.0 (1.7)	7.1 (2.0)	6.3 (2.0)	7.3 (2.5)	7.4 (2.0)	7.9 (2.6)	8.6 (1.8)

GPSS: Generic Patient Specific Scale; SD: standard deviation; SPADI: Shoulder Pain and Disability Index.

Table 5b Results after 5, 12, and 52 weeks for within-groups comparison

	Difference within groups at 5 weeks		Difference within groups between 5 and 12 weeks		Difference within groups between 12 and 52 weeks		Difference within groups between 0 and 52 weeks	
Outcomes	Mean (SD) (CI95%)		Mean (SD) (CI95%)		Mean (SD) (CI95%)		Mean (SD) (CI95%)	
	Intervention (n= 46)	Control (n= 44)	Intervention (n= 44)	Control (n= 44)	Intervention (n= 44)	Control (n= 43)	Intervention (n= 44)	Control (n= 43)
SPADI (0-100)	16.2 (18.2)*** (10.8 – 21.6)	14.4 (17.1)*** (9.2 – 19.6)	7.5 (12.3)*** (3.7 – 11.2)	7.0 (13.8)** (2.8 – 11.2)	0.8 (18.0) (-4.6 – 6.3)	9.4 (15.2)*** (4.8 – 14.1)	25.2 (21.5)*** (18.7 – 31.7)	31.5 (16.5)*** (26.5 – 36.6)
Pain SPADI (0-100)	18.0 (20.2)*** (12.0 – 24.0)	18.0 (21.4)*** (11.5 – 24.5)	9.8 (15.2)*** (5.2 – 14.4)	7.4 (16.6)** (2.4 – 12.5)	2.4 (18.1) (-3.1 – 8.0)	11.3 (16.8)*** (6.1 – 16.5)	31.1 (22.5)*** (24.2 – 37.9)	37.4 (18.8)*** (31.6 – 43.2)
Function SPADI (0-100)	14.4 (18.8)*** (8.8 – 20.0)	10.8 (15.8)*** (6.0 – 15.6)	5.1 (10.8)** (1.9 – 8.4)	6.7 (12.6)*** (2.8 – 10.5)	-0.8 (19.3) (-6.7 – 5.1)	7.6 (14.7)** (3.1 – 12.1)	19.3 (23.0)*** (12.3 – 26.3)	25.7 (17.7) (20.2 – 31.1)
GPSS (0-10)	3.0 (2.3)*** (2.3 – 3.7)	2.3 (2.2)*** (1.6 – 3.0)	0.3 (1.8) (-0.27– 0.81)	1.1 (2.0)*** (0.5 – 1.7)	-0.6 (1.9) (-2.0 – 0.1)	1.2 (2.1)*** (0.5 - 3.6)	3.9 (2.8)*** (3.1 - 4.8)	4.6 (2.8)*** (3.9 - 5.3)

*: significant at p=0.05; **: significant at p=0.01; ***: significant at p=0.001; GPSS: Generic Patient Specific Scale; SD: standard deviation; SPADI = Shoulder Pain and Disability Index.

To identify the influence of group allocation, baseline SPADI and pain scores, overall duration of symptoms, the FABQ activity sub-score, the PCS total score, and of the time factor on our primary outcome measure, we included them into our mixed model analysis for the total SPADI score. During the analysis group allocation was kept in the model because of our primary research question. The final model included random intercepts for subjects and fixed effects for group allocation, duration of symptoms, baseline SPADI score and the time factor in weeks.

Subject heterogeneity accounted for part of the residual variability (estimated *intra-class correlation* 37.9%; Wald *z* =4.11, p =0.000). Group allocation did not significantly influence the result of our main outcome measure (p = 0.38, 95%CI = -7.45 to 2.85).

PGIC and patients with a MCID after 1 year

The number of patients with a clinically important difference as defined a priori and the number of patients who rated their treatment as a success increased progressively over the observation period (table 6). Because no differences between groups could be found at any follow up point, only numbers for the total group are given.

Table 6 Total group numbers (percentages) of patients with a clinically important change for every outcome measures.

Outcomes	At 5 weeks (n= 90)	At 12 weeks (n= 88)	At 52 weeks (n= 87)
Total SPADI Score (>10)	51 (56.7)	67 (76.1)	72 (82.8)
GPSS (>2)	39 (43.3)	60 (68.2)	68 (78.2)
PGIC (slightly & much better)	79 (87,8)	81 (92.1)	79 (90.8)
PGIC (much better)	42 (46.7)	50 (56.8)	67 (77.0)

GPSS: Generic Patient Specific Scale; PGIC: Patient's Global Impression of Change; CI95%: confidence interval; SPADI: Shoulder Pain and Disability Index.

Adverse events

One patient showed a deterioration of 12 points and another patient of 38 points after having had an accident involving the shoulder.

DISCUSSION

This randomized controlled trial investigated the long term effect of individualized physiotherapy combined with individualized exercises in comparison to individualized

exercises only on pain and function in patients with a clinical signs of shoulder impingement syndrome.

Both groups improved significantly during the one year follow up period, but no differences between groups in costs or any of the outcome measures could be found. These results question the additional benefit of individualized manual physiotherapy.

Direct and indirect costs

Contrary to our expectations, patients from the intervention group had more additional interventions and diagnostics during the first five weeks of the intervention phase compared to the controls. We would have thought that the more intensive therapeutic contact and the more tailored education in the intervention group would rather lead to a reduction of additional measures. However, we could not totally control the influence of general practitioners and orthopedic surgeons on these decisions. Although indirect costs did not significantly differ between groups, the difference between the absolute amounts of money was impressive with much higher costs in the control group (table 4) and may therefore also influence therapeutic decisions. In comparison the significant differences in direct costs at 5 weeks become less important.

Efficacy analysis

SPADI score

Both groups showed a significant improvement in SPADI score over the follow up period. However, our mixed models analysis showed that group allocation and therefore the IMPT had no influence on these results (p=0.38).

While the intervention group showed no further improvement during the last follow up period a remarkable improvement of the control group in total SPADI score was seen. This development is difficult to explain. We can hypothesize that patients from the control group may have established a clearer association between exercising and improvement of complaints and therefore a stronger belief in the effectiveness of their exercises. They may have then restarted their exercises quicker when complaints recurred.

MCID after 1 year in the primary outcome measures

The number of patients with a clinical important improvement in total SPADI score increased progressively during the observation period with a peak of about 83% (n=72) for the total group in the final assessment. One may argue that patients with a high SPADI baseline score had a better chance to improve more than 10 points than pa-

tients with a comparably low score at baseline. Comparing therefore these results to an analysis based on a minimum change of 30% of the initial score (instead of the absolute MCID of 11 we defined a priori) (25), we can see that 87% (n=76) of the total group showed a 30% improvement or more of the SPADI baseline score and still 81% (n=70) of 50% or more respectively. In a concept which accounts for the baseline score, a large improvement in patients with high baseline scores is needed to reach this cut off in contrast to patients with relatively low baseline scorings. However, similar results from both concepts and the ongoing improvement over time seen in our patient group supports the suggestion to wait with further treatments for about a year after having had physiotherapy for SIS. This positive development is also very well reflected in the patients' impression of change (PGIC) with 91% (n=79) being "slightly & much improved" at 1 year. Although at first appearance results for the PGIC seem to remain unchanged over time, the positive development becomes obvious in the increasing percentages of patients scoring the development of their complaints as "much improved", increasing from 47% (n=42) at 5 weeks up to finally 77% (n=67) after 1 year.

Comparisons with other studies

Few data are available about the additional effect of manual physiotherapy to exercises in patients with SIS. Former studies reported short term results but unfortunately none of them presented long term results (26-28). Our results suggest that IMPT is of no additional effect in the long term, but the significant and progressive improvement of both of our groups may support the positive effect of exercises in SIS, not seen in groups treated with sham or no treatment (29-31), and also different from the natural course of shoulder complaints over time described in literature (32). Based on this evidence we looked at studies with a follow up of 1 year or longer comparing exercises, which we used as the basic treatment in both of our groups, to other physiotherapeutic measures or surgery in patient with SIS. Engebretsen et al. (33, 34) compared exercises to shockwave therapy, two clearly different types of interventions. Both of their groups showed a significant improvement in total SPADI but no difference between groups after 1 year. Similar results are seen by Beaudreuil et al. (35) who compared a supervised dynamic humeral centering training to a supervised non-specific mobilization program. Dorrestijn et al. (36) summarized studies comparing physiotherapy or exercises to surgery in a systematic review; even between these interventions no differences in pain or functioning could be found in the long term. These results are confirmed in a randomized controlled trial by Ketola et al. (37). Interestingly, in most of the studies surgery was followed by an exercise program which would even more

question the effect of surgery. Cummins et al. (38) followed a cohort of 100 patients treated with a single corticoid injection and 4 weeks of physiotherapy followed by home exercises. Within a 2 years observation period 79% of a SIS group did not require surgery. To a lot of patients in our sample surgery was offered by the orthopaedic surgeon as an appropriate intervention, even if patients have not had physiotherapy as an initial treatment beforehand. Unfortunately we did not systematically collect data on recommendations made prior to inclusion in this trial; therefore no clear statement can be made. From the three patients who underwent surgery after the intervention phase, one had a total SPADI score of 12 points and a 19 points improvement from baseline. The decision for surgery in this case was maybe based on other reasons than objective functional status of the patient. Altogether, recommendations for surgery as an initial treatment for SIS seem difficult to justify, because surgery is not proven to deliver better results in the short and long term compared to physiotherapy.

However, similar results after one year are seen with different exercise protocols, shock wave therapy or surgery. It can therefore be questioned whether the planned intervention itself is solely responsible for the improvement. The question arises, which other mechanisms, shared by all these interventions, do contribute to the overall improvement. A recent systematic review by Chester et al. (39) identified low baseline disability and a short duration of symptoms as the two most important predictors for a good outcome in patients with musculoskeletal shoulder pain. This is according to our mixed model results with duration of symptoms and the initial SPADI score as the two remaining baseline variables with a significant influence on outcome. At baseline our group started with a relatively low mean (SD) SPADI sub-score for function (32.2 (18.9)) but had a comparably long mean (SD) duration of symptoms (104.8 (152.6) weeks). The good overall improvement after one year may indicate, that duration of symptoms may had less influence on outcome than the baseline SPADI score, but further research is needed to answer this question.

Strengths & Limitations of the study

Because of the low dropout rate and a standard deviation around the mean SPADI score below the standard deviation used for power calculation this study has sufficient power. Besides a sound statistical analysis controlling for possible confounders, covariates and time, further data about additional medication, diagnostics, co-interventions and sick leave are given, which enables the reader to draw a comprehensive picture of the patient group. Both interventions are described in detail and can therefore easily be reproduced.

Due to ethical and practical reasons it was not possible for us to include a placebo group. Therefore we could not analyze the contribution of the natural course to the improvement. However, other studies found a significant difference between exercise treatment and placebo or no intervention. Due to the nature of our interventions and outcome measures it was not possible to blind either therapists or patients, but patients were kept naive to group allocation. Because no difference existed between groups, the influence of therapists' beliefs about the applied treatments or the longer contact times in the intervention group seemed to be of no relevant influence.

Implications for further research

More study results are needed to allow a definite conclusion about the effect of individualized manual physiotherapy in this context. For the sake of comparability, a standard set for assessment of patients with shoulder pain is required. Further, eligibility criteria should be set up according to the clinical pattern instead of structure based diagnoses. When the effect of different interventions is investigated in clinical trials, potential prognostic factor need to be analyzed to clarify their importance and contribution to baseline scores and to treatment effects. These factors can then be therapeutically addressed to reinforce or reduce their impact on outcome.

Clinical implications

Data from this study are indicative for a sustained and progressively increasing improvement of pain and functioning over time after the intervention has ceased. From this we reason that patients after having had physiotherapy should be observed for a certain time period before another treatment is tested out.

Final conclusions

To our knowledge this is the first study presenting long term results for an additional effect of individualized manual physiotherapy to exercises compared to exercises alone. Although our results suggest that additionally applied manual interventions are of no benefit this must be confirmed by further research before a clear statement can be made. Exercises can be recommended as a first line treatment because they are less expensive and carry less risk than for example shockwave therapy or even surgery. Because of the ongoing improvement over the follow up period we suggest to wait with further interventions for about half a year after the start of treatment.

REFERENCES

1. Huisstede BMA, Bierma-Zeinstra SMA, Koes BW, Verhaar JAN. Incidence and prevalence of upper-extremity musculoskeletal disorders. a systematic appraisal of the literature. BMC Musculoskelet Disord 2006; 7.
2. Luime JJ. Shoulder complaints: the occurence, course and diagnosis [Proefschrift]. Rotterdam: Erasmus Universiteit; 2004.
3. Rekola KE, Keinanen-Kiukaanniemi S, Takala J. Use of primary health services in sparsely populated country districts by patients with musculoskeletal symptoms: consultations with a physician. J Epidemiol Community Health 1993; 47: 153-157.
4. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. Ann Rheum Dis 1995; 54: 959-964.
5. Gartsman GM, Brinker MR, Khan M, Karahan M. Self-assessment of general health status in patients with five common shoulder complaints. J Shoulder Elbow Surg 1998; 7: 228-237.
6. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. Rheumatology 2005; 44: 800-805.
7. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy 2001; 87: 458-469.
8. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology 2006; 45: 215-221.
9. Peters D, Davies P, Pietroni P. Musculoskeletal clinic in general practice: study of one year's referrals. Br J Gen Pract 1994; 44: 25-29.
10. Faber E, Kuiper JI, Burdorf A, Miedema HS, Verhaar JAN. Treatment of impingement syndrome: a systematic review of the effects on functional limitations and return to work. J Occup Rehabil 2006; 16: 7-25.
11. Green SE, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. The Cochrane Database of Systematic Reviews, Issue 2 Art No: CD004258 2003.
12. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. J Hand Ther 2004; 17: 152-164.
13. Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskelet Disord 2010; 11:114.
14. Kromer TO, de Bie RA, Bastiaenen CHG. Physiotherapy in patients with clinical signs of shoulder impingement syndrome: a randomized controlled trial. J Rehabil Med 2013; 45: 488- 497.
15. MacDermid J, Solomon P, Prkachin K. The shoulder pain and disability index demonstrates factor, construct and longitudinal validity. BMC Musculoskelet Disord 2006; 7: 12.
16. Williams JW, Holleman DR, Simel DL. Measuring shoulder function with the shoulder pain and disability index. J Rheumatol 1995; 22: 727-732.
17. Stratford PW, Gill C, Westaway MD, Binkley JM. Assessing disability and change on individual patients: a report of a patient specific measure. Physiother Can 1995; 47: 258-263.
18. Farrar JT, Young Jr. JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94: 149-158.
19. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J Pain 2004; 8: 283-291.

20. Carette S, Moffet H, Tardif J, Bessette L, Morin F, Fremont P, et al. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder. Arthritis Rheum 2003; 48: 829-838.
21. Chen JF, Ginn KA, Herbert RD. Passive mobilisation of shoulder region joints plus advice and exercise does not reduce pain and disability more than advice and exercise alone: a randomised trial. Aust J Physiother 2009; 55: 17-23.
22. Dogru H, Basaran S, Tunay S. Effectiveness of therapeutic ultrasound in adhesive capsulitis. Joint Bone Spine 2008; 75: 445-450.
23. Tveita EK, Tariq R, Sesseng S, Juel NG, Bautz-Holter E. Hydrodilatation, cortocosteroids and adhesive capsulitis: a randomized controlled trial. BMC Musculoskelet Disord 2008; 9: 53.
24. Destatis. Verdienste und Arbeitskosten-Ergebnisse fuer Deutschland: Fachserie 16 Heft 1. Wiesbaden: Statistisches Bundesamt; 2010.
25. Ostelo RWJG, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, et al. Interpreting change scores for pain and functional status in low back pain. Spine 2008; 33: 90-94.
26. Bang MD, Deyle GD. Comparison of supervised exercise with and without manual physical therapy for patients with shoulder impingement syndrome. J Orthop Sports Phys Ther 2000; 30: 126-137.
27. Conroy DE, Hayes KW. The effect of joint mobilization as a component of comprehensive treatment for primary shoulder impingement syndrome. J Orthop Sports Phys Ther 1998; 28: 3-14.
28. Ginn KA, Cohen M. Exercise therapy for shoulder pain aimed at restoring neuromuscular control: a randomized comparative clinical trial. J Rehabil Med 2005; 37: 115-122.
29. Brox JI, Gjengedal E, Uppheim G, Bohmer AS, Brevik JI, Ljunggren AE, et al. Arthroscopic surgery versus supervised exercises in patients with rotator cuff disease (stage II impingement syndrome): A prospective, randomized, controlled study in 125 patients with a 2.5-year follow up. J Shoulder Elbow Surg 1999; 8: 102-111.
30. Dickens VA, Williams JL, Bahmra MS. Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. Physiotherapy 2005; 91: 159-164.
31. Ludewig PM, Borstad JD. Effects of a home exercise programme on shoulder pain and functional status in construction workers. Occup Environ Med 2003; 60: 841-849.
32. Croft PR, Pope DP, Silman AJ. The clinical course of shoulder pain: prospective cohort study in primary care. Br Med J 1996 September 7; 313: 601-602.
33. Engebretsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, et al. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised trial. Br Med J 2009; 339: b3360.
34. Engebretsen K, Grotle M, Bautz-Holter E, Sandvik L, Ekeberg OM, Juel NG, et al. Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial. Phys Ther 2011; 91: 37-47.
35. Beaudreuil J, Lasbleiz S, Richette P, Seguin G, Rastel C, Mounir A, et al. Assessment aof dynamic humeral centering in shoulder pain with impingement syndrome: a randomised clinical trial. Ann Rheum Dis 2011; 70.
36. Dorrestijn O, Stevens M, Winters JC, van der Meer K, Diercks RL. Conservative or surgical treatment for subacromial impingement syndrome? A systematic review. J Shoulder Elbow Surg 2009; 18: 652-660.
37. Ketola S, Lehtinen J, Arnala I, Nissinen M, Westenius H, Sintonen H, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? J Bone Joint Surg 2009; 91-B: 1326-1334.
38. Cummins CA, Sasso LM, Nicholson D. Impingement syndrome: Temporal outcomes of nonoperative treatment. J Shoulder Elbow Surg 2009; 18: 172-177.
39. Chester R, Shepstone L, Helena Daniell H, Sweeting D, Lewis J, Jerosch-Herold C. Predicting response to physiotherapy in the treatment of musculoskeletal shoulder pain: a systematic review. BMC Musculoskelet Disord 2013; 14:203.

