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Complete List of Authors:	Schwank, Ariane; University of Antwerp, Department of Rehabilitation Sciences and Physiotherapy (REVAKI); Kantonsspital Winterthur, Institute for Therapy and Rehabilitation Struyf, Filip; Universiteit Antwerpen Campus Drie Eiken, REHABILITATION SCIENCES Mertens, Michel; University of Antwerp Faculty of Medicine and Health Sciences, Rehabilitation Sciences and Physiotherapy Blazey, Paul; The University of British Columbia, Centre for Hip Health and Mobility Gisi, David; KSW Kantonsspital Winterthur, Institute for Therapy and Rehabilitation Pisan, Markus; Kantonsspital Winterthur, Orthopaedics and Traumatology Struyf, Thomas; Katholieke Universiteit Leuven, Department of Public Health and Primary Care Meeus, Mira; Universiteit Antwerpen Campus Drie Eiken; University of Ghent, Department of Rehabilitation Sciences
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Study Protocol

Identifying Modifiable Prognostic Factors of Shoulder Function, Disability, Pain and Quality of Life after Rehabilitation for Rotator Cuff Repair: A Protocol and Study Design for a Prospective Longitudinal Cohort Study

Corresponding and first author:

Ariane Schwank[1,2,3]: ariane.schwank@student.uantwerpen.be, ariane.schwank@ksw.ch

Co-Authors:

Second author: Prof. Dr. Filip Struyf [1], filip.struyf@uantwerpen.be

Third author: Michel GCAM Mertens [1,3], michel.mertens@uantwerpen.be

Fourth author: Paul Blazey [4, 5], paul.blazey@ubc.ca

Fifth author: David Gisi [2], david.gisi@ksw.ch

Sixth author: Dr. med. Markus Pisan [6], markus.pisan@gzw.ch

Seventh author: Thomas Struyf [7], thomas.struyf@kuleuven.be

Last author: Prof. Dr. Mira Meeus [1,3,8], mira.meeus@uantwerpen.be

[1]MOVANT research group, Department of Rehabilitation Sciences and Physiotherapy (REVAKI), University of Antwerp Wilrijk, Belgium

[2]Institute for Therapy and Rehabilitation, Kantonsspital Winterthur, Switzerland

[3]Pain in Motion, International research group, www.paininmotion.be

[4]Centre for Hip Health and Mobility, University of British Columbia, Vancouver, Canada

[5]Department of Physical Therapy, Faculty of Medicine, University of British Columbia, Vancouver, Canada.

[6] Former Head of Shoulder and Elbow Surgery Unit, Clinic of Orthopaedics and Traumatology Kantonsspital Winterthur, Switzerland

[7]Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium

[8]Department of Rehabilitation Sciences, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

Abstract

Introduction

Prognosis following surgical rotator cuff repair (RCR) is often established through the assessment of non-modifiable biomedical factors such as tear size.[1] There is a need for further investigation into modifiable and psychosocial factors that may influence RCR prognosis. Our aim is to identify demographic and patient characteristics, psychosocial, life-style and central pain processing factors as possible prognostic factors following RCR.

Methods and Analysis

This longitudinal cohort study will analyse 125 participants undergoing usual care for first time RCR. Data will be collected 1 to 21 days preoperatively (T1), 11 to 14 weeks (T2) and 12 to 14 months (T3) postoperatively. We will use mixed-effects linear regression to identify relationships between potential prognostic factors and our primary outcome measure – the Western Ontario Rotator Cuff Index. Secondary outcome measures that will be assessed against prognostic indicators include: The Constant-Score and Subjective Shoulder Value; Maximal Pain (Numeric Rating Scale); and Quality of Life (European Quality of Life 5 Dimensions 5 Levels – EQ-5D-5L). Our potential prognostic factors include: four psychosocial variables — pain catastrophizing, perceived stress, injury perceptions and patients' expectations for RCR; one lifestyle factor — sleep; and four factors related to central pain processing — central sensitisation inventory, temporal summation, thermal hyperalgesia and pressure pain threshold. The potential prognostic factors will be assessed for correlations with our primary and secondary outcomes. Interaction effects will be

assessed to determine the strength of relationships between all potential prognostic indicators.

Ethics and Dissemination

The results of the study will be disseminated at conferences (e.g. European Pain Congress (EFIC)). One or more manuscripts will be published in peer reviewed SCI-ranked journals. Findings will be reported in accordance with the STROBE statement. Results will be presented with full disclosure. Ethical approval is granted by the Ethical commission of Canton of Zurich, Switzerland, No: ID_2018-02089.

Registration

Registered at ClinicalTrials.gov, registration number: NCT04946149

Funding

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Keywords

Rotator cuff tears, prognostic factors psychosocial factors, expectations, central sensitisation, quantitative sensory testing, sleep

Article Summary

Strengths of this study

- The first study *adequately* powered to identify modifiable psychosocial factors as potential prognostic factors of Western Ontario Rotator Cuff Index (WORC) after rotator cuff repair (RCR)
- Prospective longitudinal study design including 3 measurement points, starting preoperatively (RCR), and including a comprehensive biopsychosocial assessment.

Limitations of this study

- The questionnaires for sleep and patients' expectations were not previously translated, therefore these outcome measures have yet to have their validity determined in German.

Introduction

Shoulder pain is the third-most common musculoskeletal disorder seen in primary care (1) with low recovery rates (50-60%) 12 to 18 months post onset.(2) Rotator cuff (RC) disorders are the most frequently reported amongst shoulder pain patients with a life-time prevalence of around 70%.(3, 4) However, many people present with structural changes of their RC, yet they do not suffer pain.(5) Reports from the United States acknowledge that only one third of RC lesions are symptomatic.(6) As a consequence there is a lack of consensus concerning the exact cause of rotator cuff related shoulder pain.(2, 7)

Patients who demonstrate structural changes of their RC, are predominantly managed using biomedical reasoning, e.g. via surgery.(6, 8) There was a reported ≥270'000 annual surgeries (9) in the USA and an increase of 204% in rotator cuff repairs (RCR) between 1998 and 2011 in Finland.(10) Satisfactory outcomes ranged from 38% to 95%.(11-14) Orthopaedic research on prognostic factors of RCR outcomes focuses primarily on biomedical indicators, which are often non-modifiable (e.g. tear size, patient-age) in the pre-or postoperative (RCR) phase.(11, 13-16) This assertion was backed up by a systematic review and meta-analysis (17) where multiple tendon involvement, diabetes, large tear size, higher age, preoperative muscle weakness and status of insurance payment as workers' compensation were moderate predictors, and fatty muscle infiltration a strong predictor of poor outcome.(17) Prognostic factors are markers of natural history of disease associated to a succeeding clinical outcome in patients who receive a standard intervention, for example RCR.(18, 19)

Despite the reliance on biomedical factors, there is growing evidence that psychosocial factors impact persistent shoulder pain,(6, 20-23) and the outcomes after RCR.(24-26) Factors such as: high distress; maladaptive beliefs such as catastrophic thinking and pain self-efficacy;(22) and the perception of high job demand and poor social support,(23) can lead to persistent shoulder pain and disability. Absence of psychological distress may advocate improved self-efficacy (27) and lower levels of shoulder pain and disability.(22) Patients with existing preoperative psychological conditions like depression and anxiety,(14) high degrees of pain catastrophizing and kinesiophobia (24) or psychological distress (14, 28) may evoke higher preoperative RCR pain levels.(14, 24) Patients who anticipate a good recovery (patients' expectation) post RCR show independent and strong associations with satisfactory outcomes for pain and disability measured one-year post surgery.(11, 12, 29)

Prior research on psychosocial factors post RCR has been restricted to: preoperative measures (pain catastrophizing); (24) has lacked the power to demonstrate true effects (distress);(14, 28) or failed to investigate potential prognostic factors altogether (patient expectations and injury perceptions).(11, 12, 29) Therefore it is perhaps unsurprising that studies on the prognosis of psychosocial factors post RCR, have only demonstrated weak interactions. Further investigation on psychosocial factors like pain catastrophizing, distress, injury perceptions and expectations for RCR is warranted.

Lifestyle factors may also play a huge role in the recovery from rotator cuff related shoulder pain. Sleep disturbances are highly prevalent (up to 89%) in patients undergoing RCR, (30, 31) and shoulder pain appears to foster sleep disturbances.(32)

RCR seems to reduce this interplay between shoulder pain and sleep disturbances as findings demonstrate an overall post RCR improvement of sleep quality.(14, 33) Yet, 41% of RCR patients still demonstrate sleep disturbances at 24 months follow up.(31) Investigations of sleep disturbance in relation to shoulder pain and RCR are incomplete with multiple factors affecting the relationship.(34) This implies that further exploration is needed.