CHAPTER 6

The influence of fear avoidance beliefs on pain and disability in patients with shoulder impingement syndrome in primary care:

A secondary analysis

ABSTRACT

Background Contrary to low back pain, little information exists about the role of fear-avoidance beliefs and catastrophizing in shoulder impingement syndrome.
Objective To investigate the associations between fear, pain, and disability as well as the contribution of fear avoidance beliefs and catastrophizing to pain and disability in this patient group.
Design Cross sectional design.
Methods 90 patients were included in this analysis. At initial consultation demographic and clinical data including pain, fear avoidance beliefs, and catastrophizing were assessed. Function was measured with the Shoulder Pain and Disability Index, pain intensity was rated on a numeric rating scale. First, bivariate and partial correlations were calculated between pain, fear avoidance beliefs and disability based on the fear avoidance model. Second, two separate hierarchical multivariable linear regression analyses were performed to determine the contribution of fear avoidance beliefs and catastrophizing to either function or pain.
Results We found a direct and independent association of pain and fear-avoidance beliefs on disability. The final regression models identified fear avoidance beliefs and catastrophizing as significant contributors to pain and disability levels.
Limitations We investigated patients with shoulder impingement; therefore results should be transferred with caution to other shoulder diagnoses. We could not prospectively analyze the development of fear avoidance beliefs and catastrophizing and their influence on outcome which limits the external validity of the results.
Conclusions Fear avoidance beliefs and catastrophizing are important contributors to pain and disability in this patient group. Our results help caregivers to recognize their importance and to consider them for treatment planning. We further recommend the assessment of fear avoidance beliefs and catastrophizing in patients with shoulder impingement syndrome as a standard feature in primary care.

The influence of fear avoidance beliefs on pain and disability in patients with shoulder impingement syndrome in primary care: a secondary analysis.
Submitted to the Physical Therapy Journal on 22 November 2013.

INTRODUCTION

With an incidence of 9.5 per 1000 patients shoulder complaints are among the most common musculoskeletal complaints presented to primary care givers[1]. Many shoulder patients show clinical signs of subacromial impingement syndrome (SIS)[1,2] leading to pain and functional restrictions especially with overhead activities, often persisting far beyond expected tissue recovery times[3,4]. Besides biomechanical deficits in strength or coordination of the rotator cuff[5,6] and other shoulder girdle muscles[7], stability[8,9] and posture[10], fear avoidance beliefs (FAB) and catastrophizing also seem to negatively influence pain, functioning and recovery times[11,12].

Although well investigated in low back pain (LBP), the role of FAB and catastrophizing in the development of chronic pain and disability in shoulder disorders and especially in shoulder impingement syndrome (SIS) is still unclear. In LBP, the fear avoidance model (FAM)[13] tries to explain why acute LBP becomes chronic in a minority of patients and describes two possible pathways. In the adaptive pathway, labeled "confrontation", patients interpret pain as non-threatening and are likely to maintain their daily life activities despite pain, which facilitate spontaneous recovery. In the maladaptive pathway, labeled "avoidance", pain is interpreted as a threat, initiating a vicious circle of catastrophizing, pain related fear, hypervigilance and avoidance behavior. Consecutively, this leads to chronic pain, disuse, increased pain sensitivity, psychological distress and ongoing disability. The FAM is widely accepted in chronic LBP. However, studies investigating patients with acute LBP found stronger correlations between pain and disability than between pain related fear and disability[14]. In a cohort of 174 patients with acute LBP Sieben et al[15] found that pain intensity was a stronger predictor for chronic disability than FAB. This is supported by results of van der Windt et al[16], who could not identify FAB as a prognostic factor for a negative outcome in acute LBP. Gheldof et al[17] and Wideman and Sullivan[18] prospectively identified unique relationships between fear avoidance and long term work disability, and between catastrophizing and long-term pain intensity in patients with sub-acute low back pain emphasizing the differential character of fear avoidance and catastrophizing. These contradictory results suggest different underlying mechanisms for patients with acute and chronic LBP respectively.

The role of FAB have also been investigated in musculoskeletal disorders other than LBP.

Hart et al[19] found similar scores for FAB in acute stages of upper and lower extremity disorders, neck and low back pain, indicating that FAB are not specific to LBP but also present in other musculoskeletal complaints. Other studies found a negative influence of FAB on recovery times in a mixed population of musculoskeletal pain pa-

tients[20], in neck pain[21,22], after knee-anterior cruciate ligament rehabilitation[23], knee osteoarthritis[24], and patellofemoral pain[25].

Also in patients with shoulder pain, associations between clinical and psychological characteristics and disability have been shown[26,27]. However, clinical characteristics seem to have a stronger influence on pain and functioning than psychological factors in both sub-acute and chronic complaints[16,28-31], but study results are contradictory and no data exist for patients with SIS specifically.

Because complaints in the shoulder region summarized under the term "shoulder pain" are diverse in their impact on functional ability of the patient, it is important to investigate the influence of psychological factors separately in each of the different diagnoses. Patients with SIS represent the biggest group with about 70% to 80% [1]. We hypothesize that FAB and catastrophizing are important contributors to pain and disability in patients with SIS. Therefore this study investigates the relationship between pain, FAB, and disability at the time of consultation and tests, whether associations between these variables are in line with the FAM. It further analyzes to what degree FAB and catastrophizing contribute to the variance of disability and pain scores in patients with SIS.

METHODS

Participants

Data were gathered from patients with SIS who gave their informed consent to participate in a randomized controlled trial investigating the effect of two different physiotherapy interventions in this patient group in general practice. Inclusion criteria set for this trial were: (1) age between 18 and 75 years, (2) symptoms for at least four weeks, (3) main complaints in the glenohumeral joint region or the proximal arm, (4) presence of one of the following signs indicating SIS: Neer impingement sign, Hawkins-Kennedy impingement test, painful arc with active abduction or flexion, (5) pain during one of the following resistance tests: external rotation, internal rotation, abduction, or flexion.

Exclusion criteria were: (1) average 24-hours pain of 8/10 or more on a visual numeric rating scale (VNRS), (2) primary scapulothoracic dysfunction due to paresis, (3) diagnosed instability or previous history of dislocation, (4) adhesive capsulitis (frozen shoulder), (5) more than 1/3 restriction of elevation compared to the unaffected side, (6) substantial shoulder weakness or loss of active shoulder function, (7) shoulder surgery in the last 12 months on the involved side, (8) reproduction of symptoms with active or passive cervical movements, (9) neurological involvement with sensory and

muscular deficit, (10) inflammatory joint disease (e.g. rheumatoid arthritis), (11) diabetes mellitus, (12) intake of psychotherapeutic drugs, (13) compensation claims, (14) inability to understand written or spoken German.

188 patients were assessed for eligibility of which 55 patients did not fulfil the eligibility criteria and 33 refused participation. 10 patients were not included due to other reasons (3 moved, 4 didn't get a prescription for physiotherapy, 3 couldn`t fulfil the treatment schedule). Finally, 90 participants were included in the trial.

Measures

Assessment at time of consultation comprised of demographic data including age and gender, clinical data including the overall duration of shoulder complaints, the episodic character of complaints during the last 12 months, sick leave, and sports hours per week.

Assessment of fear avoidance beliefs (FAB)

A validated questionnaire used to measure fear avoidance is the Fear Avoidance Beliefs Questionnaire (FABQ), a 16-item questionnaire developed by Waddell et al.[32] This questionnaire was initially designed in patients with LBP but has recently also been used to measure FAB in other musculoskeletal disorders.

The FABQ consists of 16 items and comprises of two sub-scales, one for physical activity (FABQ-PA) and one for work activities (FABQ-W). Because focus was on shoulder function and not on work loss we only used the FABQ-PA subscale in this study. Each item of this scale is scored on a seven-point Likert scale (0 = strongly disagree, 6 = strongly agree). The total FABQ-PA score is calculated by adding up the scores of the single items with higher scores reflect a higher level of fear avoidance believes. To adapt the FABQ to our patient group the word "back" was replaced by the word "shoulder". This modification was previously made in other studies investigating anatomic areas other than the low back[26,33].

Assessment of catastrophizing

Catastrophizing was measured using the Pain Catastrophizing Scale (PCS), a multidimensional, reliable and valid 13-item measurement tool with a strong association to pain and disability[34-37]. The PCS has been validated for the German population[38]. For this study the total score was calculated by adding the ratings for each item, with higher scores representing higher levels of catastrophizing.

Assessment of pain

Average weekly pain intensity was assessed on an 11-point visual numeric rating scale (VNRS), a recommended core outcome measure in the assessment of pain[39]. 0 on the left end of the VNRS was defined as "no pain at all", 10 at the right end as "as much pain as I can imagine".

Assessment of disability

The Shoulder Pain and Disability Index (SPADI) is a shoulder-specific self-report questionnaire measuring pain and disability in patients with shoulder pain of musculoskeletal origin[40]. It contains 5 items assessing pain and 8 items assessing shoulder function. Each item is scored on a 100 mm visual analogue scale (VAS) with the right end defined as "worst pain imaginable/so difficult required help", and the left end as "no pain/no difficulty". The SPADI has shown to be valid and highly responsive in assessing shoulder pain and function[40,41]. In this study, only the SPADI sub-scale for function (SPADI-F) was used to get a pure score for disabled function and to prevent an overlap between the two concepts of pain measured with the VNRS and the SPADI total score as it includes the pain sub-scale which was highly correlated with the SPADI-F (r = 0.7). The total SPADI-F score reaches from 0 to 100 with higher scores reflecting higher disability levels.

Analysis

Patient characteristics

Descriptive statistics were generated for the total group and data were analysed for distribution. Normality of data was tested with the Kolmogorov-Smirnov test. Possible differences in baseline characteristics between subacute (≥ 4 weeks and ≤ 3 months) and chronic (> 3 months) patients were assessed, because most of the measures taken can be influenced by symptom duration as a possible confounder.

First aim: association between FAM-variables

Bivariate correlations (Pearson's r for normally distributed data, Spearman's *rho* for non-normally distributed data) were calculated between pain, FAB and disability. In a second step, partial correlations were calculated with every correlation between two of the variables in the triangle being adjusted for the third variable to see their mediating effect.

Second aim: contribution of FAB and catastrophizing to pain and disability

In order to determine the contribution of FAB and catastrophizing to the variance of pain and disability scores, two separate hierarchical linear regressions were performed

using SPADI-F and pain intensity as the dependent variable respectively. Demographic and clinical factors that could be associated with pain and disability scores were identified from literature and used as possible independent variables for multivariable regression analysis. Furthermore, variable selection was preceded by checking for multicollinearity by calculating correlation coefficients between the independent variables. In case of correlated variables ($r \geq 0.5$) the most easily obtainable variable in clinical practice was chosen for further analysis.

A separate model was calculated for each of the dependent variables (SPADI-F, pain intensity). In each model gender and age were included in a first step to control for these potentially influencing factors; they were then kept in the model throughout the following analyses even if insignificant. In a second step the clinical variables and in a third step the psychological variables were entered in the model to see their contribution to the models' variance. In each step, variables with the lowest predictive value were removed sequentially, until all remaining predictors were significantly associated with the dependent variable or until R^2 was reduced significantly by removing the next variable from the model (stepwise backward strategy). All statistical tests were two-sided and statistical significance was determined with an alpha level of 0.05 unless reported otherwise. Regression coefficients and beta coefficients were calculated for all variables in each of the final models.

Assuming that 15 participants are needed to include one independent variable[42], we can include a maximum of six variables in the final model with sufficient statistical power. Data analysis was performed using SPSS (IBM Statistics, ver.19.0).

RESULTS

Complete data were available from all patients included in the study (n=90). Demographic and clinical data are displayed in table 1. Except for SPADI-F and age, all data were non-normally distributed and skewed to the lower end of the scales as expected, because of the defined eligibility criteria set up for this trial. Scores for the psychological measures (median (IQR)) were relatively low even in the chronic patient group (FABQ-PA 16 (7), PCS 9 (12)).

Table 1 Demographic and clinical data (n=90)

Measure	Median (IQR)	Mean (SD)
Gender, female, %(n)	51.1 (46)	
Age, years	51.0 (18.3)	51.8 (11.2)
Overall duration of complaints in weeks	38 (114)	104.8 (152.6)
History of complaints, %(n)	32 (35.6)	
Pain score (VNRS)	5 (2)	5.1 (1.8)
SPADI total score	37.6 (24.4)	40.4 (17.0)
SPADI sub-score for pain	45 (26)	48.7 (18.0)
SPADI sub-score for function	28.9 (30.1)	32.2 (18.9)
FABQ sub-score for physical activity	16 (7)	14.6 (4.9)
FABQ sub-score for work	12 (20)	12.1 (9.9)
PCS total score	9 (11)	11.4 (8.5
Sports hours per week, %(n)		
0-2	37.8 (34)	
3-5	62.2 (56)	
Days of sick leave		0.5 (2.7)

FABQ: Fear Avoidance Beliefs Questionnaire; PCS: Pain Catastrophizing Scale; SD: standard deviation; SPADI: Shoulder Pain and Disability Index; VNRS: Visual Numeric Rating Scale.

Within the triangle based on the FAM, disability showed a stronger correlation with pain than with FAB; no significant correlation was found between pain and FAB (Figure 1). Calculating partial correlations by adjusting the bivariate correlation between two variables for the third one (dotted arrows) did not change results, indicating that pain and FAB are independently associated with disability, and that their association is not mediated by the third variable.

For assessing the influence of psychological factors on disability and pain scores we identified six independent variables for analysis: (i) duration of complaints at baseline, (ii) pain intensity, (iii) disability[11,16,28,30,31,43-47], (iv) age [48,49], (v) gender [50], (vi) pain-related fear and catastrophizing[11,12,28,47]. These variables were categorized for analysis as shown in table 2.

Table 2 Contentwise structured blocks for regression analysis

Step 1	Step 2	Step 3
Demographic factors	Clinical factors	Psychological factors
Age	Duration of complaints	PCS
Gender	Pain intensity/SPADI-F	FABQ-PA

Gender, FABQ-PA, PCS, duration of complaints, SPADI-F, and pain intensity were significantly correlated with either pain intensity (VNRS) or disability (SPADI-F) and were included in the analysis. Disability was highly correlated with pain, catastrophizing, and FAB which is in line with the FAM.

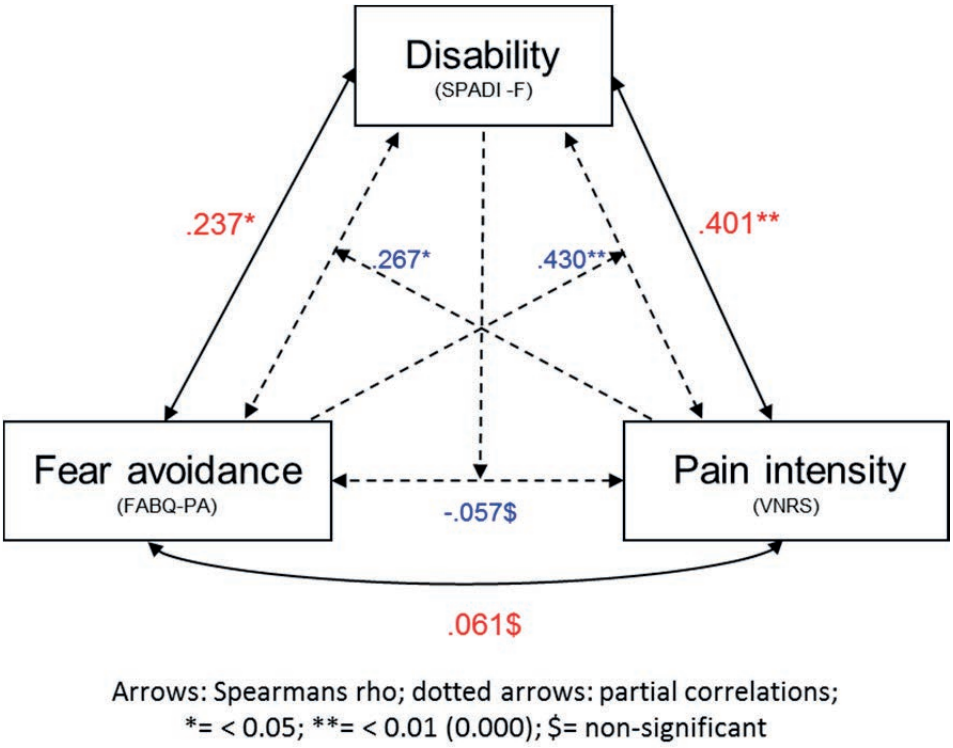


Figure 1 Associations and mediation between pain, fear avoidance beliefs, and disability

Regression model 1 with disability (SPADI-F) as the dependent variable.

According to table 2, categories of independent variables were entered stepwise in the model and variables with the lowest predictive value were then sequentially removed as described in the method section. Age and gender entered in step 1 explained 14.9% of the variance in SPADI-F score. At the end of step 2 the total variance explained by the model as a whole (including age, gender and pain intensity) was 28.1%. The total variance explained by the model as a whole at the end of step 3 (including age gender, pain intensity and FABQ-PA) was 36.5%. Of the two remaining variables, pain intensity explained an additional 13.1% and the FABQ-PA an additional 8.4% of the variance in SPADI-F; both variables had similar beta values. These results and the modeling process are displayed in table 3.

Table 3 Steps of the hierarchical regression analysis. Dependent variable: SPADI-F

Step	Variables in model	Variables removed	R^2	R^2 adjusted	R^2 change	F	F change	Sig. F change	Beta	Beta Sig.	Beta 95%CI	VIF
1	Block 1:		.149	.130	.149		7.64	.001				
	age								.184	.076	(-.03 to .65)	1.07
	gender								.391	.000	(7.03 to 22.29)	1.07
2	Block *1* and 2:		.281	.247	.131		7.76	.001				
	age								.101	.310	(-.16 to .50)	1.15
	gender								.324	.001	(4.96 to 19.38)	1.11
	Duration of complaints								.004	.970	(-.02 to .02)	1.08
	Pain intensity								.373	.000	(1.93 to 6.02)	1.11
3		Duration of complaints										
4	Block *1* and 2:		.281	.256	.131		15.69	.000				
	age								.101	.299	(-.15 to .49)	1.12
	gender								.324	.001	(4.99 to 19.33)	1.11
	Pain intensity								.374	.000	(1.98 to 5.98)	1.06
5	Block *1,2* and 3:		.370	.333	.090		5.98	.004				
	age								.230	.026	(.05 to .72)	1.37
	gender								.322	.001	(4.94 to 19.23)	1.24
	Pain intensity								.296	.003	(1.01 to 5.21)	1.26
	FABQ-PA								.287	.006	(.32 to 1.89)	1.40
	PCS								.090	.403	(-.27 to .67)	152
6		PCS										

Step	Variables in model	Variables removed	R^2	R^2 adjusted	R^2 change	F	F change	Sig. F change	Beta	Beta Sig.	Beta 95%CI	VIF
7	Block *1,2* and 3:		.365	.335	.084	12.22	11.29	.001				
(final)	*age*								.240	.019	(.07 to .74)	1.35
	gender								.347	.000	(6.21 to 19.80)	1.11
	Pain intensity								.326	.001	(1.56 to 5.38)	1.09
	FABQ-PA								.319	.001	(.50 to 1.96)	1.21

CI: confidence interval; FABQ-PA: Fear Avoidance Beliefs Questionnaire Physical Activity sub-scale; PCS: Pain Catastrophizing Scale; SPADI-F: Shoulder Pain and Disability Index Functional sub-scale; sig: significance; VIF: variance inflation factor.

Regression model 2 with pain intensity (VNRS) as the dependent variable.

The same approach was used for pain intensity; in step 2 the independent variable pain was replaced with disability (SPADI-F). Age and gender entered in step 1 explained 6.0% of the variance in pain score. At the end of the second step the total variance explained by the model as a whole (including age, gender and SPADI-F) was 20.5%, and the total variance explained by the model as a whole after step 3 (including age, gender, SPADI-F and PCS) was 27.8%. Of the two remaining variables, SPADI-F explained an additional 14.5% and the PCS an additional 7.3% of the variance in pain intensity score. Both were statistically significant with similar beta values (table 4).

Table 4 Steps of the hierarchical regression analysis. Dependent variable: PAIN

Step	Variables in model	Variables removed	R^2	R^2 adjusted	R^2 change	F	F change	Sig. F change	Beta	Beta Sig.	Beta 95%CI	VIF
1	Block 1:		.060	.039	.0.60		2.79	.067				
	age								.221	.043	(.00 to .69)	1.07
	gender								.178	.102	(-.13 to 1.38)	1.07
2	Block *1* and 2:		.230	.194	.170		9.38	.000				
	age								.115	.262	(-.14 to .05)	1.15
	gender								.020	.850	(-.67 to .82)	1.26
	Duration of complaints								.161	.101	(-.00 to .00)	1.05
	SPADI-F								.399	.000	(.02 to .06)	1.18
3		Duration of complaints										
4	Block *1* and 2:		.205	.177	.145	7.40	15.69	.000				
	age								.145	.156	(-.01 to .06)	1.11
	gender								.016	.879	(-.70 to .81)	1.25
	SPADI-F								.413	.000	(.02 to .06)	1.18
5	Block *1,2* and 3:		.284	.241	.079		4.61	.013				
	age								.110	.323	(-.17 to .05)	1.43
	gender								-.062	.568	(-.98 to .54)	1.38
	SPADI-F								.337	.003	(.01 to .05)	1.43
	FABQ-PA								-.095	.407	(-.12 to .05)	1.52
	PCS								.329	.003	(.02 to .11)	1.38
6		FABQ-PA										

Step	Variables in model	Variables removed	R^2	R^2 adjusted	R^2 change	F	F change	Sig. F change	Beta	Beta Sig.	Beta 95%CI	VIF
7	Block *1,2* and 3:		.278	.244	.073	8.18	8.55	.004				
(final)	*age*								.153	.118	(-.01 to .06)	1.11
	gender								-.039	.711	(-.87 to .60)	1.29
	SPADI-F								.311	.004	(.01 to .05)	1.32
	PCS								.300	.004	(.02 to .11)	1.24

CI: confidence interval; FABQ-PA: Fear Avoidance Beliefs Questionnaire Physical Activity sub-scale; PCS: Pain Catastrophizing Scale; SPADI-F: Shoulder Pain and Disability Index Functional sub-scale; sig: significance; VIF: variance inflation factor.

DISCUSSION

Our first aim was to analyze associations between pain, FAB and disability. Disability had a stronger correlation with pain than with FAB. The low correlation between pain and FAB and the absent mediating effect of these factors on disability suggests that in this patient group pain and FAB coexist, with a direct and independent influence on disability, not following a sequential order as described in the FAM. Therefore, the FAM as a theoretical construct to explain disability may not be entirely valid in patients with SIS. Our findings further indicate that in both early and later stages of SIS, significant associations between FAM variables exist. The apparent association between pain and disability found in this study corresponds very well to the findings of Sieben et al.[14] in acute LBP. At the same time it reflects a clinically relevant difference to the group of patients with chronic LBP. From these results it can be concluded that in SIS of short and long duration, similar to acute LBP, pain intensity is more important as a direct cause for disability than initially suggested by Vlaeyen and Linton, based on data collected in chronic LBP patients[13].

Our second aim was to analyze the contribution of psychological variables to the variance of disability and pain at the time of consultation. The final model for disability confirmed the results from the associations tested before, with pain intensity and FABQ-PA as the remaining significant contributors. Pain intensity was still a stronger contributor explaining disability than FAB. This may have been facilitated by the ability to compensate some of the provocative movements with the healthy side leading to a more specific pattern of avoidance but not in a reduction of the overall activity level. Parr et al[51] found similar results after inducing muscle injury to the shoulder in a healthy sample with pain as the most important factor predicting disability followed by kinesiophobia. These results may also indicate that in patients with SIS pain is still of nociceptive origin functioning as a warning sign in order to protect injured body structures (at least at the time of consultation).

In the final model for pain, only disability and catastrophizing had a significant influence. This is in line with results from other studies also identifying catastrophizing as a significant predictor for shoulder pain[28,51]. Although FAB had an influence on disability, they did not contribute to pain intensity. Similar results were also found by Simon et al[52] and George and Stryker[26] in patients with musculoskeletal upper extremity disorders. George and Hirsh[53] found an association between FAB and experimental shoulder pain sensitivity, but not with clinical pain intensity, which was significantly associated with pain catastrophizing.

Contrary to our expectations, duration of symptoms, a predictive factor often identified in literature, had no significant influence in any of the two models. In sum-

mary, it can be stated that in patients with SIS clinical and psychological factors are simultaneously present, with FAB and catastrophizing explaining a substantial degree of variance in both pain and disability.

Implications for clinical practice

In order to link our results to clinical practice, we suggest to interpreting them against the background of pain mechanisms, a practical classification system proposed by Gifford and Smart et al.[54-56]. Pain mechanisms are well embedded in the clinical reasoning process used by manual physiotherapists specialized in musculoskeletal disorders[57-59]. Based on the patients' clinical signs and symptoms, the therapist is able to identify the dominant pain mechanism as for example nociceptive or centrally sensitized (see Appendix 1).

Because of the eligibility criteria set for the trial, our patient group fits best with the nociceptive pain mechanism. However, we identified FAB and catastrophizing as contributing factors to pain and disability, indicating that these factors, usually viewed as typical clinical aspects of a chronic (centrally sensitized) state, are also associated with a dominantly nociceptive presentation but may serve a different purpose here. Patients in our sample seemed to selectively control or avoid painful movements to a certain degree as an adaptive strategy, for example by taking over certain movements with their non-affected arm. On the one hand this led to a shoulder-specific disability on the affected side (a temporary and partial limitation of function) but on the other hand enabled them to stay at work and to continue other activities. The fact that pain was clearly connected to specific movements and hence predictable and controllable and the ability to compensate some of the provocative movements with the healthy side may have helped to maintain activity and improve control. This can further explain the relatively low rating on the FABQ-PA, although FAB are a significant factor in the model. It also may explain the small number of sick days in this sample and the fact that a longer duration of complaints did not change the underlying pain mechanism from a dominantly nociceptive into a dominantly centrally sensitized state. In consequence patients did not develop general and permanent disability and disuse symptoms over time. This clearly differs from chronic (centrally sensitized) patients showing more general disability because their pain is often unpredictable, changeable and therefore difficult to control. However, in SIS patients not showing improvement of pain and functioning within an expected time frame the dominant pain mechanism must be reviewed and psychological factors must be addressed because they may facilitate the process of central sensitization and seem to be predictive for a poor treatment outcome[12,16,27].

Although still unclear from the literature how to optimally do this, it is worth making suggestions. Besides physiotherapeutic exercises and hands-on interventions to improve physical function, the patients' understanding of the problem must be improved by explaining how these factors contribute to pain and disability[60-62]. Stopping rules for activities of daily living should be defined to prevent overuse. However, some provocative activities happen unnoticed (like lying on the affected shoulder while sleeping), or result in a delayed onset of pain. Patients will then lose a clear connection between activity and pain sensation, and as a result, their feeling of control. Catastrophizing triggered by pain arising from these activities may amplify pain perception, facilitate suffering and hence the development of a centrally sensitized pain state. Therefore patient information about these mechanisms is also of particular importance.

Implications for further research

To get further insight and to support or refute the results from this study, catastrophizing and FAB should be standardly assessed in future SIS studies, as both were significantly associated with pain and disability. We further suggest to prospectively investigating the influence of psychological factors on treatment outcome and the effect of interventions specifically targeting catastrophizing and FAB.

Methodological considerations

This study has several limitations that need to be considered when interpreting the results. We investigated patients with SIS, a diagnostic subgroup of shoulder disorders. Results should therefore be transferred with caution to other shoulder diagnoses or clinical populations. Due to the cross-sectional nature of our data and it was not possible for us to prospectively analyse the development of FAB and catastrophizing and their influence on outcome, thus the external validity is limited. However, we had a good sample size, used validated self-report measures, and did a sound statistical analysis including clinical and psychological factors often mentioned in literature. Thus, results from this study help to clarify the contribution of these factors to pain and disability in patients with SIS at the time of their first consultation, which is a very important moment from a clinical perspective. The fact that we linked our results to the clinical concept of pain mechanisms will encourage therapists to integrate assessment and treatment of psychological factors in their daily routine.

Conclusion

To our knowledge this is the first study elucidating the role of FAB and catastrophizing in patients with SIS. Our results suggest that SIS patients experience the different constructs included in the FAM at the same time and not in a consecutive order. Similar to acute LBP, pain and disability in SIS appears to be the result of a dominantly nociceptive problem already including FAB and catastrophizing thoughts. In both LBP and SIS and maybe in many more musculoskeletal disorders, the vital point is therefore to prevent chronicity by assessing and addressing both clinical and psychological factors. Especially in SIS, even if long lasting, nociceptive tissue based components may still be dominant, which seems to be a clinically relevant difference between SIS and LBP. Thus, treatment of SIS should be guided by the clinical presentation of the individual patient and not by duration of symptoms only.

REFERENCES

1. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology.* 2005;44:800-805.
2. van der Windt DAWM, Thomas E, Pope DP, et al. Occupational risk factors for shoulder pain: a systematic review. *J Occup Environ Med.* 2000;57:433-442.
3. Winters JC, Sobel JS, Groenier KH, Arendzen JH, Meyboom-de Jong B. The long-term course of shoulder complaints: a prospective study in general practice. *Rheumatology.* 1999;38:160-163.
4. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. *Physiotherapy.* 2001;87:458-469.
5. Irlenbusch U, Gansen H-K. Muscle biopsy investigations on neuromuscular insufficiency of the rotator cuff: a contribution to the functional impingement of the shoulder. *J Shoulder Elbow Surg.* 2003;12:422-426.
6. Leroux J-L, Codine P, Thomas E, Pocholle M, Mailhe D, Blotman F. Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. *Clin Orthop Relat Res.* 1994;304:108-113.
7. Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. *Phys Ther.* 2000;80:276-291.
8. Glousman R, Jobe FW, Tibone J, Moynes D, Antonelli D, Perry J. Dynamic electromyographic analysis of the throwing shoulder with glenohumeral instability. *J Bone Joint Surg.* 1988;70A:220-226.
9. Kibler BW. The role of the scapula in athletic shoulder function. *Am J Sports Med.* 1998;26:325-337.
10. Solem-Bertoft E, Thuomas K-A, Westerberg C-E. The Influence of scapular retraction and protraction on the width of the subacromial space. *Clin Orthop Relat Res.* 1993;296:99-103.
11. Bot SDM, van der Waal JM, Terwee CB, et al. Predictors of outcome in neck and shoulder symptoms. *Spine.* 2005;30:E459-E470.
12. Karels CH, Bierma-Zeinstra SMA, Burdorf A, Verhagen AP, Nauta AP, Koes BW. Social and psychological factors influenced the course of arm, neck and shoulder complaints. *J Clin Epidemiol.* 2007;60:839-848.
13. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain:a state of the art. *Pain.* 2000;85:317-332.

14. Sieben JM, Portegijs PJM, Vlaeyen JWS, Knottnerus JA. Pain-related fear at the start of a new low back pain episode. *Eur J Pain.* 2005;9:635-641.
15. Sieben JM, Vlaeyen JWS, Portegijs PJM, et al. A longitudinal study on the predictive validity of the fear–avoidance model in low back pain. *Pain.* 2005;117:162-170.
16. van der Windt DA, Kuijpers T, Jellema P, van der Heijden GJMG, Bouter LM. Do psychological factors predict outcome in both low-back pain and shoulder pain? *Ann Rheum Dis.* 2007;66:313-319.
17. Gheldof ELM, Crombez G, Van den Bussche E, et al. Pain-related fear predicts disability, but not pain severity: a path analytic approach of the fear avoidance model. *Eur J Pain.* 2010;14:870.e871-870.e879.
18. Wideman TH, Sullivan MJ. Differential predictors of the long-term levels of pain intensity, work disability, heathcare use, and medication use in asample of workers' compensation claimants. *Pain.* 2011;152:376-383.
19. Hart DL, Werneke MW, George SZ, et al. Screening for elevated levels of fear-avoidance beliefs regarding work or physical activities in people receiving outpatient therapy. *Phys Ther.* 2009;89:770-785.
20. Westman AE, Boersma K, Leppert J, Linton SJ. Fear-avoidance beliefs, catastrophizing, and distress: a longitudinal subgroup analysis on patients with musculoskeletal pain. *Clin J Pain.* 2011;27:567-577.
21. George SZ, Fritz JM, Erhard RE. A comparison of fear avoidance beliefs in patients with lumbar spine pain and cervical spine pain. *Spine.* 2001;26:2139-2145.
22. Landers MR, Creger RV, Baker CV, Stutelberg KS. The use of fear-avoidance beliefs and nonorganic signs in predicting prolonged disability in patients with neck pain. *Man Ther.* 2008;13:239-248.
23. Ross MD. The relationship between functional levels and fear-avoidance beliefs following anterior cruciate ligament reconstruction. *J Orthop Traumatol.* 2010;11:237-243.
24. Scopaz KA, Piva SR, Wisniewski S, Fitzgerald GK. Relationships of fear, anxiety, and depression with physical function in patients with knee osteoarthritis. *Arch Phys Med Rehabil.* 2009;90.
25. Piva SR, Fitzgerald GK, Wisniewski S, Delitto A. Predictors of pain and function outcome after rehabilitation in patients with patellofemoral pain syndrome. *J Rehabil Med.* 2009;41:604-612.
26. George SZ, Stryker SE. Fear-avoidance beliefs and clinical outcomes for patients seeking outpatient physical therapy for musculoskeletal pain conditions. *J Orthop Sports Phys Ther.* 2011;41:249-259.
27. Kuijpers T, van der Windt DAWM, van der Heijden GJMG, Twisk JWR, Vergouwe Y, Bouter LM. A prediction rule for shoulder pain related sick leave: a prospective cohort study. *BMC Musculoskelet Disord.* 2006;7:97.
28. Reilingh ML, Kuijpers T, Tanja-Harfterkamp AM, van der Windt DA. Course and prognosis of shoulder symptoms in general practice. *Rheumathology.* 2008;47:724-730.
29. Lentz TA, Barabas JA, Day T, Bishop MD, George SZ. The relationship of pain intensity, physical impairment, and pain-related fear to function in patients with shoulder pathology. *J Orthop Sports Phys Ther* 2009;39:270-277.
30. Kuijpers T, van der Windt DAWM, van der Heijden GJMG, Bouter LM. Systematic review of prognostic cohort studies on shoulder disorders. *Pain.* 2004;109:420-431.
31. Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Brox JI. Predictors of shoulder pain and disability index (SPADI) and work status after 1 year in patients with subacromial shoulder pain. *BMC Musculoskelet Disord* 2010;11:218.
32. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low-back pain and disability. *Pain.* 1993;52:157–168.
33. Mintken PEP, Cleland JA, Whitman JM, George SZ. Psychometric properties of the fear-avoidance beliefsbquestionnaire and Tampa scale of kinesiophobia in patients with shoulder pain. *Arch Phys Med Rehabil.* 2010;91:1128-1136.