Altered central pain processing (CPP) such as measures of central sensitisation demonstrate conflicting evidence with regards to its presence in musculoskeletal shoulder pain. CPP is almost absent in studies of patients undergoing RCR.(20, 21, 35) Two trials (36, 37) investigated the role of central sensitisation, measured with quantitative sensory testing (QST) on outcome (pain and disability) after different shoulder surgeries (RCR, superior labrum from anterior to posterior (SLAP) repair, shoulder arthroscopy (SA) and subacromial decompression). Both studies found small effects of CPP on post-operative outcomes. If a high amount of CPP was present pre-operatively, it was related to a worse outcome 3 months post-subacromial decompression.(36) In contrast, if a small amount of CPP was present 3 months postoperatively (RCR, SLAP-Repair, SA) it was associated to better functioning at 6 months post-surgery.(37)

Overall, we lack knowledge of potential modifiable prognostic indicators related to psychosocial factors, sleep and CPP and their effects on pain, shoulder function, disability, and quality of life following RCR.(6, 24) Neither the local tissue pathology-pain model nor the growing knowledge about local biochemical changes in rotator cuff tendons sufficiently describe the relationship between tissue changes and patients'

perceived shoulder pain.(4, 5, 20, 38) Amplifying our understanding would improve prognostic modelling for outcomes post RCR. This holds the potential to improve treatment selection choices and reduce unnecessary surgical interventions.(5, 6, 21, 28, 39)

This study aims to answer the following questions:

1. Which factors; psychosocial, sleep, central pain processing and patient demographics and characteristics, best predict shoulder function, disability, pain and quality of life in adults, 12 weeks and 12 months after RCR?

2. To what extent do these baseline factors (psychosocial: pain catastrophizing, perceived stress, injury perceptions, patients' expectations on RCR); sleep; central pain processing: central sensitization inventory, temporal summation, thermal hyperalgesia to cold, pressure pain threshold and patient characteristics) predict post-operative RCR outcome at 12 weeks and 12 months?

Methods

Study Design and setting

The longitudinal cohort study will be implemented and reported in line with the STROBE statement for observational studies.(40)

Data are obtained monocentric in the shoulder and elbow surgery unit in the clinic of orthopaedic surgery and traumatology in alliance with the institute of therapy and rehabilitation of the acute care hospital, "Kantonsspital Winterthur" in Switzerland.

The current research project will analyse data from three selected time points in the clinical routine of the RCR management; 1-21 days preoperatively (T1), 11-13 weeks

postoperatively (T2) and 12-14 months postoperatively (T3). Data from July 2019 onwards will be considered. Data collection including 12months follow-up is estimated to be complete in Summer 2022.

See table 1 for overview of measurement points.

Participants

The population of interest includes adult patients undergoing elective RCR, for tears of traumatic and non-traumatic origin.

Eligibility Criteria

Inclusion criteria:

- Adult men or women ≥18 years of age;
- Scheduled for elective arthroscopic RCR;
- First time RCR on the target shoulder

Exclusion criteria:

- Changes of intra operative procedure (e.g. anything but RCR)
- Re-repair of tendon;
- No surgery;

Outcome measures and variables

Our outcome measures are consistent with those used in the existing literature. We consulted the guidelines from the OMERACT 2016 Shoulder Core Outcome Set Special Interest Group.(41)

Our dependant variables are the *primary outcome measure* Western Ontario Rotator Cuff Index (WORC) for disease-specific function, disability and quality of life. The *secondary outcome measures* are: maximum pain over the last 7 days on Numeric Rating Scale (NRS); Constant – Murley – Score (CMS) and Subjective Shoulder Value (SSV) for shoulder function; and European Quality of Life, 5 dimensions, 5 levels (EQ-5D-5L) for quality of life and health status.

Potential prognostic factors for postoperative outcome are; psychosocial factors including 1) pain catastrophizing, 2) perceived stress, 3) injury perceptions and 4) patients' expectations for RCR; 5) sleep; CPP including 6) central sensitization inventory (CSI) to assess key somatic and emotional complaints associated to CPP 7) temporal summation (TS), 8) thermal hyperalgesia (TH, cold) and 9) pressure pain threshold (PPT).

Other potential prognostic factors include patient related characteristics such as; demographics (11) age and 12) sex; 13) trauma vs non-traumatic tendon tear; 14) health care insurance or accident insurance; health status such as 15) body mass index (bmi) and 16) comorbidities (e.g. obesity, diabetes, depression); and 17) current profession / work.

Four (AS, WB, QdG, FM) experienced and especially trained (by the first author AS) shoulder specialist physiotherapists will perform the measurements (CMS, QST, SSV, NRS Pain). Next to physical skills training, the assessment files incorporate detailed descriptions with respect to how the assessor should formulate questions and offer answer suggestions. A detailed description of the prognostic indicators we collect can be found in table 1, further details including the baseline documents can be found in the appendix.

Table 1 presents an overview of the primary and secondary outcome measures, the potential prognostic factors and measurements of change including detailed descriptions of all the measurement tool

Table 1	Type / Mode	Psychometric properties / Clinimetrics / in which cohort	T1: Baseline - 3weeks pre RCR	T2: 12 weeks post RCR	T3: 12 months post RCR
Primary outcome measure					
Shoulder function and disease specific disability quality of life	***Western Ontario Rotator Cuff Index (WORC)***	Positive evidence for 5 psychometric properties: • internal consistency, • reliability, • content validity, • hypothesis testing and • responsiveness(42, 43) German version showed satisfactory construct validity, internal consistency, test-retest reliability. No specific testing for responsiveness.(42) The minimal important difference (MID) is calculated at ≥ 300mm.(44)	x	x	x
Description	This 21 – items self-reported questionnaire represents a quality of life measure in rotator cuff pathology.(45) The WORC measures 5 dimensions (pain, sports/leisure, work, daily living, feelings) with 3-6 questions per domain, measured on a 100mm Visual Analogue Scale (VAS). Left endpoint equals “no” and right endpoint equals “extreme”. The total WORC score ranges from 0 (best) to 2100 (worst) (21 items x 100mm).				
Secondary outcome measures					
Shoulder function	***Constant – Murley Score (CMS)***	Validated in different shoulder diseases and recommended for rotator cuff and osteoarthritis patients due to highest responsiveness in these groups.(46) Reliability was moderately rated with ICCs > 0.8. Results about content and structural validity seem to be lacking.(43)	x	- No strength measure	x
	Subjective Shoulder Value (SSV)	High correlations to Constant-Murley Score, tested in diverse shoulder diseases.(46)	x	x	x
Description CMS	The Constant-Murley Score assesses shoulder function of which 35% are subjective variables (maximum pain intensity, work, sport/leisure, sleep, pain free height for light work), and 65% are objective variables (range of motion (ROM) and strength measure). A sum score of 100 represents perfect shoulder function, 0 represents no functionality.(43)				
Description SSV	The SSV is evaluated by one single standardized question:” What is the overall percent value of your shoulder, if a completely normal shoulder represents 100%?”.(46)				
Max. pain	***Numeric Rating Scale (NRS)***	Reported to be sensitive to measure change of pain level on the 11-point scale. Minimal Clinical	x	x	x

		important difference is found to be 30-33% of pain reduction.(47)			
Description	Patients are asked to indicate the maximum perceived shoulder pain felt in daily life in the last 7 days on an NRS from 0 (no pain at all) to 10 (worst imaginable pain).(48)				
Quality of life	***European Quality of Life, 5 Dimensions, 5 Levels (EQ - 5D -5L)***	Adopted and tested in Germany among general population.(49)	x	x	x
Description	The research group EuroQol developed the EQ-5D-5L tool "in order to provide a simple, generic measure of health for clinical and economic appraisal". It contains of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and depression/anxiety and 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems.(50)				
Potential Prognostic factors					
Psychosocial factors					
Catastrophic thinking	***Pain Catastrophizing Scale (PCS)***	German PCS showed same factor structure like original version and acceptable to good reproducibility.(51) Validated in Low Back Pain Patients.	x	x	x
Description	The Pain Catastrophizing Scale assesses whether or not there is presence of catastrophic thinking about pain. Thirteen items entail aspects about different thoughts and feelings whilst experiencing pain. Items are scored on a 5-point Likert scale. Higher scores indicate more severe catastrophic thinking about pain. There is a total score and a score for three subscales (e.g. helplessness, magnification and rumination) (52).				
Perceived distress	***Perceived Stress Scale (PSS)***	The German version showed good psychometric properties like validity and reliability in the general population.(53)	x	x	x
	The Perceived Stress Scale (PSS – 10) includes 10 questions and assesses the degree to which life has been experienced as unpredictable, uncontrollable and overloaded in the past months. The questions are answered by "yes" (1) or "no" (0). The questions are general in nature and therefore the usage for shoulder pain patients undergoing RCR is reasonable.				
Perceptions about injury	***Illness Perception Questionnaire – Revised (IPQ-R)***	The clinimetric properties for musculoskeletal pain are reported to be sufficient.(54) For rotator cuff tears and rotator cuff repair, the word "injury" seems to be more matching, therefore we exchanged the word illness (German: Krankheit) with injury (in German Verletzung).	x	x	x
Description	Designed to assess the cognitive and emotional representations of illness. The items are formed by experiences, provided information and interpretation of symptoms. The IPQ-R is not disease specific and may be used in any group of interest.(55) The questionnaire has 9 dimensions of injury perception: 1) Timeline (acute/chronic), 2) Consequences, 3) Personal control, 4) Treatment control 5), Injury coherence, 6) Timeline cyclical, 7) Emotional representations as well as 8) Identity and 9) Causes. We amalgamated dimensions 1) and 6) into "timeline" and dimensions				