34. Osman A, Barrios FX, Guittierrez PM, Kopper BA, Merrifield T, Grittmann L. The pain catastrophizing Ssale: further psychometric evaluation with adult samples. *J Behav Med.* 2000;23:351-365.
35. Osman A, Barrios FX, Kopper BA, Hauptmann W, Jones J, O'Neill E. Factor structure, reliability, and validity of the pain catastrophizing scale. *J Behav Med.* 1997;20:589-605.
36. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychol Assess.* 1995;7:524-532.
37. Sullivan MJ, Stanish W, Waite H, Sullivan M, Tripp DA. Catastrophizing, pain, and disability in patients with soft-tissue injuries. *Pain.* 1998;77:253-260.
38. Meyer K, Sprott H, Mannion AF. Cross-cultural adaptation, reliability, and validity of the German version of the pain catastrophizing scale. *J Psychosom Res.* 2008;64:469-478.
39. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain.* 2005;113:9-19.
40. MacDermid J, Solomon P, Prkachin K. The shoulder pain and disability index demonstrates factor, construct and longitudinal validity. *BMC Musculoskelet Disord.* 2006;7:12.
41. Beaton DE, Richards RR. Measuring function of the shoulder. A cross-sectional comparison of five questionnaires. *J Bone Joint Surg.* 1996;78A:882-890.
42. Pallant J. *SPSS survival manual - a step by step guide to data analysis using SPSS*. 4 ed. Maidenhead: Open University Press; 2010.
43. Feleus A, van Dalen T, Bierma-Zeinstra SMA, et al. Kinesiophobia in patients with non-traumatic arm, neck and shoulder complaints: a prospective cohort study in general practice. *BMC Musculoskelet Disord.* 2007;8:117.
44. Croft PR, Pope DP, Silman AJ. The clinical course of shoulder pain: prospective cohort study in primary care. *BMJ.* September 7 1996;313:601-602.
45. Hoving JL, de Vet HCW, Twisk JWR, et al. Prognostic factors for neck pain in general practice. *Pain.* 2004;110:639-645.
46. van der Windt DAWM, Koes BW, Boeke AJP, Deville WLJM, de Jong BA, Bouter LM. Shoulder disorders in general pracitce: prognostic indicators for outcome. *Br J Gen Prac.* 1996;46:519-523.
47. De Bruijn C, de Bie R, Gereats J, et al. Effect of an education and activation programme on functional limitations and patient-perceived recovery in acute and sub-acute shoulder complaints – a randomised clinical trial. *BMC Musculoskelet Disord.* 2007;8.
48. Kuijpers T, van der Windt DAWM, Boeke AJP, et al. Clinical prediction rules for the prognosis of shoulder pain in general practice. *Pain.* 2006;120:276-285.
49. Miranda H, Viikari-Juntura E, Martikainen R, Takala E-P, Riihimäki H. A prospective study of work related factors and physical exercise as predictors of shoulder pain. *Occup Environ Med.* 2001;58:528-534.
50. Kröner-Herwig B, Gaßmann J, Tromsdorf M, Zahrend E. The effect of sex and gender role on responses to pressure pain. *Psychosoc Med.* 2012;9:Doc01.
51. Parr JJ, Borsa PA, Fillingim RB, et al. Pain-related fear and catastrophizing predict pain intensity and disability independently using an induced muscle injury model. *J Pain.* 2012;13:370-378.
52. Simon CB, Stryker SE, George SZ. Comparison of work-related fear-avoidance beliefs across different anatomical locations with musculoskeletal pain. *J Pain Res.* 2011;4:253-262.
53. George SZ, Hirsh AT. Psychologic influence on experimental pain sensitivity and clinical pain intensity for patients with shoulder pain. *J Pain.* 2009;10:293-299.
54. Smart KM, Blake C, Staines A, Doody C. The Discriminative validity of "nociceptive," "peripheral neuropathic," and "central sensitization" as mechanisms-based classifications of musculoskeletal pain. *Clin J Pain.* Oct 2011;27:655-663.
55. Smart KM, Blake C, Staines A, Doody C. Clinical indicators of 'nociceptive', 'peripheral neuropathic' and 'central' mechanisms of musculoskeletal pain. A Delphi survey of expert clinicians. *Man Ther.* Feb 2010;15:80-87.

56. Gifford L. Pain, the tissues and the nervous system: a conceptual model. *Physiotherapy.* 1998;84:27-36.
57. Jones MA, Rivett DA. *Clinical Reasoning for Manual Therapists*. Edinburgh: Elsevier Limited; 2004.
58. Butler DS, Moseley L. *Explain pain*. Adelaide: Noigroup Publications; 2003.
59. Maitland GD. *Manipulation der Wirbelsäule*. 2nd ed. Berlin: Springer Verlag; 1994.
60. Nijs J, Paul van Wilgen C, Van Oosterwijck J, van Ittersum M, Meeus M. How to explain central sensitization to patients with 'unexplained' chronic musculoskeletal pain: practice guidelines. *Man Ther.* Oct 2011;16:413-418.
61. Moseley GL. Evidence for a direct relationship between cognitive and physical change during an education intervention in people with chronic low back pain. *Eur J Pain.* 2004;8:39-45.
62. Moseley GL. Widespread brain activity during an abdominal task markedly reduced after pain physiology education: fMRI evaluation of a single patient with chronic low back pain. *Aust J Physiother.* 2005;51:49-52.

APPENDIX 1

Signs and symptoms defining the nociceptive pain pattern according to Smart et al. (2010)

- Clear, proportionate mechanical/anatomical nature to aggravating and easing factors.
- Pain associated with and in proportion to trauma or a pathological process (Inflammatory nociceptive) or movement/postural dysfunction (Ischaemic nociceptive).
- Pain localised to the area of injury/dysfunction (with/without some somatic referral).
- Usually rapidly resolving or resolving in accordance with expected tissue healing/pathology recovery times.
- Responsive to simple analgesia/NSAID's.
- Usually intermittent and sharp with movement/mechanical provocation; may be a more constant dull ache or throb at rest.
- Pain in association with other symptoms of inflammation (i.e. swelling, redness, heat) (Inflammatory nociceptive).
- Pain of recent onset.
- Clear, consistent and proportionate mechanical/anatomical pattern of pain reproduction on movement/mechanical testing of target tissues
- Localised pain on palpation
- Absence of or expected/proportionate findings of (primary and/or secondary) hyperalgesia and/or allodynia.
- Antalgic (i.e. pain relieving) postures/movement patterns.

Signs and symptoms defining the central sensitization pattern according to Smart et al[55]

- Disproportionate, non-mechanical, unpredictable pattern of pain provocation in response to multiple/non-specific aggravating/easing factors.
- Pain persisting beyond expected tissue healing/pathology recovery times.
- Pain disproportionate to the nature and extent of injury or pathology.
- Widespread, non-anatomical distribution of pain.
- History of failed interventions (medical/surgical/therapeutic).

- Strong association with maladaptive psychosocial factors (e.g. negative emotions, poor self-efficacy, maladaptive beliefs and pain behaviours, altered family/work/social life, medical conflict).
- Unresponsive to NSAID's and/or more responsive to anti-epileptic (e.g. Neurontin, Lyrica)/anti-depressant (e.g. Amitriptyline) medication.
- Reports of spontaneous (i.e. stimulus-independent) pain and/or paroxysmal pain (i.e. sudden recurrences and intensification of pain).
- Pain in association with high levels of functional disability.
- More constant/unremitting pain.
- Night pain/disturbed sleep.
- Pain in association with other dysesthesias (e.g. burning, coldness, crawling).
- Pain of high severity and irritability (i.e. easily provoked, taking a long time to settle).
- Disproportionate, inconsistent, non-mechanical/non-anatomical pattern of pain provocation in response to movement/mechanical testing.
- Positive findings of hyperalgesia (primary, secondary) and/or allodynia and/or hyperpathia within the distribution of pain.
- Diffuse/non-anatomic areas of pain/tenderness on palpation.
- Positive identification of various psychosocial factors (e.g. catastrophisation, fear-avoidance behaviour, distress).

CHAPTER 7
General discussion

The aim of primary care in the musculoskeletal domain is the rehabilitation and (if possible) primary, secondary or tertiary prevention of pain and functional disability due to injury, trauma or the consequences of aging to maintain employability, autonomy, independence, and quality of life as long as possible. Nearly 80% of all physiotherapeutic treatments in Germany, address musculoskeletal problems. Over 10% of all prescriptions ask for manual therapy as a specific intervention to restore musculoskeletal function (1). Exercises in general are one of the most common possibilities to improve physical fitness and performance in healthy and in disabled persons. Our study focused on the treatment of patients with shoulder impingement syndrome as the biggest subgroup of shoulder complaints, a not self-limiting and recurrent disease leading to pain, disability, reduction of participation, and of quality of life. The following chapter presents and discusses our main findings, the limitations, and implications for clinical practice and future research.

I. MAIN FINDINGS

Systematic review

To obtain an overview about current evidence for physiotherapy interventions in patients with shoulder impingement syndrome we conducted a systematic review of the literature. Our review identified only a few trials with sufficient quality investigating a great variety of different types of interventions. Nearly all authors measured either pain or functioning or both, some authors also used examination findings (as for example pain on isometric resistance) as outcome measures. However, many different measurement tools were used and hardly any author was interested in individual activity restrictions of the patient.

As a main result, our systematic review revealed strong evidence for an equal short and long term effect of exercise therapy and surgery. This was surprising for us but led us to the conclusion that patients with SIS should first and foremost be treated with exercises before undergoing surgery. This is supported by the fact, that exercise therapy is far less expensive and carries less risk for medical complications or adverse events. It further found moderate evidence for an additional effect of manual therapy on pain when added to an exercise program and for a similar effect of physiotherapy and exercises of which both seem to be more effective than no intervention. These conclusions seem to be still valid when looking at the current literature (2). Taking into account the low number of studies, the methodological flaws, short follow ups, and low sample sizes it becomes quite clear that this evidence is treading on thin ice and that there is a need for more high quality trials and longer follow up times. Another

important point that became clear from this review was the insufficient description of the applied interventions. In our opinion there is no better way to prevent a transfer from research into practice than to give insufficient instructions on the interventions applied.

However, besides our initial purpose of getting an overview about the evidence, these findings helped us in the planning stage of a randomized controlled trial on this topic.

Short term effects of manual physiotherapy (MPT) on pain and functioning in patients with shoulder impingement syndrome

The main question of this thesis was to investigate the effect of MPT when added to an exercise program. A prerequisite to obtain a valid result was that the patients of the control group do perform the same exercise protocol as the intervention group. On this basis the additional effect of manual physiotherapy could then be analyzed. The intervention had two parts: within the first 5 weeks both groups had ten contact sessions, two per week. During the following 7 weeks all participants continued their exercises at home. Our baseline data showed mean (SD) SPADI scores for the intervention and control group of 39.7 (17.2) and 41.3 (17.0) respectively. After 5 weeks the mean (SD) improvement for the total group was 14.9 (18.5) and after 12 weeks 22.7 (17.8). Therefore our power calculation turned out to be successful; together with a good adherence of therapists and participants to the protocol and small drop-out rate our study had sufficient power.

Patients in both groups improved significantly in pain and disability on all outcomes. During the first 5 weeks the mean improvement for all outcome measures was greater than the minimally clinically important difference (MCID) defined a priori still increasing up to the end of week 12. For example the absolute number of patients with a MCID in the total SPADI score after 5 weeks was 51 (56.7%) also increasing up to 66 (75%) at the end of the 12th week. Significant differences between groups were found for pain at 5 weeks but not for any other outcome measure. This minor difference got lost at 12 weeks. Because all outcomes were in slight advantage of the intervention group, MPT may have accelerated improvement during the first 5 weeks to a certain degree but made no significant difference. This effect continued only for total SPADI score up to week 12 but not for the other outcomes. The effect of MPT on pain after 5 weeks corresponds very well with the conclusion of our systematic review. However, the effect was minor and did not sustain until the end of the intervention phase and did not lead to a difference between the groups in scoring their personal impression of

change ("Slightly and Much better") on the PGIC-scale, although a tendency towards the intervention group could be seen (RR (CI95%) = 1.06 (0.93 to 1.27)).

The initial concern that patients assigned to the control group could perhaps be dissatisfied because of an expectation to receive at least some kind of passive treatment was proven to be redundant since both groups were very well satisfied with treatment. Again a tendency towards the intervention group was seen but the difference was also not significant (RR (CI95%) = 1.16 (0.95 to 1.42)).

In order to understand why MPT had no greater effect on group differences we adjusted results for identified baseline differences and co-interventions, which led to a decrease in p-value but did not change result to a significant level.

Clinical examination results at baseline – indications for manual therapy?

The missing effect of MPT is even more surprising when looking at some of the clinical examination findings during baseline assessment. Besides the positive impingement signs which were part of our inclusion criteria, physical examination revealed typical indications for MPT. More than 80% of all patients had restriction of translational movements at the glenohumeral joint, over 50% had comparable signs of the cervical spine and about 24% to 30% had minor restrictions in elevation or external rotation (table 7.1). One would expect that if these components contribute to the patients' complaints that the possibility to address these factors with specific treatment techniques is a clear advantage for the intervention group resulting in better outcome results. Even if the additional treatment in itself had no considerable effect one can argue that the more individualized instructions, the more intensive physical contact, and the longer contact time in the beginning is in favor of the intervention group, but also these factors did not lead to a significant difference between groups.

Summarizing these results we conclude that a well-designed exercise program is an appropriate treatment for patients with SIS leading to clinically important improvements in pain and functioning and high patient satisfaction. MPT cannot be recommended as a standard intervention. Eligibility criteria defined for inclusion seem to be sufficient to define the clinical pattern with no need for additional information from specific manual testing, because addressing these findings did not influence outcome in the short term.

Table 7.1 Positive clinical test results at baseline

Clinical tests (positive results)	Intervention (n=46)	Control (n=44)	Total group (n=90)
	n (%)	*n* (%)	*n* (%)
Painful arc	44 (95.7)	43 (97.7)	87 (96.7)
Hawkins-Kennedy test	34 (73.9)	33 (75.0)	67 (74.4)
Neer compression test	38 (82.6)	42 (95.5)	80 (88.9)
ER lag sign	0 (0.0)	1 (2.3)	1 (1.1)
Lift off test	0 (0.0)	1 (2.3)	1 (1.1)
Hornblower's sign	0 (0.0)	0 (0.0)	0 (0.0)
Restriction of caudal glide	39 (84.8)	38 (86.4)	77 (85.6)
Restriction of posterior glide	35 (76.1)	38 (86.4)	73 (81.1)
Restriction of passive elevation (up to 20°)	14 (30.4)	14 (31.8)	28 (31.1)
Restriction of passive ER (up to 15°)	11 (23.9)	13 (29.5)	24 (26.7)
Comparable signs of the cervical spine	27 (58.7)	23 (52.3)	50 (55.6)

ER: external rotation

Long term effects of manual physiotherapy on pain and functioning in patients with shoulder impingement syndrome

After the analysis of our short term results we were curious to see the one year results, because at that point in time no information existed about the long term effect of the tested interventions. Therefore, these results were of particular interest and certainly one of the most important findings of this thesis.

After one year data were available for 96.7% (n=87) of all initially included patients. During follow up further significant improvements were seen in the control group whereas the intervention group remained more or less the same (figure 7.1). Despite this development no significant differences could be detected between the groups, although there was now a positive tendency in favor of the control group.

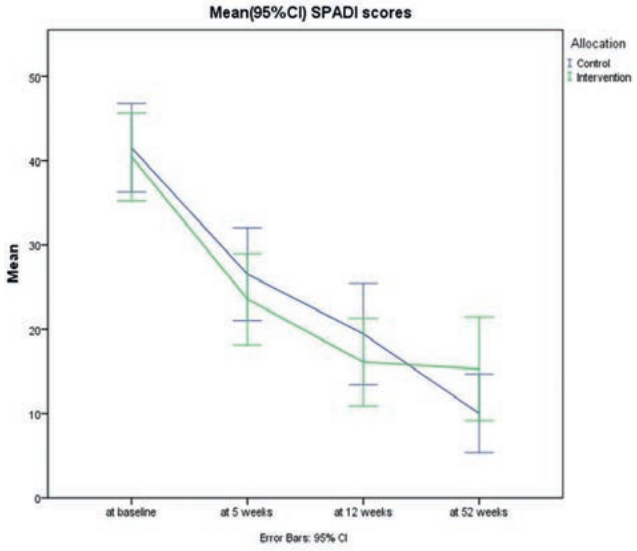


Figure 7.1 Mean (CI95%) SPADI scores

Based on this unexpected improvement of the control group between the end of week 12 (after the cessation of the intervention) and the last measurement point at one year we would suggest to wait with further treatments in patients who do not show a satisfactory result after the intervention phase and monitor their development over a few months. This is of particular importance because "failed physiotherapy" is often used as an indication for surgery. This continuous improvement is supported by the subjective impression of the participants themselves. Our data show that although the absolute number of patients who rated their improvement as "Slightly or Much better", stayed nearly unchanged compared to the 12 weeks results (92.1% and 90.8% respectively), the number of patients who rated their change as "Much better" increased from 56.8% at twelve weeks to 77% at one year respectively. Looking at the overall development over time we possibly could expect a further improvement of the control group which would then be indicative that MPT is a sort of contraindication in patients with SIS.

Cost differences between the intervention and the control group.

Besides the effect of the applied interventions we also analyzed direct (health care) and indirect (non-health care) costs. Nowadays, costs have an increasing influence on the decision made by health insurance companies and patients for or against an offered treatment, particularly if different interventions do show similar effects.

A significant difference in direct costs was noted between groups at 5 weeks in favor of the control group with a mean difference of about 24€ per patient. This difference was mainly based on different costs for the different prescriptions needed for treatment ("Manual Therapy" for the intervention group and "Physiotherapy" for the control group). All other comparisons at any follow up point were statistically insignificant. Indirect mean costs incurring for sick leave and paid help did not significantly differ between groups at any follow up point. However, after one year overall indirect costs were excessively higher in the control group (16714€) than in the intervention group (4363€). Appraising overall costs together with the effect of the two interventions over a one year time frame, the treatment protocol applied to the intervention group could be favored; because of the huge difference in overall indirect costs the significant but small absolute difference in direct costs could easily be accepted.

Influence of psychological factors on pain and disability scores at the time of inclusion

In patients with low back, pain and disability levels are negatively influenced by the patients' perspective on his situation, which is mainly determined by the patients' beliefs and attitudes. Especially the influence of fear avoidance beliefs (FAB) and catastrophizing, depicted in the so called fear avoidance model (FAM), seem to play an important role in the development of chronic low back pain and disability. Because little is known about the influence of these factors on patients with SIS we analyzed their influence on pain and disability in our sample at the time of inclusion with a hierarchical regression analysis, which resulted in a few interesting findings.

Firstly, FAB and catastrophizing contributed significantly to baseline pain and disability scores. However, in contrast to the consecutive sequence described in the FAM their influence was independent from each other.

Secondly, patients of our study group still presented a dominantly nociceptive and therefore tissue based pattern, despite a mean (SD) symptom duration of 104.8 (152.6) weeks. This statement can be made because of the eligibility criteria set for the trial, small numbers of sick days, low ratings on the FABQ-PA, the PCS, relatively high activity levels, pain provocation clearly connected to specific activities, and last but not least by the significant improvement our patients in the RCT (the interventions clearly targeted physical aspects of the problem). A dominantly tissue based problem is further supported by the results of our regression analysis revealing a greater influence of pain intensity on disability and of disability on pain intensity than of the psychological factors. If we would have assigned our patients to an acute or chronic group only based on the often used criterion "time" (duration of symptoms) and a cut off at 3

months, about 81% of our sample would have been labelled “chronic”. With a 6 months cut off, still about 60% would have been assigned to the chronic group. For me this clearly implies that the factor “time”, as a standalone criterion to determine acute, sub-acute, or chronic pain states, is insufficient and can only be interpreted together with other clinical signs and symptoms. Otherwise conclusions for treatment may be misleading and thus ineffective.

Thirdly and based on our second point, we identified FAB and catastrophizing as parts of a nociceptive pattern. Both factors are often viewed as typical aspects of centrally sensitized and therefore chronic presentations. From my clinical experience this is not surprising but it emphasizes the need to address these cognitive/affective components in patients with SIS (and maybe other pathologies with a nociceptive character) because they significantly contributed to pain and disability in this group.

Summarizing these findings the following statements can be made:

1. SIS patients experience the different constructs included in the FAM not in a consecutive order, therefore this model cannot be transferred to patients with SIS.
2. Patients with SIS seem to present a dominantly nociceptive, tissue based pattern, even after a longer period of complaints.
3. FAB and catastrophizing are significantly influencing pain and disability levels and are therefore part of the clinical pattern.
4. It is worth considering these factors during the assessment and treatment of these patients.

II. METHODOLOGICAL CONSIDERATIONS

Systematic review: Eligibility criteria for study selection

As a startup for this thesis we conducted a systematic review to get a comprehensive overview about current evidence of physiotherapy interventions in patients with subacromial impingement syndrome.

Studies were included if study participants had the diagnosis SIS, whether primary or secondary. We also included studies when participants had a structural diagnosis such as rotator cuff tendinitis, supraspinatus tendinitis, or subacromial bursitis, because these structures are closely connected to SIS (3) and likely to cause typical symptoms of subacromial impingement (4). Therefore, these patients had to show at least one of the following signs typical for SIS: pain with overhead activities, painful arc sign, Neer impingement sign, or a positive Hawkins-Kennedy sign. Studies investigating participants with frozen shoulder, osteoarthritis, fractures, systemic diseases, neo-

plasm or metastasis, or professional athletes were excluded. Finally 16 studies fulfilled our quality and eligibility criteria and were included in this review.

Table 7.2a Categorized inclusion criteria in order of their frequency

Categories	Studies (*n*=)
Painful arc	10
Pain with active movements	9
Pain on resisted movements	7
Pain area	5
Full passive shoulder ROM	5
Specific impingement signs	4
Combination of tests	4
Neer impingement test	4
Pain with palpation	3
Duration of symptoms	3
Age	2
Imaging/technical assessment	2
Clinical examination	2
Diagnostic ACJ injection	1
Failed previous treatment	1

ROM: range of motion; ACJ: acromioclavicular joint

Table 7.2b Categorized exclusion criteria in order of their frequency

Categories	Studies (*n*=)
Frozen shoulder	8
Rotator cuff tear	8
Cervical pain/radiculopathy	7
(Other) Neurological conditions	6
ACJ involvement	5
Traumatic lesions / fractures /previous surgery	5
Previous treatment (physiotherapy, injection)	5
Glenohumeral instability	4
Systemic disease	4
Degenerative signs of the GHJ	4
Compensation claims	3
Calcifying tendinitis	3
(Acute) bursitis	2
Other musculoskeletal disorders	2
Pregnancy	1
Primary scapulothoracic dysfunction	1
Biceps tendinitis	1
Insufficient language skills	1

ACJ: acromioclavicular joint; GHJ: glenohumeral joint

Analyzing the eligibility criteria used in in these studies we identified more than thirty different inclusion criteria and more than forty different exclusion criteria across all studies. This was partly due to different names used for the same criteria as for example “frozen shoulder” or “adhesive capsulitis”, “rotator cuff tear” or “stage III impingement”. After categorizing similar criteria and assigning umbrella terms to these categories still about 15 inclusion and 18 exclusion criteria remained, displayed in table 7.2a,b. One can doubt whether all criteria summarized for example under the umbrella term “cervical involvement” (table 7.3) do reflect the same thing. Some criteria were handled conflicting as for example some studies excluded patients who had previously been treated, in another study previous treatment was used as an inclusion criterion. Further, important exclusion criteria such as systemic disease, primary scapulothoracic dysfunction, or insufficient language skills were not addressed in most cases. Altogether, eligibility criteria were diverse which questions whether the samples investigated in

the included studies represent the same population of interest. However, some of these criteria were frequently (painful arc, pain with active movements or on resistance, pain area, pain free passive range of motion and clinical impingement signs) seem to be, together with the exclusion criteria, the most important to define SIS and to distinguish it from other pathologies.

Table 7.3 Example for categorized inclusion criteria

Given umbrella term	Identified criteria from included RCT's
Cervical involvement	• severe neck pain • cervical pain • cervical syndrome • peri-scapular pain • cervical radiculopathy • shoulder symptoms reproduced by cervical assessment • peri-scapular or cervical pain during arm elevation

RCT: randomized controlled trial

Systematic review: Quality assessment of eligible studies

Quality of results from systematic reviews is inevitably dependent on quality of included studies; to increase the chance for good quality results it is therefore important to limit bias.

Thus we included only randomized controlled trials (RCT's) of sufficient quality in our review. RCT's carry a low risk for bias, do rank high in the hierarchy of evidence (5, 6), and were most qualified to answer our research question. Quality of included studies was appraised with the PEDro tool, designed to critically appraise experimental studies in physiotherapy (7). PEDro is a reliable tool (8) containing ten criteria mainly focusing on the internal validity of a study; from these criteria an average score is calculated. The PEDro tool addresses important aspects such as concealment of allocation (selection bias), blinding of therapists and patients (performance bias), drop-out rates (attrition bias), and blinding of assessors (detection bias). Although results from systematic reviews can also be limited by other aspects such as differences in content or frequency of treatments, different follow up times, missing power calculations or insufficient intervention descriptions, which are not necessarily relevant for the internal validity of a study, a good internal validity is an essential prerequisite to draw reliable conclusions for clinical practice (for its generalizability). The average quality score of included studies in our review was 6.8/10. However, in 12 studies allocation was not concealed, therapists were not blinded in 12 and patients in 10 studies which increased the risk of selection and performance bias in these studies.

There is an ongoing discussion about the best way to critically appraise the literature and the question is not answered yet. Katrak et al. (9) identified 45 different appraisal tools for experimental studies. Only very few of them were tested for their psychometric properties. Arguments for choosing the PEDro tool were its good reliability, that it was designed for the use in allied health research and frequently used in other systematic reviews.

As long as there is no perfect tool for the quality assessment of RCT's we think that being aware of the problems that may occur with different types of measurement tools, and in this case when using a summary score, helps to consider these flaws when interpreting results and hence to draw reasonable, and in consequence more conservative conclusions in most of the cases.

Randomized controlled trial: Defining the population of interest – function-based (clinically reasoned) versus structure-based (biomedical) diagnosis

As already outlined in the introduction of this thesis, establishing a diagnosis in the physiotherapeutic context is mainly based on clinical information gained from the patients' history and physical examination than on a specific structure or tissue affected. This clinical pattern defined through the clinical findings determines the focus of treatment (10). Using such an approach is practical because patients with shoulder complaints are often referred to physiotherapists on the basis of a pure clinically established diagnosis; technical methods of examination as for example MRI or ultrasonography are often not available or used in first instance (11). Therefore we believe that using clinical findings as eligibility criteria would very well reflect clinical practice. Based on literature (12-21) we then defined in- and exclusion criteria for the RCT which are displayed in table 7.4.

However, using this approach made us unable to assess several criteria that may contribute to SIS or are predictive for a poor outcome with conservative treatment such as primary impingement due to structural changes in the subacromial space (e.g. osteophytes, bone spurs or ACJ osteoarthritis), or the shape of the acromion (17). With a mean age of 51.8 (11.2) years one could expect at least some patients to have such degenerative changes. On the one hand this may have impeded the ability to adapt treatment or even eligibility criteria accordingly and thus decreased the effect of our interventions, on the other hand our positive study results do suggest, that these factor had little influence on outcome.

Table 7.4 Eligibility criteria defined for RCT

Inclusion criteria	Exclusion criteria
1. Age between 18 and 75 years 2. Symptoms for more than four weeks 3. Main complaints in the glenohumeral joint region or the proximal arm 4. Presence of one of the following signs indicating SIS: Neer impingement test, Hawkins-Kennedy impingement test, painful arc with active abduction or flexion 5. Pain with one of the following resistance tests: external rotation, internal rotation, abduction, or flexion.	1. Average 24-hours pain of 8/10 or more on a visual numeric rating scale (VNRS) 2. Primary scapulothoracic dysfunction due to paresis 3. Diagnosed instability or previous history of dislocation 4. Adhesive capsulitis (frozen shoulder) 5. More than 1/3 restriction of elevation compared to the unaffected side 6. Substantial shoulder weakness or loss of active shoulder function 7. Shoulder surgery in the last 12 months on the involved side 8. Reproduction of symptoms with active or passive cervical movements 9. Neurological involvement with sensory and muscular deficit 10. Inflammatory joint disease (e.g. rheumatoid arthritis) 11. Diabetes mellitus 12. Intake of psychotherapeutic drugs 13. Compensation claims 14. Inability to understand written or spoken German.

Because of its importance for shoulder function we assessed the integrity of the rotator cuff with the lift off test (22), the external rotation lag sign (23), and the hornblowers' sign (24), which are three commonly used rotator cuff tests. The risk of having a partial or complete rotator cuff tears seems to increase progressively from the age of about 49, but existing tears are not necessarily connected with clinical symptoms of pain or restricted physical function (25). However, impingement symptoms are closely linked to (partial) rotator cuff tears (3) (table 7.5). Therefore it was surprising that only two patients were tested positive, one with a positive lag sign and another with a positive lift off test. As a consequence one might either doubt the usefulness of these tests or the usefulness of the classification system proposed by Neer (3) in our patient group. We further think that knowledge about the most often impaired activities summarized in table 7.6, which we identified through the Generic Patient Specific Scale (GPSS), may also contribute to a completion of the clinical pattern "subacromial impingement syndrome".

Table 7.5 Staging of impingement lesions according to Neer (1983)

	Stage	Typical age
I	Edema and hemorrhage of the rotator cuff	< 25
II	Fibrosis and tendinitis of the rotator cuff	25-40
III	Partial or complete tears of the rotator cuff, biceps ruptures, and bone changes	> 40

Table 7.6 Most often impaired activities from the GPSS (*n*=90)

Activity	Frequency
Activities in an upward direction	89
Reaching overhead / upwards	18
Working overhead	19
Lifting above shoulder height	17
Drying / combing or washing hair	11
Getting something down from a cupboard	9
Holding something in front of the body	15
Lying on the affected shoulder	33
Sports activities	24
Playing tennis	2
Swimming	2
Fitness training	4
Other	16
Getting dressed	23
Putting on a jacket	6
Pushing forward with the affected arm	21
Cleaning windows	7
Housework	16
Activities with hand behind back	16
Steering a car	12
Carrying	10
Computer work (with/without a mouse)	10
Body care	5
Leaning on/Stemming	5
To buckle up in the car	3
Other	3
Total	270

Randomized controlled trial: Blinding

Blinding of patients, therapists and assessors to the treatment received or applied reduces their influence on outcomes and outcome measures and helps to ensure an equal distribution of attention, co-interventions or additional diagnostics between groups. Blinding seems to be of particular importance in the assessment of subjective outcome measures (26). Due to the nature of most physiotherapeutic interventions, blinding subjects and therapists is often a problem in physiotherapy trials.

In our study we only used outcome measures where patients also acted as assessors. Together with the nature of our intervention it was therefore not possible for us to blind either therapists nor patients and thus assessors. We encountered this by blinding therapists of the control group to assessment and clinical examination results and we kept patients naive to group allocation.

Randomized controlled trial: Design and effect of manual physiotherapy (MPT)

With the design of our MPT intervention we tried to live up to recent developments in manual therapy. Therefore, we tried to build up a patient-centered model including the most important forms of the clinical reasoning process such as diagnostic reasoning (pattern recognition, understanding of the patients' problem, identification of the patients' restrictions/abilities according to the ICF), procedural reasoning (basically reflecting the process displayed in figure 1.1), and interactive/collaborative reasoning (relationship and interaction between patient and therapist, shared decision making) (27, 28). To guarantee a uniform application to every patient and thus reproducibility of MPT we standardized initial clinical examination and the consequences to be drawn from it (general introduction, figure 1.2) as well as a test-retest-procedure to assist further decision making. We also standardized number, frequency, and duration of treatment sessions as well as the overall duration of the intervention.

However, standardization seems to be at least to some degree restrictive to a patient centered approach. At this point we saw ourselves confronted with the difficulty of reproducing the complexity of an individualized examination and treatment process without having too much variance in the process itself. Especially in a research design that tries to control for possible influencing factors besides the planned intervention. Within this context the general question appears whether or not a RCT design is sufficient to investigate such complex interventions often used in physiotherapy.

Standardization itself but also the complexity of the intervention might have reduced the effect of MPT. Although research therapists were experienced and well trained, we had to extend contact times during the first few visits to guarantee a sufficient application of the planned intervention.