	3) and 4) into "control" and end up with 6 subscales for illness perceptions and one for caused. Further it includes 3 domains.(56, 57) The first domain is called illness identity, the second is called the beliefs domain and the third is labelled as the consequence domain.(58) The authors adjusted the questionnaire to the cohort and exchanged illness with injury. The 32 injury perceptions and 18 causes answers are captured on a 5-point Likert scale from "strongly disagree" (1) to "strongly agree"(5).				
Expectations	***Study designed, 6 Questions about expectations***	Lack of German translated questionnaires in the field. Consequently, the research team formulated 6 Questions from the literature (12, 13) by also studying the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) questionnaire.(29)	x	-	-
Description	Patients' expectations will be assessed using 5 questions: 1) expected shoulder function in percentage at 12 weeks post OP 2) expected shoulder function at 12 months postop 3) expected pain reduction in percentage at 12 weeks post OP 4) expected pain reduction in percentage at 12 months post OP 5)/6) open questions about driver for high (>80%) or low (<80%) expectations for shoulder function and pain reduction.				
Sleep					
	Study designed, 4 Questions about sleep quality and behaviour	Due to study feasibility, we formulated 4 questions. Not validated.	x	x	x
Description	4 Questions regarding sleep quality, sleep efficiency, sleep disturbance, number of awakening per night. The first question is transformed from the Pittsburgh Sleep Quality Index (PSQI), for sleep quality and is rated on a 4-point Likert Scale. The question 2 to 3 are formulated by suggestion from research(59) and adapted to shoulder pain by the first author.				
Central Pain Processing (CPP)					
Self-reported symptoms of central Sensitisation	***Central Sensitisation Inventory (CSI)***	It is a high-quality measurement tool, with high construct validity and test-retest reliability. The defined cut-off point is at 40 points.(60) German version is to be validated by the research group among Laekemann. Contract for their usage.	x	x	x
Description	The original English questionnaire was developed in 2011 (61) to assess key symptoms in relation to central sensitivity symptoms (CSS) and to assess key somatic and emotional complaints associated to CPP. It consists of two parts; Part A with 25 items relating to pain, psychosocial aspects, cognitive and functional aspects. Part B with 7 different CSSs, like restless legs, irritable bowel, and multiple chemical sensitivities and 3 disorders like neck pain (whiplash), depression and anxiety or panic attacks.				
Temporal summation	***Frey hair filament, 10g calibrated***	No factor analysis available for testing loading of TS for CPP. TS is a common method in research to measure CPP.(62)	x	x	x
Description	Locations for applications will be at two local and one remote site: 1. Local painful site: the most painful site of the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized				

	site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral belly of anterior tibial muscle at 5cm distal to the tibial tuberosity and 2cm laterally (63). The patient is asked to rate the first touch on an NRS from 0 (no pain at all) to 10 (worst imaginable pain). Then the measurement is repeated once per second (1Hz) for 30 seconds on a surface of maximum 1 cm^2, (48). The standardization of the frequency is important, as wind-up of the C-fibers only arrives if the stimulus is provided at least once every 3 seconds (<0.33Hz).(64) After the 30 seconds application, the patient is asked to rate the last touch on an NRS. The difference between the last and the first rating is calculated. Fifteen seconds after the test, patients need to rate any ongoing pain sensation on NRS again.(65) Patients will be advised that the method does not aim to measure pain tolerance (66) and a number should only be given if the sensation was burning, stabbing, pulling or gnawing.				
Thermal hyperalgesia (TH) cold	***Ice pack***	No factor analysis available for testing loading of TH for CPP. TH is a common method in research to measure CPP.(62)	x	x	x
Description	Cold hyperalgesia is measured with a cold pack, kept in the deep freezer which is simultaneously the cubes for the ice test.(67) Locations for applications will be at two local and two remote sites: 1. Local painful site: the most painful site on the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral belly of anterior tibial muscle at 5cm distal to the tibial tuberosity and 2cm laterally.(63) The cold application is kept for 10 seconds, and the patients will rate the experienced pain on a NRS from 0 (no pain at all) to 10 (worst imaginable pain).(67) Patients will be advised the measurement does not aim for pain tolerance and the pain should be reported if a burning, stabbing, pulling or gnawing sensation is felt.(66)				
Pressure Pain Threshold (PPT)	***Wagner Instruments***	No factor analysis available for testing loading of PPT for CPP. PPT is a common method in research to measure CPP.(62)	x	x	x
Description	PPT represents a static psychophysical test, which measures the point of pressure evolving into pain. Its report of large to nearly perfect reliability in neck pain patients, demonstrates its great potential as measurement tool also for the present cohort.(68) The measurements will be conducted by digital hand-held pressure algometer with a rubber tip of approximately 1 cm^2 (FPX 50, FORCE TEN by Wagner Instruments), increasing pressure will be given perpendicular to the skin.(69) Measurements are taken at five standardized sites. 1. Two cm caudal from the acromion at the muscle belly of middle deltoid, bilaterally. 2. At the muscle belly in middle of the upper trapezius, bilaterally. 3. At the contralateral anterior tibial muscle belly at 5cm distal to the tibial tuberosity and 2cm laterally, as remote site.(63) All measurements will be repeated once and the mean PPT in kilopascals per site will be calculated.				
Pain distribution and localisation	***Body Chart***		x	x	x
Description	Patients report their pain location and pain distribution. The assessor is painting the body chart.				
Additional prognostic factors					
Age	Date of birth				

Sex	Female / male				
Cause of tear	Traumatic vs. non-traumatic /				
Insurance type	Health care insurance vs accident insurance				
Body Mass Index (BMI)	Kg and cm				
Comorbidities	Diabetes Coronary Heart Disease (KHK) Rheumatological Diseases Depression Adiposity Insomnia Sleep Apnea Neurological Diseases Hypertension Asthma Back Pain / Neck Pain Others None N/A				
Profession	Current work: Manual labor (painter, carpenter, locksmith.) Construction (Streets, buildings...) Office work Repetitive work (supermarket, post office, industry, hairdresser...) Health Care Practitioner (nurse, medical doctor, PT, OT...) Pensioner Student other N/A				
Self-reported measures of change					
Anchor for Change	***Global Rating of Change (GRoC)***	Satisfactory test-retest reliability ICC 0.90, construct validity: correlation to diverse questionnaires e.g. Euroqol, Pain rating scale, face validity r= 0.7-0.9, Minimal Clinical Important Change 2 Points on 11-point scale.(70)	-	x	x
Description	Represents an anchor of change, not a true change. GRoC is simple and easy to administer it is recommended to include an 11-point scale with endpoints at -5 and +5, with -5 = “very much worse”, 0 = “no change” and +5 = “completely recovered”. The recommendation for the single question				

	asked by the assessor is: “With respect to your shoulder problem, how would you describe yourself now compared to pre-surgery?”(70)				
Satisfaction	***Satisfaction questionnaire***	No validation of this questionnaire into German language. Forward backward translation with native speakers and expert physiotherapists was best compromise.	-	-	x
	Self-rated questionnaire containing 8 questions. Four questions cover current state of satisfaction, 1 question asks for quality of life improvement, 2 questions ask about repetition of surgery and recommendation for others and 1 question asks for timing of the surgery. The survey originates from total shoulder arthroplasty research(71) and is modified to RCR. It is clear and simple to administer.				
CPP = Central Pain Processing, CSI = Central Sensitisation Inventory, CSS = Central Sensitivity Symptoms EQ-5D-5L = EuroQol, GRoC = Global Rating of Change, IPQ-R = Illness Perception Questionnaire – Revised, NRS = Numeric Rating Scale, PCS = Pain Catastrophising Scale, PPT = Pressure Pain Threshold, PROM = Patient Rated Outcome Measure, PSS = Perceived Stress Scale, PT = Physiotherapist, QST = Quantitative Sensory Testing, SSV = Subjective Shoulder Value, TS = Temporal Summation, WORC = Western Ontario Rotator Cuff Index					

Table 1: Outcome measures and potential prognostic factors

Sample Size

We will use a linear mixed-effects regression model for repeated measures. This will have the power to detect a moderate effect size that is still clinically relevant (15% difference in WORC score) (72) with confidence level α=0.5, (two-tailed) and a desired power of 90%. The required total sample size was calculated to be 125 subjects (R, Edland package).(73, 74) Mixed models do not require complete datasets to produce accurate results, through correct specification of the likelihood function.(75) The power is set at 90% to minimize the chance of making a type II error.

Statistical Methods and Analysis

Statistical analyses will be performed using SAS (SAS 9.4, SAS Institute Inc., Cary, NC, USA). Level of significance is set at p = 0.05. Measurements will take place at three time points in the perioperative management, as described above (T1 = at baseline 2-3 weeks prior to RCR, T2 = at 12 weeks post RCR and T3 = at 12 months post RCR as follow-up).

The primary outcome (WORC) will be analysed using multilevel linear regression models for repeated (longitudinal) measures, using an unstructured covariance matrix. Dependent variables are the primary and secondary outcomes. Continuous secondary outcomes will be assessed in a similar way to the primary outcome. The models will be developed by stepwise reduction of the *a priori* determined 17 potential prognostic factors (as described above). A factor will be retained in the model if it has a significant effect on the initial outcome, on the outcome over time or if the fit statistics (Deviance, AIC, BIC and R2) of the model improves after reduction of the variable, in order to increase the precision of the fixed effects estimates.(75-77)

Data security and management

Data generation, transmission, storage and analysis within this project strictly follow Swiss legal requirements for data protection. The electronic data capture (EDC) software REDCap (78, 79) will be used for data processing and management. REDCap was developed by an informatics core at Vanderbilt University in 2004, with ongoing support from US National Center for Research Resources (NCRR) and US National Institute of Health (NIH), grants NIH/NCATS UL1 TR000445. REDCap was specifically developed around HIPAA security guidelines and is Good Clinical Practice-compliant and fulfils the regulatory requirements regarding the collection of patient data in clinical trials or non-interventional studies and patient registries and the EU data protections laws. Appropriate coded identification (e.g. pseudonymisation) is used in order to enter subject data into the database. The coding list of target data is saved in a secured folder on the hospital's server. Only the project leader, study nurses and principal investigator have access to it. Between the members of the research team only coded and de-identified data will be shared. Safe handling of the coded data will be covered by the software REDCap.

Study Monitoring

An audit trail and history of data transmission are provided by REDCap. The steering committee of the research project will oversee all aspects of design, delivery, quality assurance and data analysis according to good clinical practice and local legislation.

Ethics and dissemination

The study follows the principles of the Helsinki Declaration. Only data of patients who gave general consent to the hospital or informed written consent to the project will be considered for analysis. Ethical approval received January 2019 (ID 2018-02089) by the Ethical Committee of the Canton of Zurich, Switzerland.

Dissemination of results

The research team is committed to full disclosure of the results of the study. The results of the study will be disseminated for research purpose at different conferences and as published articles in peer reviewed journals. Findings will be reported in accordance to the STROBE statement and we aim to publish in high impact journals.

Authors' contributions

AS simultaneously is the project leader, who receives support from FS and MM with respect to topic and study design. TS controls the statistical model and will support statistical data analysis. MM and PB contribute to the protocol by reviewing and providing feedback. DG and MP support the feasibility of the study and provide access to clinical data in daily routine of the physiotherapy and orthopaedic clinic and support data security by providing REDCap software. AS wrote the protocol together with FS and MM.

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Competing of Interest

The authors declare no conflicts of interest.

Patients' consent for publication

Obtained

Provenance and peer review

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Appendix

1. Baseline Assessment

Patientenkennzeichen:

Quantitativ Sensorische Testung - QS

Datum:.....**betr. Seite:**.....

Schmerzgebiet 1 :.....

Temporal summation (TS) Differenz NRS 0-10	**Links**		**Rechts**		**Differenz: Letzter minus erster Wert**	**Sz 15 Sek. Nach Anwendung**
	Erster	Letzter	Erster	Letzter		
Schmerzgebiet 1 (lokal)						
Trapezius desc. ipsilateral						
Tib. Anterior kontralateral						

Gerät: Monofilament 30g.
Lokalisation: Schmerzhafte Stelle/n UND Tibialis anterior kontralaterale Seite.

Pressure Pain Threshold (PPT)	**Links**			**Rechts**		
	1. Messung	2. Messung	Durchschnittswert	1. Messung	2. Messung	Durchschnittswert
Deltoideus p. acromialis						
Trapezius p. descendens						
Tibialis anterior						

Durchführung: Monofilament muss sich **immer maximal beugen**. 1. Berührung 0-10/10 NRS, danach Berührungen am selben Ort (1cm^2) in 1Hz Frequenz (1 pro Sekunde) für 30Sek → Maximaler Wert angeben. UND wie ist der Schmerz 15sek nach der Anwendung?
Anweisung an den Patienten: Auf einer Skala von 0-10, wie stark schmerzt diese Berührung (bohren, ziehen, stechen oder brennen)
Auswertung: Differenz: letzte Zahl minus erste Zahl

Gerät: FORCE Ten FDX50. Immer im 90° Winkel zum Muskelbauch halten.
Lokalisation: Deltoideus p. acromialis: 2cm Kaudal des Acromions, Muskelbauch; Trapezius descendens: Muskelbauch zwischen lat. Drittel Klavikula und C7; Tibialis anterior: Muskelbauch.
Durchführung: ca. 5N/Sek. Druck steigern, Display nach unten halten, 30Sek Pause zwischen JEDER Messung, 2 Messungen pro Lokalisaiton, IMMER bilateral Schulter messen, nur kontralateral Tib. Ant. messen
Auswertung: Durchschnittswert nehmen.
Anweisung an den Patienten: Geben Sie an, ab wann sich der Druck in Schmerz verwandelt und sagen Sie klar und deutlich STOPP.

Sensibilität auf (Eis)Kälte 5 Sek. NRS 0-10	**Links**	**Rechts**
Schmerzgebiet 1 (lokal)		
Trapezius descendens ipsilateral		
Tibialis anterior kontralateral		

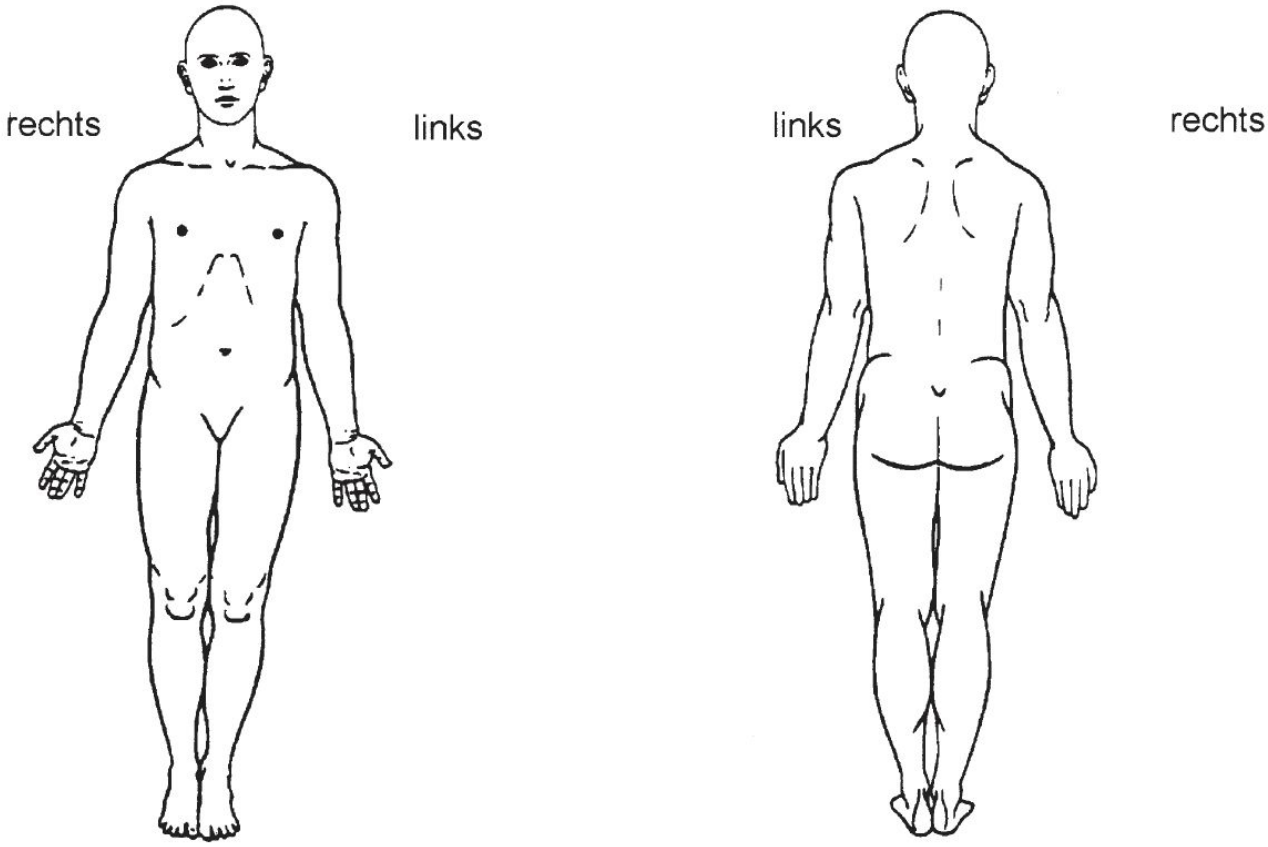
Gerät: Coldpack aus Tiefkühler, vor jeder Messung neu.
Durchführung: 10sek. Eisanwendung, dann NRS 0-10/10
Anweisung an den Patienten: Ist diese Kälteanwendung schmerzhaft für Sie? (bohren, ziehen, stechen oder brennen) NRS 0-10/10