Another important point that might explain the lack of effect of MPT was the exercise program we used as the basic intervention in both groups. It was designed to restore muscular deficits in strength, mobility, or coordination of the rotator cuff and the shoulder girdle, to unload the subacromial space, and improve centering of the humeral head in the glenoid fossa during active movements. To achieve this aim, exercise were selected from papers investigating exercises for shoulder rehabilitation (29-46), and exercises specifically addressing muscular deficits in patients with SIS (47-53). Further selection of exercises was determined by their practicability, their potential for pain provocation, and the possibility to perform these exercises at home. Patients were supervised during their contact sessions and parameters such as resistance, number of repetitions or sets, and range of movement could be adapted to the patients' momentary situation. This adaptation was guided by a standardized reassessment of the patients' reaction to the program (figure 7.2) leading also to an adapted continuous progression of the program. Thus the program was to a certain degree "individualized".

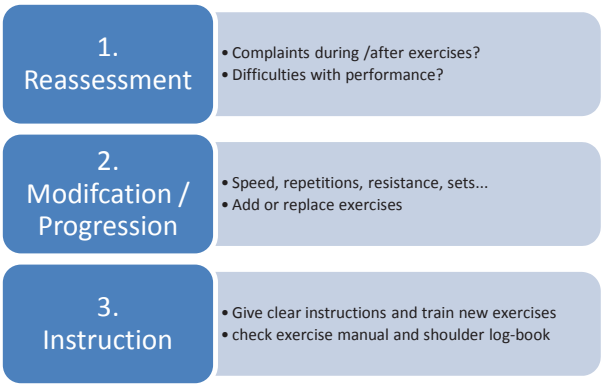


Figure 7.2 Course of a supervised exercise session

Comparing our program to exercise programs used in other studies on the same topic we think that design and application of our program was much more qualified to reach maximum effect and hence may not have left enough space for MPT to add a significant effect to it. After having analyzed our short term results we now question the conclusion about the additional effect of manual therapy in our systematic review which in our opinion was only possible because of the insufficient exercise regimen used in the included studies. Our results suggest that exercises alone are an effective treatment for this patient group showing continuous improvement up to one year.

Influence of fear avoidance beliefs on pain and disability at the time of inclusion

At the moment little is known about the importance of these factors in patients with SIS. The assumption that pain and disability are caused by musculoskeletal disorders consists of two parts, namely organic and non-organic factors. We therefore analyzed the contribution of fear avoidance beliefs and catastrophizing to pain and disability in our patient group at the time of inclusion. We further interpreted our findings against the background of pain mechanisms. Despite the fact that both psychological factors contributed significantly to disability and pain levels, clinical factors such as disability or pain were still stronger contributors indicating that SIS, even if long lasting or episodic, is a dominantly mechanical and nociceptive driven event.

However, although MPT treatment incorporated aspects like individually adapted patient education, information giving, partly addressing these factors this had no significant influence on group differences.

Unfortunately we did not reassess these factors so we were not able to analyse their development with treatment over time and a possible association between them and outcomes for pain and disability.

III. IMPLICATIONS FOR FURTHER RESEARCH

From the systematic review, the randomized controlled trial and the analysis done on the psychological factors the following implications for further research can be summarized:

i. Because physiotherapy interventions are often complex in their composition a detailed description of examination and treatment modalities should be provided together with the publication of the results. Furthermore the underlying decision making process and criteria on how these modalities are applied should be clearly defined. This would help to transfer research results into clinical practice.
ii. To reflect clinical practice and to define the population seen in primary care, eligibility criteria for studies investigating physiotherapeutic interventions should be based on a functional diagnosis (clinical pattern) instead on a structural based diagnosis.
iii. A standard set of shoulder specific outcome measures for pain and activity/participation restrictions should be defined and an agreement about the measurement points should be reached to facilitate comparability of study results and pooling of data.
iv. In clinical trials investigating the effect of different physiotherapy interventions, potential prognostic factors need to be analyzed to clarify their contribution to baseline scores and treatment effects. Two of these, namely fear avoidance beliefs

and catastrophizing, should be standardly assessed in future studies on shoulder impingement syndrome as they seem to have a significant influence on pain and disability levels. Because little is known about their development over time or about their influence on treatment outcome we further suggest to prospectively investigating their influence on these outcomes.

v. Regarding the exercise program used in the randomized controlled trial further research is needed to confirm its effect, to investigate how the program can be improved, how the distribution of contact sessions over time can be optimized, or to what degree contact sessions can be reduced without losing effect.

vi. Our interventions had a significant effect on outcome in our sample. However, there are long term results from other studies comparing exercises to other treatments such as surgery, shock-wave therapy, or steroid injections that found no significant differences, even if short term results favored exercises. An interesting question to answer with further research is the one about the mechanism shared by all these interventions leading to a similar improvement over time.

IV. EXTERNAL GENERALIZABILITY AND IMPLICATIONS FOR CLINICAL PRACTICE

Results presented in this thesis are mainly derived from our randomized controlled trial investigating the effect of physiotherapy in patients with SIS. Besides a sound statistical analysis study results are based on good study power and a nearly complete data set. The population as well as all interventions and effect measures are described in detail and thus can easily be reproduced. From the results of this thesis we can therefore derive some interesting and strong implications for clinical practice.

First, manual physiotherapy (MPT) had only a minor effect on pain intensity after five weeks when added to an exercise program. This effect was already lost after 3 months with no difference between groups after 3 or 12 months. Therefore MPT cannot be recommended as an additional treatment to exercises in patients with SIS.

Second, the supervised exercise program used in our RCT can be recommended as a sufficient treatment for SIS as it resulted in significant and clinically important improvements in pain and functioning in our sample.

Third, a progressive improvement of pain and functioning over time could be detected after the intervention has ceased. Thus we recommend that patients should be observed for a certain time period after the physiotherapy intervention before another treatment is tested out.

Fourth, the third statement is of particular importance in patients not showing an immediate effect after the intervention because this is often interpreted as “failed physiotherapy” and used as an indication for immediate surgery. Although this was

indeed one of the conclusions drawn from our systematic review we now think that it is reasonable to wait with surgery for about three to six months and to monitor the development of these patients before schedule them for surgery.

Fifth, we encourage clinicians to pay more attention on psychological factors such as fear avoidance beliefs or catastrophizing as they seem to contribute significantly to the clinical presentation of SIS even if their final role is not clear yet. This will lead to more insight into and clinical experience with these factors and from there useful research questions can be formulated.

V. PERSONAL VIEW AND FINAL CONCLUSION

To our knowledge this thesis delivers the first results about the long term effect of physiotherapy in patients with subacromial impingement syndrome and gives a first insight into the role of fear avoidance beliefs and catastrophizing in this patient group. We finally conclude that exercises can be recommended as a first line treatment. Manual physiotherapy did not contribute significantly to the treatment effect and can therefore not be recommended. In case of an insufficient improvement at the end of the intervention period we recommend to monitor a patients' development for about three to six months before another treatment is started. Although further research is necessary to confirm these conclusions we welcome these results because a specific qualification in manual therapy is not needed and hence the described exercise program can be easily applied by most physiotherapists working in the musculoskeletal field. This increases the generalizability of our results and may at the same time decrease costs for their implementation. Further research is also necessary to evaluate whether addressing psychological factors would further improve the effect of the exercises.

REFERENCES

1. Walterbacher A. Heilmittelbericht 2012. Berlin: Wissenschaftliches Institut der AOK (WIdO); 2012.
2. Braun C, Bularczyk M, Heintsch J, Hanchard NCA. Manual therapy and exercises for shoulder impingement revisited: a systematic review update. Physical Therapy Reviews 2013; in press.
3. Neer CS. Impingement lesions. Clin Orthop 1983; 173: 70-77.
4. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy 2001; 87: 458-469.
5. Straus SE, Jansen Howerton L, Richardson WS, Brian Haynes R. Evidence-Based Medicine: How to Practice and Teach it. 4th ed. London: Churchill Livingstone; 2011.
6. CEBM. Levels of Evidence Working Group - The Oxford 2011 Levels of Evidence. Oxford Centre for Evidence-Based Medicine; 2011 [cited 2013 8 August]; Available from: http://www.cebm.net/-mod_product/design/files/CEBM-Levels-of-Evidence-2.1.pdf.

7. CEBP. PEDro scale. Missenden: Centre for Evidence -Based Physiotherapy; 2013 [cited 2013 8 August]; Available from: http://www.pedro.org.au/english/downloads/pedro-scale/.
8. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther 2003; 83: 713-721.
9. Katrak P, Bialocerkowski AE, Massy-Westropp N, Kumar SVS, Grimmer KA. A systematic review of the content of critical appraisal tools. BMC Medical Research Methodology 2004; 4: http://www.biomed-central.com/1471-2288/1474/1422.
10. Burnett J, Grimmer K, Saravana K. Development of a generic dritical appraisal tool by consensus: presentation of first round Delphy survey results. Internet Journal of Allied Health Sciences and Practice 2005; 3.
11. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence ad incidence of adults consulting for shoulder conditions in UK primary care: patterns of diagnosis and referral. Rheumathology 2006; 45: 215-221.
12. Brox JI. Shoulder pain. Best Practice & Research Clinical Rheumatology 2003; 17: 33-56.
13. Irlenbusch U, Nitsch S, Uhlemann C, Venbrocks R. Der Schulterschmerz. Stuttgart: Thieme Verlag; 2000.
14. Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CHG. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. Journal of Rehabilitation Medicine 2009; 41: 470-480.
15. Lewis JS, Wright C, Green A. Subacromial impingement Syndrome: the effect of changing posture on shoulder range of motion. J Orthop Sports Phys Ther 2005; 35: 72-87.
16. Mantone J, K., Burkhead WZ, Noonan J. Nonoperative treatment of rotator cuff tears. Orthop Clin North Am 2000; 31: 295-311.
17. Morrison DS, Frogameni AD, Woodworth P. Non-operative treatment of subacromial impingement syndrome. J Bone Joint Surg Am 1997; 79-A: 732-737.
18. Peters G, Kohn D. Medium-term clinical results after operative and non-operative treatment of subacromial impingement (German). Der Unfallchirurg 1997; 100: 623-629.
19. Rahme H, Solem-Bertoft E, Westerberg C-E, Lundberg E, Sörensen S, Hilding S. The subacromial impingement syndrome. Scand J Rehabil Med 1998; 30: 253-262.
20. Wülker N, Vocke AK. Subacromial disorders. In: Wülker N, Mansat M, Fu FH, editors. Shoulder Surgery. London: Martin Dunitz Ltd; 2001. p. 143-169.
21. Wurnig C. Impingement. Orthopade 2000; 29: 868-880.
22. Gerber C, Krushell RJ. Isolated rupture of the tendon of the subscapularis muscle. Journal of Bone and Joint Surgery 1991; 73B.
23. Hertel R, Ballmer FT, Lombert SM, Gerber C. Lag signs in the diagnosis of rotator cuff rupture. J Shoulder Elbow Surg 1996; 5: 307-313.
24. Walch G, Boulahia A, Calderone S, Robinson AHN. The 'dropping' and 'hornblower's' signs in evaluation of rotator-cuff tears. Journal of Bone and Joint Surgery Br 1998; 80: 624-628.
25. Yamaguchi K, Ditsios K, Middleton WD, Hildebolt CF, Galatz LM, Teefey SA. The demographic and morphological features of rotator cuff disease.a comparison of asymptomatic and symptomatic shoulders. J Bone Joint Surg Am 2006; 88A: 1699-1704.
26. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions 4.2.6, updated September 2006 In: The Cochrane Library, Issue 4, 2006 Chichester, UK: The Cochrane Collaboration; 2006.
27. Jones MA, Rivett DA. Clinical Reasoning for Manual Therapists. Edinburgh: Elsevier Limited; 2004.
28. Edwards I, Jones M. Clinical Reasoning in three different fields of physiotherapy – A qualitative study. Fifth International Congress, Australian Physiotherapy Association; Melbourne1998.
29. Hintermeister RA, Lange GW, Schultheis JM, Bey MJ, Hawkins RJ. Electromyographic activity and applied load during shoulder rehabilitation exercises using elastic resistance. The American Journal of Sports Medicine 1998; 26: 210-220.

30. Decker MJ, Hintermeister RA, Faber KJ, Hawkins RJ. Serratus anterior muscle activity during selected rehabilitation exercises. The American Journal of Sports Medicine 1999; 27: 784-791.
31. Alpert SW, Pink MM, Jobe FW, McMahon PJ, Mathiyakom W. Electromyographic analysis of deltoid and rotator cuff function under varying loads and speeds. J Shoulder Elbow Surg 2000; 9: 47-58.
32. Jenp Y-N, Malanga GA, Growney ES, An K-N. Activation of the rotator cuff in generating isometric shoulder rotation torque. The American Journal of Sports Medicine 1996; 24: 477-485.
33. Kelly BT, Kadrmas WR, Speer KP. The manual muscle examination for rotator cuff strength. The American Journal of Sports Medicine [An electromyographic investigation] 1996; 24: 581-587.
34. Kronberg M, Broström L-A. Electromyographic recordings in shoulder muscles during eccentric movements. Clin Orthop 1995; 314: 143-151.
35. Lear LJ, Gross MT. An electromyographical analysis of the scapular stabilizing synergists during a push up progression. J Orthop Sports Phys Ther 1998; 28: 146-157.
36. Levy AS, Kelly BT, Lintner SA, Osbahr DC, Speer KP. Function of the long head of the biceps at the shoulder: Electromyographic analysis. J Shoulder Elbow Surg 2001; 10: 250-255.
37. Swanik KA, Lephart SM, Swanik B, Lephart SP, Stone DA, Fu FH. The effects of shoulder plyometric training on proprioception and selected muscle performance characteristics. J Shoulder Elbow Surg 2002; 11: 579-586.
38. Reinold MM, Wilk KE, Fleisig GS, Zheng N, Barrentine SW, Chmielewski T, et al. Electromyographic analyses of the rotator cuff and deltoid musculature during common shoulder external rotation exercises. J Orthop Sports Phys Ther 2004; 34: 385-394.
39. Uhl TL, Carver TJ, Mattacola CG, Mair SD, Nitz, J. A. Shoulder musculature activation during upper extremity weight bearing exercise. J Orthop Sports Phys Ther 2003; 33: 109-117.
40. Moseley BJ, Jobe FW, Pink MM, Perry J, Tibone J. EMG analysis of the scapular muscles during a shoulder rehabilitation program. Am J Sports Med 1992; 20: 128-134.
41. Lintner D, Mayol M, Uzodinma O, Jones R, Labossiere D. Glenohumeral Internal Rotation Deficits in Professional Pitchers Enrolled in an Internal Rotation Stretching Program. Am J Sports Med 2007; 35: 617-621.
42. Reinold MM, Escamilla R, Wilk KE. Current concepts in the scientific and clinical rationale behind exercises for glenohumeral and scapulothoracic musculature. J Orthop Sports Phys Ther 2009; 39: 106-117.
43. Reinold MM, Macrina LC, Wilk KE, Fleisig GS, Dun S, Barrentine SW, et al. Electromyographic analysis of the supraspinatus and deltoid muscles during 3 common rehabilitation exercises. Journal of Athletic Training 2007; 42: 464-469.
44. Townsend H, Jobe FW, Pink M, Perry J. Electromyographic analysis of the glenohumeral muscles during a baseball rehabilitation program. The American Journal of Sports Medicine 1991; 19: 264-272.
45. McClure P, Balaicuis J, Heiland D, Broersmsma ME, Thorndike CK, Wood A. A randomized controlled comparison of stretching procedures for posterior shoulder tightness. J Orthop Sports Phys Ther 2007; 37: 108-113.
46. Cools AM, Dewitte V, Lanszweert F, Notebaert D, Roets A, Soetens B, et al. Rehabilitation of scapular mucle balance: which exercises to prescribe? Am J Sports Med 2007; 35: 1744-1750.
47. Ludewig PM, Cook TM. Alterations in shoulder kinematics and associated muscle activity in people with symptoms of shoulder impingement. Phys Ther 2000; 80: 276-291.
48. Leroux J-L, Codine P, Thomas E, Pocholle M, Mailhe D, Blotman F. Isokinetic evaluation of rotational strength in normal shoulders and shoulders with impingement syndrome. Clinical Orthopaedics and Related Research 1994; 304: 108-115.
49. Reddy AS, Mohr KJ, Pink MM, Jobe FW. Electromyographic analysis of the deltoid and rotator cuff muscles in persons with subacromial impingement syndrome. J Shoulder Elbow Surg 2000; 9: 519-523.
50. Tyler TF, Nicholas SJ, Roy T, Gleim GW. Quantification of posterior capsule tightness and motion loss in patients with shoulder impingement. Am J Sports Med 2000; 28: 668-673.

51. Warner JJP, Micheli LJ, Arslanian LE, Kennedy J, Kennedy R. Pattern of flexibility, laxity, and strength in normal shoulders and shoulders with instabilityand impingement. American Journal of Sports Medicine 1990; 18: 366-375.
52. Cools AM, Witvrouw EE, Declercq GA, Danneels LA, Cambier DC. Scapular muscle recruitment patterns: Trapezius muscle latency with and without impingement symptoms. The American Journal of Sports Medicine 2003; 31: 542-549.
53. Cools AM, Witvrouw EE, Mahieu NN, Danneels LA. Isokinetic scapular muscle performance in overhead athletes with and without impingement syndrome. Journal of Athletic Training 2005; 40: 104-110.