Datum:……
…….

Patienten
ID:……..

Betr.
Seite:……

Wo verspüren Sie Schmerzen? Welches ist der Hauptschmerz?



Numeric Rating Scale – NRS 0 - 10

Was ist der maximale Schmerz, den Sie in Ihrem alltäglichen Leben verspüren?

_____/10

Constant-Schulter–Score

Name, Vorname:_____ Geb.-Datum:_____ Untersuchungsdatum:_____	Betroffene Schulter: □ re □ li Dominanter Arm: □ re □ li

Schmerzen: (der am stärksten verspürte im Verlauf des täglichen Lebens)

keine	milde	mäßig	**starke Schmerzen**
	0 – 1 – 2 – 3 – 4 – **5** – 6 – 7 – 8 – 9 – **10** – 11 – 12 – 13 – 14 – **15**		
Punkte:	15 – 14 - 13 – 12 – 11 – 10 – 9 – 8 –7 – 6 – 5 – 4 – 3 – 2 – 1 – 0		

_____ **15**

Alltagsaktivitäten

Arbeitsfähigkeit:	0 – 1 – 2 – 3 – 4
Freizeit-/Sportfähigkeit	0 – 1 – 2 – 3 – 4
Schlaffähigkeit	0 – 1 – 2
Handreichweite: Verrichtung von Arbeiten schmerzlos möglich bis: Keine Arbeit (0) - Gürtellinie – Xiphoid – Hals – Scheitel - über den Kopf hinaus (10)	0-2 – 4 – 6 – 8 - 10

_____ **20**

Mobilität: Schmerzfrei + aktiv !

	Flexion	**Abduktion:**
0° - 30°	0	0
31° - 60°	2	2
61° - 90°	4	4
91° - 120°	6	6
121° - 150°	8	8
151° - 180°	10	10

Außenrotation: (Punkte jeweils addieren)

Hand auf dem Scheitel, Ellenbogen nach vorne	2
Hand auf dem Scheitel, Ellenbogen zur Seite	2
Hand am Hinterkopf, Ellenbogen nach vorne	2
Hand am Hinterkopf, Ellenbogen zur Seite	2
Uneingeschränkte Überkopfbeweglichkeit	2

Innenrotation:

Handrücken auf Außenseite des Oberschenkels	0
Handrücken auf Gesäß	2
Handrücken auf lumbosacralem Übergang	4
Handrücken auf Gürtellinie (3. LWK)	6
Handrücken auf 12. Rückenwirbel	8
Handrücken zwischen den Schulterblättern	10

_____ **40**

Kraft: Messwert:_____kg ____Punkte; entsprechenden Punktwert unten markieren

90° Abduktion in der Scapularebene (30° Anteversion), Hand proniert.
Messung mit Isobex Kraftmessgerät (Cursor AG, Bern, Schweiz). 1 Punkt entspricht einem Pfund (=0,45 kg)
1 P 0,45 kg **6 P** 2,7 kg **11 P** 4,95 kg **16 P** 7,2 kg **21 P** 9,45 kg **2 P** 0,9 kg **7 P** 3,15 kg **12 P** 5,4 kg **17 P** 7,65 kg **22 P** 9,9 kg **3 P** 1,35 kg **8 P** 3,6 kg **13 P** 5,85 kg **18 P** 8,1 kg **23 P** 10,35 kg **4 P** 1,8 kg **9 P** 4,05 kg **14 P** 6,3 kg **19 P** 8,55 kg **24 P** 10,8 kg

5 P 2,25 kg **10 P** 4,5 kg **15 P** 6,75 kg **20 P** 9,0 kg **25 P** 11,25 kg	
Subjective Shoulder Value (SSV): _____/100%	**25**

Untersucher:_____ Gesamtpunktzahl: _____/100

2. Baseline Questionnaire

Patientenetikette

Sehr geehrte Patientin, sehr geehrter Patient

Dies sind 8 Fragebögen zu Ihrer Schulterproblematik. Wir möchten Sie bitten, diese zu Hause oder im Verlauf des Morgens der SDS Sprechstunden bei der Physiotherapie, Orthopädie und Anästhesie auszufüllen.

Diese Fragen dienen dazu, die Einschränkung durch die Schulterprobleme bestimmter zu erfassen und den Behandlungsverlauf individuell auf Sie anzupassen.

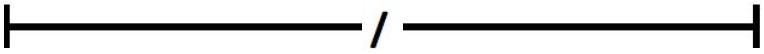
Bitte NICHT per Post senden, sondern bei Ihrem präoperativen Termin am KSW der Physiotherapeutin / dem Physiotherapeuten abgeben.

Herzlichen Dank
Ihr KSW-Schulter-Team

Western Ontario Rotator Cuff Index – WORC

Teil 1: Körperliche Beschwerden

Die folgenden Fragen betreffen die Beschwerden, die Sie aufgrund Ihrer Schulterproblematik haben. Bitte tragen Sie bei jeder Frage jenen Schweregrad Ihrer Beschwerden ein, den Sie in der letzten Woche verspürt haben, indem Sie auf der horizontalen Linie ein **«/»** machen.

Beispiel: 

1. Wie viel stechende Schmerzen verspüren Sie in Ihrer Schulter?	
kein Schmerz	extremer Schmerz

2. Wie viel konstanten, bohrenden (nagenden) Schmerz verspüren Sie in Ihrer Schulter?	
kein Schmerz	extremer Schmerz

3. Wie viel Schwäche verspüren Sie in Ihrer Schulter?	
Keine Schwäche	extreme Schwäche

4. Wie viel Steifheit oder Mangel an Bewegung verspüren Sie in Ihrer Schulter?	
Keine Steifheit	extreme Steifheit

5. Wie sehr stört Sie ein Klicken, Reiben oder Knirschen in Ihrer Schulter?	
Überhaupt nicht	extrem

6. Wie viel Unbehagen verspüren Sie in Ihrer Nackenmuskulatur?	
kein Unbehagen	extremes Unbehagen

Teil 2: Sport / Freizeit

In den folgenden Fragen geht es darum wie stark Ihre Schulterproblematik Ihre Arbeit, Sport- und Freizeitgewohnheiten in der letzten Woche beeinflusst hat. Bitte tragen Sie wiederum den Schweregrad mittels eines **«/»** auf der horizontalen Linie ein.

7. Wie sehr hat Ihre Schulter Ihren Fitness Zustand beeinträchtigt?	
keine Beeinträchtigung	extreme Beeinträchtigung

8. Wie viel Schwierigkeiten bereitet Ihnen Ihre Schulter bei Liegestütz oder anderen anstrengenden Schulterübungen?	
keine Schwierigkeiten	extreme Schwierigkeiten

9. Wie sehr hat Ihre Schulter Ihre Fähigkeiten weit oder scharf zu werfen beeinflusst?	
kein Einfluss	extremer Einfluss

10. Wie sehr befürchten Sie die Berührung Ihrer Schulter mit einer Person oder einem Gegenstand?	
keine Angst	extreme Angst

Teil 3: Arbeit

Der folgende Teil beschäftigt sich mit der Summe Ihrer Schulterprobleme bei Ihrer Arbeit in und ausserhalb des Hauses. Bitte beurteilen Sie die Summe der **letzten Woche** mit einem **«/»**.