ADDENDUM

Summary
Zusammenfassung

Acknowledgements
Danksagung

About the author
List of publications

Summary

Chapter 1 introduces the theme of shoulder complaints, which are often seen in primary care. The reported incidence and 1-year prevalence ranges from 0.9 to 2.5% and from 4.7% to 46.7% respectively. About 75% to 80% of patients with shoulder pain show clinical signs of subacromial impingement, characterized by pain and functional restrictions mostly during overhead activities in daily life or sporting activities. Physiotherapy is often the first choice of treatment for SIS. Conclusions from systematic reviews favour the use of both, exercises and manual therapy, often as a combined treatment. Although short term results suggest that patients benefit from these interventions, evidence is scarce and information about the long term effect of manual therapy is lacking. The main focus of this thesis was to provide evidence about the short and long term effect of manual physiotherapy and exercises in the treatment of patients with subacromial impingement syndrome of the shoulder.

In **chapter 2** results of a systematic review are presented and discussed. This review was conducted to get a comprehensive overview about the topic and to analyze the state of current evidence at that point in time in the field of interest. Our review identified 16 trials with sufficient quality investigating a great variety of interventions. A first surprising result was the strong evidence for an equal effect of exercise therapy and surgery which led to the statement, that patients with SIS should not undergo surgery unless having tried exercises beforehand. Secondly we found moderate evidence for an additional effect of manual therapy on pain when added to an exercise program and for a similar effect of physiotherapy and exercises of which both seem to be more effective than no intervention. However, conclusions made from the results of this review were limited by low study numbers, methodological flaws, short follow ups, and low sample sizes. It became obvious that more high quality trials and longer follow up times are needed to answer the question about the effect of physiotherapy in SIS. Results also pointed out that besides good quality future studies should provide a detailed description of applied interventions to guarantee a transfer of research results into clinical practice.

Chapter 3 presents the design of the randomized controlled trial (RCT). Our first aim was to investigate the effect of individualized manual physiotherapy (IMPT) on pain and functioning compared to a standard exercise protocol (SEP) in patients presenting with clinical signs of SIS. The second aim was to compare direct and indirect costs between both interventions. When planning the RCT we followed the CONSORT

statement to guarantee a good quality of the trial. It was important for us to embed the trial in a regular outpatient physiotherapy setting in Germany to increase external validity of results. Besides scientific aspects, decisions about eligibility criteria, measurement instruments, interventions and equipment were therefore also based on the availability and practical applicability of these aspects in this setting. To apply a high quality IMPT protocol, we chose research therapists with an international qualification for manual therapy according to the standard of the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) and several years of experience in this field. In a handbook we described all procedures, assessments and treatments in detail and therapists were trained intensively before commencement of the study. According to our power calculation we aimed to include 90 patients in this trial.

Chapter 4 presents and discusses the short-term results of the RCT about the additional effect of IMPT to exercises on pain and functioning compared to exercises alone in patients with shoulder impingement syndrome. 90 patients presenting with shoulder impingement of more than 4 weeks duration were included by 6 physiotherapy clinics in Germany. Eligibility criteria were solely based on clinical findings without concerning technical diagnostics. The intervention group was treated with individually adapted exercises and examination-based IMPT, controls with individually adapted exercises only. During the first 5 weeks both groups had two treatment sessions per week. This frequency was mainly determined by the regulations of the German health system for physiotherapy prescriptions. In a second step patients of both groups continued their exercises at home for another 7 weeks. Compliance with treatment, additional diagnostics, co-interventions, and sick leave were assessed with the help of a shoulder logbook. Compliance of therapists with the treatment guidelines was monitored with the help of group meetings and regular interviews. Primary outcome measures were the Shoulder Pain and Disability Index and Patient's Global Impression of Change. Secondary outcome measures were the mean weekly pain score, the Generic Patient-Specific Scale and Patient's Satisfaction with Treatment. We finally randomized 46 patients to the intervention and 44 to the control group respectively. After 5 and 12 weeks both groups showed significant improvements in all outcome measures but without any differences between groups for any outcome at any time. Only results for mean pain differed at 5 weeks in favour of the intervention group, but this effect was already lost at 12 weeks. Therefore we concluded that IMPT had no worthwhile additional effect on outcome compared to exercises alone and that individually adapted exercises are an effective treatment of patients with SIS. However, these conclusions need to be confirmed by future research before definite recommendations can be made.

Chapter 5 presents and discusses the long-term results of the RCT as well as the analysis of direct and indirect costs. Because at that point in time no information exist-

ed about the long-term effect of the tested interventions, these results were of particular interest and certainly one of the most important findings of this dissertation. Due to the nature of our repeated-measure design we used a linear mixed models approach for calculating differences between baseline and our final follow up at 52 weeks. Data were available from 87 patients, 44 in the intervention and 43 in the control group. Both groups showed significant improvements in all outcome measures but again without any differences between them. Individualized manual physiotherapy as an additional intervention did not influence these results ($p = 0.38$, 95%CI = -7.45 to 2.85) and thus, these long-term results confirm our conclusions drawn from the short-term results. Interestingly, the total group showed a remarkable improvement over the follow up period which was approved by the subjective impression of the participants themselves. We therefore suggest waiting with further treatments in patients who do not show satisfactory results after the intervention phase and monitor their development over a few months. This is of particular importance because "failed physiotherapy" is often used as an indication for immediate surgery. The only significant difference between groups was found for direct costs after 5 weeks in favour of the control group ($p=0.03$) but not for any other follow up point. Although the difference in indirect costs was not significant between groups due to a high standard deviation, the absolute difference was enormous and clearly higher in the control group.

In **chapter 6** results about the influence of fear avoidance beliefs (FAB) and catastrophizing on pain and disability at the time of inclusion are presented. The negative influence of these factors in patients with low back pain (LBP) is widely accepted and summarized in the fear avoidance model (FAM). However, little is known about the role of them in patients with shoulder complaints. Therefore we firstly investigated the association between fear, pain and disability, and secondly the influence of a selected set of clinical and psychological variables on pain and disability levels in our sample with separate multivariable linear regression analyses for function and disability. 90 patients were included in these analyses. FAB were assessed with a modified version of physical activity sub-scale of the Fear Avoidance Beliefs Questionnaire-(FABQ-PA), catastrophizing with the Pain Catastrophizing Scale (PCS). Shoulder function was measured with the sub-scale for function of the Shoulder Pain and Disability Index (SPADI-F), pain intensity was rated on a visual numeric rating scale (VNRS). Results revealed a direct and independent association of pain and FAB on disability which is different to the consecutive order described in the FAM. Therefore results from LBP patients cannot be transferred to patients with shoulder complaints. Our multivariable regression analysis revealed a significant contribution of FAB and catastrophizing to pain and disability. This contribution was still less than the contributions of pain to disability and of disability to pain. Together with the eligibility criteria set for the trial, small numbers of sick days, low ratings on the FABQ-PA, the PCS, high activity levels,

pain clearly connected to specific activities, and last but not least with the significant improvement our patients in the RCT this would support a dominantly nociceptive and therefore tissue based pattern in our group even after a longer period of existing complaints. However, FAB and catastrophizing were significantly influencing pain and disability levels and, in our opinion, are therefore parts of the nociceptive pattern. We therefore recommend the assessment of fear avoidance beliefs and catastrophizing in patients with shoulder impingement syndrome as a standard feature in primary care.

Despite several limitations, discussed in detail in **Chapter 7**, this thesis provides important and new information about the effect of manual physiotherapy and exercises in the treatment of patients with subacromial shoulder pain showing that exercises alone seem to be a sufficient and effective treatment for SIS. It was further shown that the improvement seen during the intervention phase progressively continued during the follow up period which may help to prevent unnecessary surgery in the future. This thesis also delivers first results about the role of fear avoidance beliefs and catastrophizing in this patient group. These factors were identified as significant contributors to pain and disability and are therefore worth to be considered in clinical practice and future research. As the bio-psycho-social view relentlessly moves forward, these results are of particular interest, because they are little explored in shoulder disorders (and in other upper or lower extremity disorders, either) but growing knowledge about the psycho-social aspects may heavily challenge physiotherapists, still walking the biomedical path.

However, further research is necessary to confirm or to refute our results and to gain further insight into the factors and mechanisms contributing to subacromial shoulder pain and shoulder pain in general.

Zusammenfassung

Kapitel 1 führt in das Thema Schulterbeschwerden ein, welche in der Primärversorgung häufig vorkommen. Angaben über Inzidenz und 1-Jahres Prävalenz variieren zwischen 0,9% und 2,5%, beziehungsweise zwischen 4,7% und 46,7%. In etwa 75-80% aller Patienten mit Schulterbeschwerden findet man klinisch-diagnostische Zeichen für ein subakromiales Impingement (auch als „subakromiales Engpasssyndrom“ bezeichnet), welches durch Schmerzen und funktionelle Einschränkungen im Alltag oder Sport, meist bei Tätigkeiten über Schulterhöhe charakterisiert sind. Physiotherapie ist häufig einer der ersten Therapiemaßnahmen, die dafür verordnet werden. Ergebnisse systematischer Literaturarbeiten zu diesem Thema empfehlen sowohl Übungstherapie als auch Manuelle Therapie, oder auch beides in Kombination. Obwohl diese Maßnahmen kurzfristig positive Ergebnisse zeigen ist die Evidenz dafür noch dünn und für einen langfristigen positiven Effekt im Moment nicht existent. Das Ziel dieser Dissertation war es daher, Evidenz über die kurz- und langfristigen Effekte von Manueller Therapie und Übungstherapie in der Behandlung von Patienten mit Schulterimpingement bereitzustellen.

In **Kapitel 2** werden die Ergebnisse einer systematischen Literaturarbeit vorgestellt und diskutiert. Diese Arbeit diente uns dazu, einen umfassenden und aktuellen Überblick über das Gebiet zu erhalten. Wir konnten 16 Studien mit guter Qualität finden, welche allerdings eine große Bandbreite an Interventionen untersuchten. Ein erstes überraschendes Ergebnis war, dass sowohl kurz- als auch langfristig Übungstherapie genauso effektiv zu sein scheint wie ein operatives Vorgehen. Dies veranlasste uns zu der Empfehlung, Patienten nicht zu operieren bevor sie nicht mit Übungstherapie behandelt worden sind. Des Weiteren fanden wir moderate Evidenz für einen zusätzlichen schmerzlindernden Effekt von Manueller Therapie in Kombination mit Übungstherapie. Moderat war auch die Evidenz für einen vergleichbaren Effekt von allgemeiner Physiotherapie und Übungstherapie, wobei beide Interventionen auch effektiver zu sein scheinen als keine Behandlung zu applizieren und nur abzuwarten. Allerdings ist zu bedenken, dass die Aussagekraft unserer Ergebnisse durch kleine Patientenzahlen, methodische Unzulänglichkeiten, wenig Studien pro Intervention und kurze Nachuntersuchungszeiträume limitiert wurde. Es wurde somit auch deutlich, dass mehr Studien mit besserer Qualität sowie Langzeitergebnisse notwendig sind, um die Frage nach dem Effekt von Physiotherapie bei dieser Pathologie ausreichend beantworten zu können. Ein weiteres Fazit aus dieser Arbeit war, dass nur eine detaillier-

te Beschreibung der untersuchten Interventionen dazu führen kann, Ergebnisse in die Praxis umzusetzen.

Kapitel 3 präsentiert das Design der randomisierten kontrollierten Studie (RCT). Ziel damit war es herauszufinden, ob individuelle manuelle Physiotherapie (IMPT) einen zusätzlichen Effekt auf Schmerz und Funktion bei Patienten mit Schulterimpingement hat, wenn sie zusätzlich zu einem Übungsprogramm appliziert wird im Vergleich zu ausschließlich einem Übungsprogramm. Weiterhin wollten wir die direkten und indirekten Kosten zwischen diesen beiden Interventionen vergleichen. Um eine gute Qualität der Studie zu garantieren, erfolgte die Planung eng angelehnt an das CONSORT Statement. Wichtig war uns dabei, die Studie in den typischen deutschen Physiotherapiealltag einzubetten, um dadurch die externe Validität der Ergebnisse zu erhöhen. Daher spielten für die Auswahl der Einschlusskriterien, der Messinstrumente und der Interventionen neben den wissenschaftlichen Kriterien auch praktische Aspekte eine wichtige Rolle. Um eine gute Qualität der IMPT zu erreichen, wählten wir Therapeuten mit einer internationalen Qualifikation in Manueller Therapie nach IFOMPT-Standard (International Federation of Orthopaedic Manipulative Physical Therapists) und mit mehrjähriger Berufserfahrung. In einem Studienhandbuch wurden alle Abläufe und Prozesse, die Untersuchungsgänge und Behandlungen im Detail beschrieben und alle Therapeuten wurden vor Beginn der Studie intensiv geschult. Entsprechend den Ergebnissen unserer Powerkalkulation hatten wir zum Ziel, 90 Patienten einzuschließen.

Kapitel 4 präsentiert und diskutiert die Kurzzeitergebnisse des oben beschriebenen RCTs. 90 Patienten mit mehr als 4 Wochen Beschwerden wurden von insgesamt 6 Praxen in die Studie eingeschlossen. Die weiteren Einschlusskriterien basierten ausschließlich auf klinische Zeichen ohne dabei technische Untersuchungsergebnisse zu berücksichtigen. Die Interventionsgruppe wurde mit individuell angepassten Übungen und IMPT, die Kontrollgruppe ausschließlich mit individuell angepassten Übungen behandelt. In den ersten 5 Wochen hatten alle Patienten 2 Behandlungseinheiten pro Woche; diese Frequenz wurde im Wesentlichen aufgrund der gesetzlichen Regelungen dafür festgelegt. Während der folgenden 7 Wochen führten beide Gruppen ihre Übungen zu Hause selbständig weiter. Entsprechende Mitarbeit, zusätzliche diagnostische oder therapeutische Maßnahmen und Krankheitstage in dieser Zeit wurden mithilfe eines Schultertagebuches erfasst und ausgewertet. Die Compliance der Therapeuten mit den vorgegebenen Behandlungsrichtlinien wurde mittels Teamsitzungen und regelmassigen Gesprächen sichergestellt. Als primäre Messinstrumente benutzten wird den Shoulder Pain and Disability Index (SPADI) und den persönlichen Gesamteindruck der Patienten über die Veränderungen. Als sekundäre Messinstrumente wählten wir den durchschnittlichen wöchentlichen Schmerz, eine Patienten-spezifische Aktivitätsskala und die Zufriedenheit der Patienten mit den Behandlungen. Letztendlich konnten

wir mittels Losverfahren 46 Patienten zur Interventions- und 44 Patienten zur Kontrollgruppe zuordnen. Nach 5 und 12 Wochen zeigten beide Gruppen zwar eine signifikante Verbesserung in allen Messparametern, zu keinem Zeitpunkt gab es allerdings eine Differenz zwischen den Gruppen. Nur die durchschnittliche Schmerzintensität unterschied sich nach 5 Wochen signifikant zu Gunsten der Interventionsgruppe, was allerdings nach 12 Wochen nicht mehr feststellbar war. Aus diesen Ergebnissen schlussfolgerten wir, dass IMPT keinen zusätzlichen Nutzen hat und dass Übungstherapie eine ausreichende und effektive Behandlungsform für Patienten mit subakromialem Impingement darstellt. Nichtsdestotrotz müssen dieser Ergebnisse mit weiteren Studien belegt werden bevor es möglich ist, definitive Empfehlungen auszusprechen.

Kapitel 5 präsentiert und diskutiert zum einen die Langzeitergebnisses des RCTs, zum anderen die direkten und indirekten Kosten. Da zum Zeitpunkt der Analyse keine anderen Daten über den Langzeiteffekt der untersuchten Interventionen vorlagen, sind diese Ergebnisse natürlich von besonderem Interesse und stellen daher eine der wichtigsten Resultate dieser Thesis dar. Aufgrund unseres gewählten Studiendesigns analysierten wir die 1-Jahres-Ergebnisse mithilfe eines linearen gemischten Modells. Nach einem Jahr konnten Daten von 87 Patienten, 44 aus der Interventions- und 43 aus der Kontrollgruppe, ausgewertet werden. Beide Gruppen verbesserten sich signifikant, jedoch wiederum ohne Unterschiede zwischen den beiden Gruppen. Die zusätzlich applizierte IMPT hatte keinen Einfluss auf diese Ergebnisse ($p = 0,38$, 95%CI = -7,45 – 2,85), was die Schlussfolgerungen aus den Kurzzeitergebnissen bestätigte. Interessanterweise zeigte die ganze Gruppe eine bemerkenswerte Verbesserung über den Beobachtungszeitraum, welche durch den subjektiven Eindruck der Patienten bestätigt wurde. Daher empfehlen wir bei Patienten, welche keine zufriedenstellenden Fortschritte während der Therapie machen mit weiteren Maßnahmen trotzdem zu warten und die weitere Entwicklung für einige Monate zu beobachten. Das ist besonders deshalb wichtig, weil „ineffektive Physiotherapie“ als klare Indikation für eine sofortige Operation steht. Der einzig signifikante Unterschied zwischen den Gruppen fanden wir nach 5 Wochen für die direkten Kosten zu Gunsten der Kontrollgruppe ($p=0,03$), aber zu keinem anderen Zeitpunkt. Obwohl sich die indirekten Kosten aufgrund einer hohen Standardabweichung nicht signifikant unterschieden, war deren absolute Differenz jedoch enorm und in der Kontrollgruppe eindeutig höher als in der Interventionsgruppe.