11. Wie viel Schwierigkeiten haben Sie bei Ihrer täglichen Arbeit im Haus und im Garten?	
keine Schwierigkeiten	extreme Schwierigkeiten

12. Wie viel Schwierigkeiten haben Sie bei Arbeiten über dem Schulterniveau?	
keine Schwierigkeiten	extreme Schwierigkeiten

13. Wie viel benützen Sie Ihren nicht betroffenen Arm um Ihren verletzten zu ersetzen?

überhaupt nicht	dauernd

14. Wie viel Schwierigkeiten haben Sie beim Heben schwerer Lasten auf oder unter das Schulterniveau?	
keine Schwierigkeiten	extreme Schwierigkeiten

Teil 4: Alltag

Der folgende Teil beinhaltet Fragen, wie sehr Ihr Schulterproblem, Ihren Alltag beeinflusst. Abermals, bitte berücksichtigen Sie die Summe der letzten Woche und markieren Sie mit einem «/».

15. Wie viel Schwierigkeiten haben Sie beim Schlafen wegen Ihrer Schulter?	
keine Schwierigkeiten	extreme Schwierigkeiten

16. Wie viel Schwierigkeiten haben Sie beim Frisieren wegen Ihrer Schulter?	
keine Schwierigkeiten	extreme Schwierigkeiten

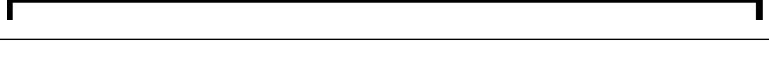
17. Wie viel Schwierigkeiten haben Sie beim Herumtollen oder «Herumziehen» mit Ihrer Familie oder Freunden?	
keine Schwierigkeiten	extreme Schwierigkeiten

18. Wie viel Schwierigkeiten haben Sie beim An- oder Ausziehen wegen Ihrer Schulter?	
keine Schwierigkeiten	extreme Schwierigkeiten

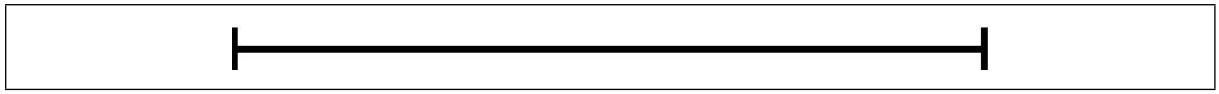
Teil 5: Gefühle

Die folgenden Fragen beziehen sich darauf, wie Sie sich in der letzten Woche wegen Ihrer Schulter gefühlt haben? Bitte markieren Sie Ihre Antwort mit einem **«/».**

19. Wie sehr fühlen Sie sich wegen Ihrer Schulter frustriert?	
keine Frustration	extreme Frustration

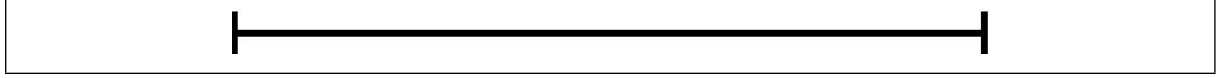


20. Wie deprimiert oder «am Boden zerstört» sind Sie wegen Ihrer Schulter?	
überhaupt nicht	extrem



21. Wie besorgt oder beunruhigt sind Sie bezüglich des Einflusses Ihrer Schulter auf Ihre berufliche Tätigkeit?

nicht beunruhigt	extrem beunruhigt



CENTRAL SENSITIZATION INVENTORY German version (CSI-GE)
„Zentraler Sensibilisierungsfragebogen“ TEIL A

Bitte umkreisen Sie bei jeder Aussage die für Sie aktuell am besten passende Antwort auf der rechten Seite.

1. Wenn ich morgens aufwache, fühle ich mich müde und nicht erholt.	nie	selten	gelegentlich	oft	immer
2. Meine Muskeln fühlen sich steif und schmerzhaft an.	nie	selten	gelegentlich	oft	immer
3. Ich habe Angstattacken.	nie	selten	gelegentlich	oft	immer
4. Ich knirsche oder beiße meine Zähne zusammen.	nie	selten	gelegentlich	oft	immer
5. Ich habe Probleme mit Durchfall und/oder Verstopfung.	nie	selten	gelegentlich	oft	immer
6. Ich brauche Hilfe bei der Verrichtung meiner Alltagstätigkeiten.	nie	selten	gelegentlich	oft	immer
7. Ich reagiere empfindlich auf helles Licht.	nie	selten	gelegentlich	oft	immer
8. Ich ermüde sehr schnell bei körperlichen Aktivitäten.	nie	selten	gelegentlich	oft	immer
9. Ich habe am ganzen Körper Schmerzen.	nie	selten	gelegentlich	oft	immer
10. Ich habe Kopfschmerzen.	nie	selten	gelegentlich	oft	immer
11. Meine Blase fühlt sich unangenehm an und/oder ich habe Brennen beim Wasserlassen.	nie	selten	gelegentlich	oft	immer
12. Ich schlafe nicht gut.	nie	selten	gelegentlich	oft	immer
13. Ich habe Konzentrationsschwierigkeiten.	nie	selten	gelegentlich	oft	immer
14. Ich habe Hautprobleme, wie z.B. trockene oder juckende Haut oder Hautausschlag.	nie	selten	gelegentlich	oft	immer
15. Stress verstärkt meine körperlichen Beschwerden.	nie	selten	gelegentlich	oft	immer
16. Ich fühle mich traurig oder niedergeschlagen.	nie	selten	gelegentlich	oft	immer
17. Ich habe wenig Energie.	nie	selten	gelegentlich	oft	immer
18. Ich habe Muskelverspannungen im Nacken- und Schulterbereich.	nie	selten	gelegentlich	oft	immer
19. Ich habe Kieferschmerzen.	nie	selten	gelegentlich	oft	immer

20. Mir wird von manchen Gerüchen, wie z.B. Parfüm, schwindlig und übel.	nie	selten	gelegentlich	oft	immer
21. Ich muss häufig Wasserlassen.	nie	selten	gelegentlich	oft	immer
22. Meine Beine fühlen sich unangenehm und ruhelos an, wenn ich versuche nachts einzuschlafen.	nie	selten	gelegentlich	oft	immer
23. Ich habe Schwierigkeiten, mich an Dinge zu erinnern.	nie	selten	gelegentlich	oft	immer
24.Ich erlitt als Kind traumatische Erlebnisse	nie	selten	gelegentlich	oft	immer
25. Ich habe Schmerzen im Beckenbereich.	nie	selten	gelegentlich	oft	immer
nie = 0, immer = 4	**Gesamtsumme =**				

Version 08.05.2018 CENTRAL SENSITIZATION INVENTORY German version (CSI-GE)
Expertenkomitee: M. Laekeman, K. Kuss, D. Seeger, A. Schäfer, A. Dieterich, F. Petzke
Übersetzungsteam: A. Dieterich, U. Mazolek, U. Paul, D. Hogan, F. Laporte Uribe / Pretest: S. Ehrhardt, A. Schäfer, M. Laekeman

CENTRAL SENSITIZATION INVENTORY German version (CSI-GE)
„Zentraler Sensibilisierungsfragebogen“ TEIL B

Hat ein Arzt/eine Ärztin bei Ihnen eine der folgenden Diagnosen gestellt? Bitte kreuzen Sie auf der rechten Seite die passende Antwort zu jeder ärztlichen Diagnose an und geben Sie das Jahr an in dem die Diagnose gestellt wurde.

	NEIN	JA	Jahr der Diagnosestellung
1. Restless-Legs-Syndrom (Syndrom der unruhigen Beine)			
2. Chronisches Erschöpfungssyndrom (Chronisches Fatigue Syndrom)			
3. Fibromyalgie			
4. Kiefergelenks-Funktionsstörung (Craniomandibuläre Dysfunktion)			
5. Migräne oder Spannungskopfschmerz			
6. Reizdarmsyndrom (Colon irritabile)			
7. Unverträglichkeit gegen verschiedene chemische Substanzen (Multiple Chemical Sensitivity)			
8. Nackenverletzung (einschließlich Schleudertrauma)			
9. Angst- oder Panikattacken			
10. Depression			

Anmerkungen:

Version 08.05.2018 CENTRAL SENSITIZATION INVENTORY German version (CSI-GE) Expertenkomitee: M. Laekeman, K. Kuss, D. Seeger, A. Schäfer, A. Dieterich, F. Petzke Übersetzungsteam: A. Dieterich, U. Mazolek, U. Paul, D. Hogan, F. Laporte Uribe / Pretest: S. Ehrhardt, A. Schäfer, M. Laekeman

Ein wichtiger Faktor rund um die Operation ist Ihre Erwartung. Danach möchten wir Sie hier gerne fragen.