In Kapitel 6 werden Ergebnisse über den Einfluss von Angst und katastrophisierenden Gedanken auf das Schmerzerleben und die Funktionseinschränkung dargestellt. Der negative Einfluss dieser Faktoren bei Patienten mit unspezifischem Rückenschmerz ist weitestgehend akzeptiert und im sogenannten „Fear Avoidance Model“ (FAM) zusammengefasst. Ungeachtet dessen ist wenig über die Rolle dieser Faktoren bei Patienten mit Schulterschmerzen bekannt. Daher haben wir zuerst die Wechselbe-

ziehungen zwischen Angst, Schmerz und Funktionseinschränkung untersucht und in einem zweiten Schritt mithilfe separater Regressionsanalysen den Einfluss einer ausgesuchten Anzahl klinischer und psychologischer Faktoren auf Schmerz und Funktion analysiert. In diese Analyse wurden 90 Patienten eingeschlossen. Angstvermeidung wurde mit einer modifizierten Version des Fear „Avoidance Beliefs Questionnaires“ (FABQ) gemessen, Katastrophisierung mit der „Pain Catastrophizing Scale“ (PCS). Schulterfunktion wurde gemessen mit dem „Shoulder Pain and Disability Index“ (SPADI), Schmerz mit einer numerischen Analogskala. Die Ergebnisse zeigten einen direkten und unabhängigen Einfluss von Schmerz und Angstvermeidung auf Funktion, was deutlich von der konsekutiven Abfolge wie sie im FAM beschrieben ist, abweicht. Daher können Ergebnisse, welche aus Untersuchungen an Rückenpatienten gewonnen worden sind nicht einfach auf Schulterpatienten übertragen werden. Unsere Regressionsanalysen zeigten einem signifikanten Beitrag von Angstvermeidung und Katastrophisierung zu sowohl Schmerz als auch zur Funktionseinschränkung. Dieser Beitrag war allerdings kleiner als der Einfluss von Schmerz auf Funktion und umgekehrt. Das, zusammen mit den Einschlusskriterien, wenigen Kranktagen, niedrigen Werten im FABQ und der PCS, einem hohen Aktivitätslevel, einem klaren Zusammenhang von Schmerz mit spezifischen Aktivitäten und nicht zuletzt mit der signifikanten Verbesserung der Patienten im RCT bestärken die Annahme, dass unsere Patienten auch nach einer längeren Zeit an Beschwerden immer noch ein dominant nozizeptives, strukturbasiertes Muster zeigen. Trotzdem haben Angstvermeidung und Katastrophisierung einen signifikanten Einfluss auf Schmerz und Funktion und sind unserer Meinung nach daher ebenfalls Teilaspekte des nozizeptiven Muster. Basierend auf unseren Ergebnissen empfehlen wir deshalb, diese beiden Faktoren standardmassig bei der Untersuchung von Patienten mit subakromialem Impingement zu messen.

Trotz einiger Einschränkungen, welche detailliert im **Kapitel 7** diskutiert werden, liefert diese Dissertation wichtige und neue Ergebnisse über den Effekt von IMPT und Übungstherapie bei der Behandlung von Patienten mit subakromialem Impingement. Diese zeigen, dass Übungstherapie für diese Pathologie eine effektive Intervention darstellt. Sie zeigen weiterhin, dass die Verbesserung auch nach der eigentlichen Intervention progressiv fortschreitet was zukünftig dazu beitragen mag, unnötige Behandlungen oder Operationen zu reduzieren. Diese Dissertation liefert außerdem erste Ergebnisse über die Rolle von Angstvermeidung und Katastrophisierung in dieser Patientengruppe. Beide Faktoren wurden als wichtige beitragende Faktoren für Schmerz und Funktionseinschränkungen identifiziert und sollten daher sowohl in der klinischen Praxis als auch bei weiteren wissenschaftlichen Untersuchungen berücksichtigt werden. Da sich die bio-psycho-soziale Sichtweise mehr und mehr verbreitet, sind diese Ergebnisse von besonderer Bedeutung, da sie bei Schulterproblemen (und bei anderen Problemen an der unteren oder oberen Extremität) nur wenig erforscht sind. Zuneh-

mendes Wissen über die psycho-sozialen Aspekte wird allerdings die Arbeit derjenigen Physiotherapeuten in Frage stellen, welche ausschließlich auf den biomedizinischen Aspekt fokussieren. Weitere Studien sind jetzt notwendig, um unsere Ergebnisse zu bestätigen oder zu widerlegen und einen umfassenderen Überblick über die Faktoren und Mechanismen zu bekommen, die zum subakromialen Impingement der Schulter und zum Schulterschmerz im Allgemeinen beitragen.

Acknowledgements

First and foremost I would like to thank my supervisor Rob de Bie and my co-supervisor Caroline Bastiaenen, who accompanied and supported me throughout all these years.

I am most grateful to you Rob, for your enthusiastic, positive and uncomplicated manner and your huge experience which often motivated me to continue and to view assumed catastrophes as solvable problems. I am especially indebted to you for giving me the opportunity to do my PhD here at Maastricht University, something I have always considered to be a privilege. In this context, I would also like to express my particular thanks to Maastricht University for offering such opportunities to international students.

To you Carolien, thank you so much for your generous support, the many discussions and helpful suggestions, which were crucial for this thesis, and for your relaxed, patient and clear-sighted manner. I have always been impressed by your vast knowledge. I am also grateful to you for making student life difficult for me at the right times. It was worthwhile as it not only helped me to better understand research and put it into practice but to also develop great enthusiasm for it. I would love to continue our cooperation in the future and to start new projects.

I would like to express my heartfelt gratitude to Prof. Dr. Ernst Wiedemann, who was willing to submit my clinical trial protocol to the ethical review board at the Ludwig-Maximilians University in Munich, thereby officially taking on responsibility for the project. Thank you very much for your confidence and all the work you put into this. Without your support and your commitment, the project would have failed right there and then.

Special thanks, which are long overdue, go to Karen Grimmer-Somers and Mark Jones who are both working at the University of South Australia in Adelaide. To Mark in particular for bringing my understanding of clinical thinking to a professional level and to Karen for introducing me to science and research as well as for inspiring and motivating me to start my PhD studies. I would also like to thank you for arranging the contact with Rob de Bie which was the starting point for this thesis. I had a fantastic time with you!

The centerpiece of my thesis is a randomized controlled trial, which cannot be carried out successfully unless a sufficient number of patients are willing to be allocated to groups by random distribution, to invest the time, work and discipline to follow

the protocol and to fill in the corresponding forms in time. Huge thanks to all participants for your trust, good cooperation and additional effort required for this trial.

Many people were involved in organizing and realizing this thesis. I am grateful to Conny de Zwart for always sending on the randomization quickly and in time. Many thanks go to my practice staff, especially Nicola Domaschka, for her support in sending out the documents and for her perseverance in 'chasing' patients and collecting data.

I would also like to express my thanks to Judith Sieben and J. Bart Staal for your constructive guidance and cooperation regarding two papers of this thesis. I very much enjoyed working with you and learned a lot from you.

To Kees Admiraal, Robert Blaser-Sziede, Isabella Knoecklein, Nils Jansen and Horst Baumgartner, I am grateful for your work as research therapists. Thank you for your time and effort, your willingness to implement an unusual protocol and your energy to keep working for 18 months right up until the end. I am very well aware of what this means. You are a great bunch of people and I am particularly thankful to you.

I would also like to thank Ariane Salm for proofreading my last papers and for translating these words of acknowledgement into English, the latter being too important for me to attempt it myself.

Thank you to my colleagues at the Department of Epidemiology in Maastricht, Audrey Merry, Esther Bols, Vivian Bruls to name just a few, and particularly to my paranymphs Sarah Dörenkamp and Stefanie Rewald, who always gave me a warm welcome and supported me wherever possible. I really enjoyed the time spent with you.

I would also like to express my gratitude to the reading committee members of my thesis and corona for their interest in my work and the time spent on reading it: Prof. Dr. L.W. van Rhijn (chairman), Prof. Dr. J. Verbunt, Prof. Dr. IJ. Kant, Dr. A.J.A. Köke and Dr. M. Poeze.

Last but not least I would particularly like to thank my parents who supported me and believed in me during all these years. I am so happy to have you in my life!

And I am most grateful to Ulrike for sharing in this project with all its ups and downs throughout the years. I cannot thank you enough for your encouragement, your support and your love.

Stegen, January 2014

Thilo Oliver Kromer

Danksagung

Zuallererst möchte ich mich bei meinem Supervisor Rob de Bie, und meiner Co-Supervisorin Caroline Bastiaenen bedanken, die mich die ganzen Jahre auf diesem Weg begleitet und unterstützt haben.

Bei Dir Rob, für deine freudige, positive und unkomplizierte Art und Deine riesige Erfahrung, die mich oft motiviert hat weiterzumachen und die vermeintlichen Katastrophen als lösbare Probleme zu betrachten. Ganz besonders dankbar bin ich Dir für die Chance, hier an der Universität Maastricht promovieren zu dürfen, was ich bis heute als ein Privileg betrachte. In diesem Zusammenhang ein großes Dankeschön an die Universität Maastricht dafür, diese Möglichkeit für internationale Studenten anzubieten.

Bei Dir Carolien, für Deine unentwegte Unterstützung, die vielen Diskussionen und Anregungen, die diese Thesis erst ermöglicht haben, für Deine ruhige, geduldige und vorausschauende Art. Dein enormes Wissen hat mich stets beeindruckt. Bedanken möchte ich mich aber auch dafür, dass Du mir an den richtigen Stellen das Studentenleben schwer gemacht hast. Das hat sich gelohnt und mir nicht nur geholfen, Forschung besser zu verstehen und umzusetzen, sondern auch große Begeisterung dafür zu entwickeln. Es würde mich freuen zukünftig mit euch zusammenzuarbeiten und neue Projekte zu starten.

Bedanken möchte ich mich ganz herzlich bei Prof. Dr. Ernst Wiedemann, der bereit war mein Studienprotokoll bei der Ethikkommission der Ludwig-Maximilian-Universität in München einzureichen und damit die offizielle Verantwortung für das Projekt zu übernehmen. Vielen Dank für das Vertrauen und die Arbeit, die Sie investiert haben. Ohne Ihre Unterstützung und Ihren Einsatz wäre dieses Projekt wohl genau an dieser Stelle gescheitert.

Ein besonderer und längst überfälliger Dank geht an Karen Grimmer-Somers und Mark Jones, beide von der University of South Australia in Adelaide. Mark im Besonderen dafür, mein Verständnis von klinischem Denken auf ein professionelles Niveau zu bringen; Karen dafür, mich mit Forschung und Wissenschaft in Kontakt zu bringen, zu begeistern und mich dazu zu motivieren, ein PhD-Studium zu beginnen. Nicht zuletzt auch für den Kontakt zu Rob de Bie, als den Startpunkt dieser Arbeit. Es war eine phantastische Zeit bei euch!

Das Kernstück meiner Thesis ist eine randomisierte kontrollierte Studie, die nur erfolgreich durchzuführen ist, wenn genug Patienten sich bereit erklären, sich per

Zufallsverteilung zu Gruppen zuteilen zu lassen, und wenn sie entsprechend Zeit, Arbeit und Disziplin auf sich nehmen, dem Protokoll zu folgen und rechtzeitig die entsprechenden Unterlagen auszufüllen. Daher einen ganz großen Dank an alle Teilnehmer in dieser Studie für das Vertrauen, die gute Mitarbeit und den zusätzlichen Aufwand, der dafür nötig war.

An der Organisation und Durchführung dieser Thesis waren eine Menge Leute beteiligt. Danke an Conny de Zwart für die immer schnelle und rechtzeitige Zusendung der Randomisierung. Meinem Praxisteam, allen voran Nicola Domaschka, für die Unterstützung beim Versenden von Unterlagen, dem hartnäckigen „Verfolgen“ von Patienten und Einsammeln von Daten.

Judith Sieben und J. Bart Staal für die konstruktive Führung und Zusammenarbeit an zwei Papieren dieser Thesis. Es hat sehr viel Spaß gemacht und ich habe viel von Euch gelernt.

Kees Admiraal, Robert Blaser-Sziede, Isabella Knoecklein, Nils Jansen und Horst Baumgartner für ihre Arbeit als Studientherapeuten. Für die Zeit und Mühe, die damit verbunden war, für die Offenheit ein ungewohntes Protokoll umzusetzen und die Energie, die 18 Monate bis zum Schluss mitzuarbeiten. Ich weiß sehr gut, was das heißt, ihr seid eine wirklich tolle Truppe; meinen größten Dank dafür.

Ariane Salm für das Korrekturlesen meiner letzten Arbeiten und für die Übersetzung dieses Dankwortes. Das war mir zu wichtig, um es selbst auf Englisch zu schreiben.

Meinen Kollegen im Department of Epidemiology in Maastricht, Audrey Merry, Esther Bols, Vivian Bruls nur um einige zu nennen, und ganz besonders meinen Paranymphen Sarah Dörenkamp und Stefanie Rewald, die mich stets herzlich empfangen und wo immer möglich unterstützt haben. Ich habe es sehr genossen bei euch zu sein.

Außerdem bedanke ich mich beim Reading Committee meiner Dissertation und meiner Corona für das Interesse an meiner Arbeit und die Zeit sich damit auseinanderzusetzen: Prof. Dr. L.W. van Rhijn (chairman), Prof. Dr. J. Verbunt, Prof. Dr. IJ. Kant, Dr. A.J.A. Köke und Dr. M. Poeze.

Nicht zuletzt bedanke ich mich bei meinen Eltern, die mich über die ganzen Jahre unterstützt und an mich geglaubt haben. Es ist so gut Euch zu haben!

Und bei Ulrike für das beständige Teilhaben an diesem Projekt mit all den Höhen und Tiefen über die Jahre. Für Deinen Rückhalt, Deine Unterstützung und Liebe mehr als nur meine Dankbarkeit von ganzem Herzen.

Stegen, im Januar 2014

Thilo Oliver Kromer

About the author

Thilo Oliver Kromer was born in Sindelfingen, Germany on 17 April 1967. He completed his secondary school at the Gymnasium Kirchzarten, Germany and qualified as a physiotherapist in Germany in 1993. He then started working in an outpatient rehabilitation centre and got specialized in the diagnosis and treatment of patients with musculoskeletal disorders. In 1999 he passed his teachers exam in Orthopaedic Medicine and completed his OMT training in 2002. 2005 he earned his Master's Degree in Physiotherapy at the University of South Australia, Adelaide and started his PhD in 2007 at Maastricht University in the Netherlands. Until the end of 2012 Thilo was working in his own private practice in Penzberg, Germany. He offers postgraduate courses for the diagnosis and treatment of upper extremity disorders, clinical reasoning and communication skills. He has also published a book and articles in this field. In 2013 he started as a lecturer at the SRH University Heidelberg, School of Therapeutic Sciences, emphasizing the musculoskeletal system.

Thilo Oliver Kromer wurde am 17. April 1967 in Sindelfingen, Deutschland geboren. Nach dem Abitur am Gymnasium Kirchzarten absolvierte er 1993 die staatliche Prüfung zum Physiotherapeuten. Danach arbeitete er in einem ambulanten Rehabilitationszentrum und spezialisierte sich auf die Diagnostik und Behandlung von Patienten mit Beschwerden am Bewegungsapparat. Nach seiner Lehrerprüfung in Orthopädischer Medizin 1999 beendete er 2002 erfolgreich seine OMT-Ausbildung in Orthopädischer Manueller Therapie (OMT). 2005 erhielt er seinen Master von der „University of South Australia" in Adelaide, Australien und begann 2007 sein PhD-Studium an der Universität Maastricht in den Niederlanden. Bis Ende 2012 arbeitete Thilo als selbständiger Physiotherapeut in eigener Praxis in Penzberg. Er bietet Kurse für Physiotherapeuten und Ergotherapeuten mit den Schwerpunkten Diagnostik und Therapie von Beschwerden an der oberen Extremität, Clinical Reasoning und Kommunikation an. Zu diesen Themen hat er ein Buch und mehrere Artikel veröffentlicht. Seit Anfang 2013 arbeitet er als Dozent mit dem Schwerpunkt Bewegungsapparat an der SRH Hochschule Heidelberg in der Abteilung für Therapiewissenschaften.

List of publications

Kromer TO (editor). Rehabilitation der Oberen Extremität. Heidelberg: Springer Verlag, 2013.

Baierle T, Kromer TO, Petermann C, Magosch P, Luomajoki H. Balance ability and postural stability among patients with painful shoulder disorders and healthy controls. BMC Musculoskeletal Disorders 2013;14:282

Kromer TO, de Bie RA, Bastiaenen CHG. Physiotherapy in patients with clinical signs of shoulder impingement syndrome: a randomized controlled trial. Journal of Rehabilitation Medicine 2013;45:488- 97

Kromer TO. Alles „Bio“ oder was? Lateraler Ellenbogrenschmerz. Manuelle Therapie 2012(16):61-66

Kromer TO, de Bie RA, Bastiaenen CHG. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskeletal Disorders 2010;11:114

Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CHG. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. Journal of Rehabilitation Medicine 2009;41(11):470-80

Kromer TO. Das Ellenbogengelenk. Heidelberg: Springer Verlag, 2004.

Kromer TO. Evidenzbasierte Therapie der Epicondylitis lateralis - Querfriktion statt Kortison. Physiopraxis 2004(9):26-29

Kromer TO. Diagnostik der perilunären karpalen Instabilität. Krankengymnastik - Zeitschrift für Physiotherapeuten 2002;54:236-45