Erwartungen an die Operation

1. Wieviel Prozent (%) **Schulterfunktion** (Beweglichkeit / Kraft / Einsatz des Armes) erwarten Sie zu erreichen durch die Operation?

Zeitpunkte:
3 Monaten nach der Operation:

……%

1 Jahr nach der Operation:

……..%

2. Wieviel Prozent (%) **Beschwerden Reduktion** (Schmerzen / Steifigkeit / Schwäche) erwarten Sie zu erreichen durch die Operation?

Zeitpunkte:
3 Monate nach der Operation:

……%

1 Jahr nach der Operation:

……..%

3. Welches sind Gründe, warum Sie hohe Erwartungen an die Operation haben?

……
……
……
……
……
……

4. Welches sind Gründe, warum Sie eher mittlere bis tiefe Erwartungen an die Operation haben?

……
……
……
……
……
……

PCS (© Kathrin Meyer et. al., Journal of Psychosomatic Research 64 (2008): 469-478**)**

Name, Vorname, Jahrgang: …… Datum: ……

Bitte lesen Sie jeweils die Einleitung und füllen Sie alle nachfolgenden Fragen aus.
Irgendwann im Leben erleidet jeder Mensch einmal Schmerzen. Dies können z. B. Kopf-, Zahn-, Gelenk oder Muskelschmerzen sein. Menschen sind oft Situationen ausgesetzt, die Schmerzen verursachen, wie Krankheiten, Verletzungen, Zahnbehandlungen oder Operationen. Wir sind an den Gedanken und Gefühlen interessiert, die Sie haben, wenn Sie Schmerzen erleiden.
Die folgenden dreizehn Sätze beschreiben verschiedene Gedanken und Gefühle, die bei Schmerzen auftreten können. Bitte markieren Sie auf der folgenden Skala, wie stark diese Gedanken und Gefühle auf Sie zutreffen, wenn Sie Schmerzen haben.

Bewertung	**0**	**1**	**2**	**3**	**4**
Bedeutung	Trifft überhaupt nicht zu	trifft eher nicht	Teils-teils	Trifft eher zu	Trifft immer zu
1. Ich mache mir ständig Sorgen, ob die Schmerzen wohl jemals wieder aufhören werden?	**0**	**1**	**2**	**3**	**4**
2. Ich denke, ich kann nicht mehr.	**0**	**1**	**2**	**3**	**4**
3. Der Zustand ist schrecklich und ich denke, dass es nie mehr besser wird.	**0**	**1**	**2**	**3**	**4**
4. Der Zustand ist furchtbar und droht mich zu überwältigen.	**0**	**1**	**2**	**3**	**4**
5. Ich habe das Gefühl, ich halte es nicht mehr aus.	**0**	**1**	**2**	**3**	**4**
6. Ich bekomme Angst, dass die Schmerzen noch stärker werden.	**0**	**1**	**2**	**3**	**4**
7. Ich denke ständig an andere Situationen, in denen ich Schmerzen hatte.	**0**	**1**	**2**	**3**	**4**
8. Ich wünsche mir verzweifelt, dass die Schmerzen weggehen.	**0**	**1**	**2**	**3**	**4**
9. Ich kann nicht aufhören, an die Schmerzen zu denken.	**0**	**1**	**2**	**3**	**4**
10. Ich denke ständig daran, wie sehr es schmerzt.	**0**	**1**	**2**	**3**	**4**
11. Ich denke ständig daran, wie sehr ich mir ein Ende der Schmerzen herbeiwünsche.	**0**	**1**	**2**	**3**	**4**
12. Es gibt nichts was ich tun kann, um die Schmerzen zu lindern.	**0**	**1**	**2**	**3**	**4**
13. Ich mache mir Sorgen, dass die Schmerzen auf etwas Schlimmes hindeuten.	**0**	**1**	**2**	**3**	**4**

Total: _____

PSS-DE

49. Kreuzen Sie bitte das Kästchen an, das Ihrer Zustimmung am besten entspricht.

		nie	fast nie	manch-mal	ziemlich oft	sehr oft
01	Wie oft wurden Sie im letzten Monat von unerwarteten Ereignissen überrascht?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
02	Wie oft hatten Sie im letzten Monat das Gefühl, dass es Ihnen nicht möglich ist, wichtige Dinge in Ihrem Leben zu kontrollieren?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
03	Wie oft haben Sie sich im letzten Monat nervös oder „gestresst" gefühlt?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
04	Wie oft haben Sie sich im letzten Monat zuversichtlich gefühlt, dass Sie in der Lage sind, persönliche Probleme zu regeln?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
05	Wie oft hatten Sie im letzten Monat das Gefühl, dass die Dinge in Ihrem Leben genauso laufen, wie sie es sollten?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
06	Wie oft hatten Sie im letzten Monat das Gefühl, dass Sie mit anfallenden Aufgaben nicht zu Rande kommen?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
07	Wie oft waren Sie in der Lage mit Widrigkeiten des Lebens kontrolliert umzugehen?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
08	Wie oft fühlten Sie sich als Herr der Lage?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
09	Wie oft haben Sie sich über Dinge geärgert, die außerhalb Ihrer Kontrolle lagen?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
10	Wie oft hatten Sie das Gefühl, dass sich Schwierigkeiten so sehr auftürmten, dass sie Ihnen über den Kopf wachsen?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Quelle: Klein, E. M., Brähler, E., Dreier, M., Reinecke, L., Müller, K. W., Schmutzer, G., ... & Beutel, M. E. (2016). The German version of the Perceived Stress Scale–psychometric characteristics in a representative German community sample. *BMC psychiatry*, *16*(1), 159.

Schlaf

1. Schlafqualität

Wie würden Sie insgesamt die Qualität Ihres Schlafes während der letzten vier Wochen beurteilen?

☐ sehr gut	☐ ziemlich gut	☐ ziemlich schlecht	☐ sehr schlecht

2. Falls ihr Schlaf gestört ist, seit wann ist das so?

.....

3. Anzahl Erwachen pro Nacht

Wie oft erwachen Sie durchschnittlich wegen Ihrer Schulter pro Nacht?

Antwort: ……Mal

4. Schlafeffizienz

a. Wieviele Stunden liegen Sie durchschnittlich im Bett? .....Stunden

b. Wieviele Stunden davon sind sie am Schlafen?.....Stunden

Bitte kreuzen Sie unter jeder Überschrift DAS Kästchen an, das Ihre Gesundheit HEUTE am besten beschreibt.

BEWEGLICHKEIT / MOBILITÄT

Ich habe keine Probleme herumzugehen ❑
Ich habe leichte Probleme herumzugehen ❑
Ich habe mässige Probleme herumzugehen ❑
Ich habe grosse Probleme herumzugehen ❑
Ich bin nicht in der Lage herumzugehen ❑

FÜR SICH SELBST SORGEN

Ich habe keine Probleme, mich selbst zu waschen oder anzuziehen ❑
Ich habe leichte Probleme, mich selbst zu waschen oder anzuziehen ❑
Ich habe mässige Probleme, mich selbst zu waschen oder anzuziehen ❑
Ich habe grosse Probleme, mich selbst zu waschen oder anzuziehen ❑
Ich bin nicht in der Lage, mich selbst zu waschen oder anzuziehen ❑

ALLGEMEINE TÄTIGKEITEN *(z.B. Arbeit, Studium, Hausarbeit, Familien- oder Freizeitaktivitäten)*

Ich habe keine Probleme, meinen alltäglichen Tätigkeiten nachzugehen ❑
Ich habe leichte Probleme, meinen alltäglichen Tätigkeiten nachzugehen ❑
Ich habe mässige Probleme, meinen alltäglichen Tätigkeiten nachzugehen ❑
Ich habe grosse Probleme, meinen alltäglichen Tätigkeiten nachzugehen ❑
Ich bin nicht in der Lage, meinen alltäglichen Tätigkeiten nachzugehen ❑

SCHMERZEN / KÖRPERLICHE BESCHWERDEN

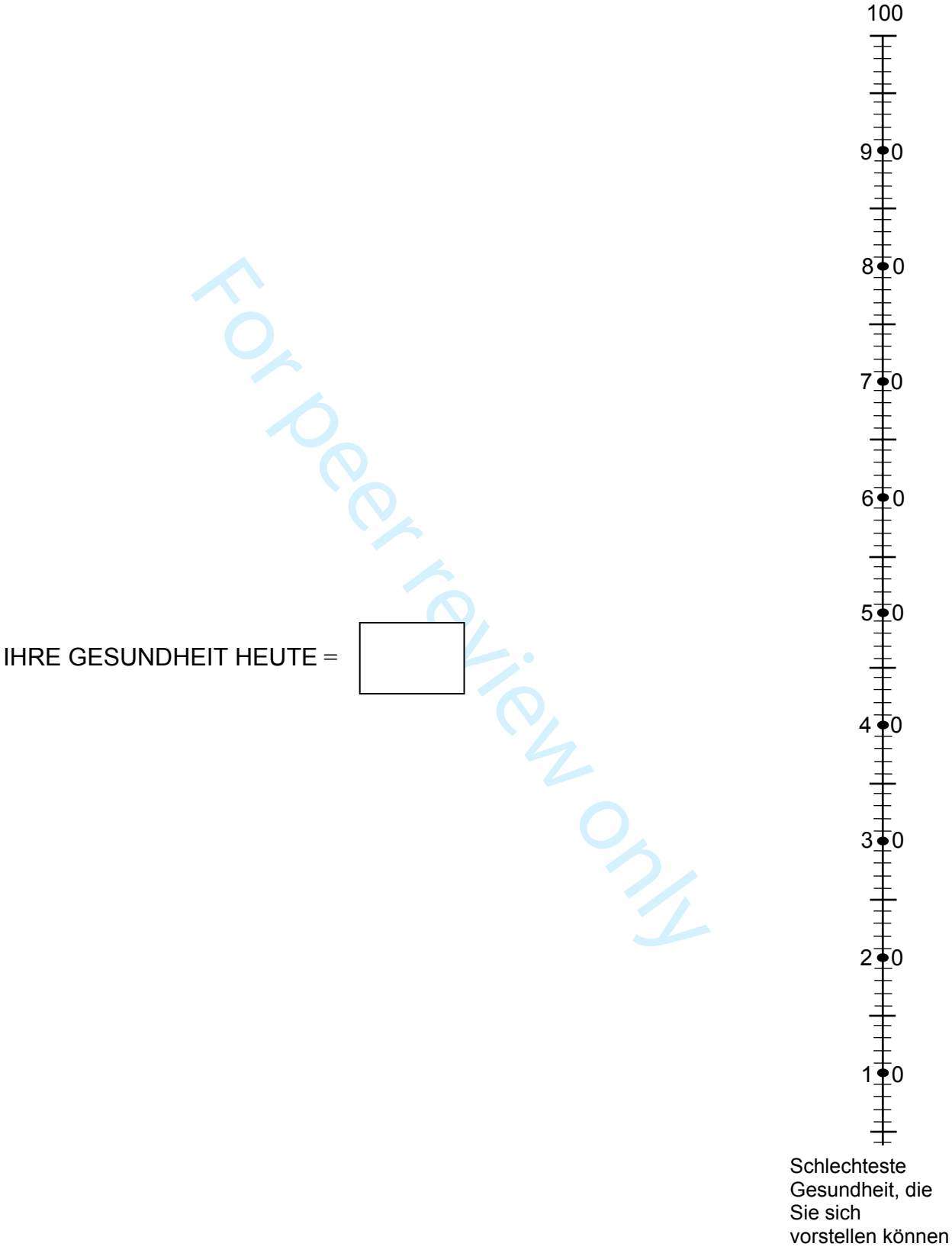
Ich habe keine Schmerzen oder Beschwerden ❑
Ich habe leichte Schmerzen oder Beschwerden ❑
Ich habe mässige Schmerzen oder Beschwerden ❑
Ich habe starke Schmerzen oder Beschwerden ❑
Ich habe extreme Schmerzen oder Beschwerden ❑

ANGST / NIEDERGESCHLAGENHEIT

Ich bin nicht ängstlich oder deprimiert	❑
Ich bin ein wenig ängstlich oder deprimiert	❑
Ich bin mässig ängstlich oder deprimiert	❑
Ich bin sehr ängstlich oder deprimiert	❑
Ich bin extrem ängstlich oder deprimiert	❑

Beste Gesundheit, die Sie sich vorstellen können ❑

- Wir wollen herausfinden, wie gut oder schlecht Ihre Gesundheit HEUTE ist.
- Diese Skala ist mit Zahlen von 0 bis 100 versehen.
- 100 ist die beste Gesundheit, die Sie sich vorstellen können. 0 (Null) ist die schlechteste Gesundheit, die Sie sich vorstellen können.
- Bitte kreuzen Sie den Punkt auf der Skala an, der Ihre Gesundheit HEUTE am besten beschreibt.
- Jetzt tragen Sie bitte die Zahl, die Sie auf der Skala angekreuzt haben, in das Kästchen unten ein.



Illness Perception Questionnaire (IPQ – R) adapted to injury

Quelle: Moss-Morris R, Weinman J, Petrie K, et al. The Revised Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.

Datum:…….

PatientIn:…….

VERLETZUNGSANNAHMEN Im Folgenden sind verschiedene Beschwerden aufgelistet, die Sie möglicherweise im Verlauf Ihrer Verletzung erlebt haben. Bitte geben Sie durch Ankreuzen an, ob Sie die betreffenden Symptome im Verlauf Ihrer Verletzung erlebt haben.

		STIMMT ÜBERHAUPT NICHT	STIMMT NICHT	WEDER NOCH	STIMMT	STIMMT VOLL UND GANZ
IP1*	Meine Verletzung wird nur kurze Zeit dauern					
IP2	Meine Verletzung wird lange Zeit andauern					
IP3*	Meine Verletzung wird schnell wieder vorbei sein					
IP4	Ich nehme an, dass ich diese Verletzung für den Rest meines Lebens haben werde					
IP5	Meine Verletzung hat grosse Auswirkungen auf mein Leben					
IP6*	Meine Verletzung hat keine grossen Auswirkungen auf mein Leben					
IP7	Meine Verletzung hat grossen Einfluss darauf, wie andere Personen mich einschätzen					
IP8	Meine Verletzung hat gravierende finanzielle Folgen für mich					
IP9	Meine Verletzung verursacht auch Schwierigkeiten für mein soziales Umfeld					
IP10	Ich kann eine Menge tun, um meine Symptome zu kontrollieren					
IP11	Mein Verhalten beeinflusst, ob meine Verletzung besser oder schlimmer wird					
IP12	Der Verlauf meiner Verletzung ist von mir abhängig					
IP13	Ich habe die Macht, meine Verletzung beeinflussen					
IP14*	Meine Verletzung wird mit der Zeit besser werden					
IP15*	Es gibt nur sehr wenig, was getan werden kann, um meine Verletzung zu verbessern					
IP16	Meine Behandlung wird meine Verletzung wirksam heilen					
IP17	Ich kann die negativen Auswirkungen meiner Verletzung durch meine Behandlung verhindern					
IP18	Meine Behandlung kann meine Verletzung kontrollieren					
IP19*	Ich kann mir die Symptome meiner Verletzung nicht erklären					
IP20*	Meine Verletzung ist für mich ein Rätsel					

IP21*	Ich verstehe meine Verletzung nicht					
IP22*	Meine Verletzung macht für mich keinen Sinn					
IP23	Ich habe ein klares Verständnis meines Zustands					
IP24	Die Symptome meiner Verletzung verändern sich von Tag zu Tag stark					
IP25	Meine Symptome kommen und gehen in einem wiederkehrenden Muster					
		STIMMT ÜBERHAUPT NICHT	**STIMMT NICHT**	**WEDER NOCH**	**STIMMT**	**STIMMT VOLL UND GANZ**
IP26	Meine Verletzung ist sehr unberechenbar					
IP27	Meine Verletzung hat einen phasenhaften Verlauf, bei dem es mal besser, mal schlechter ist					
IP28	Wenn ich über meine Verletzung nachdenke, fühle ich mich deprimiert					
IP29	Es beunruhigt mich, wenn ich über meine Verletzung nachdenke					
IP30	Meine Verletzung macht mich wütend					
IP31	Es macht mir Angst, dass ich diese Verletzung habe					
IP32	Meine Verletzung macht mir Angst					
	Stimmt überhaupt nicht = 1, stimmt voll und ganz = 5, ausser mit * dort umgekehrt				Total:	

VERLETZUNGSURSACHEN

Uns interessiert, was Sie als mögliche Ursache für Ihre Verletzung betrachten, also Ihre persönlichen Ansichten, was Ihrer Meinung nach Ihre Verletzung verursacht, also nicht unbedingt was andere (einschliesslich Arzt oder Familie) Ihnen als Ursache nahelegen. Unten finden Sie eine Liste mit möglichen Ursachen für Ihre Verletzung. Bitte geben Sie durch Ankreuzen an, wie stark sie zustimmen oder ablehnen, dass diese bei Ihnen als Ursache in Frage kommen.

		STIMMT ÜBERHAUPT NICHT	**STIMMT NICHT**	**WEDER NOCH**	**STIMMT**	**STIMMT VOLL UND GANZ**
C1	Stress und Sorgen					
C2	Vererbt - kommt in meiner Familie öfter vor					
C3	Bakterien oder Viren					
C4	Ernährungs- oder Essgewohnheiten					
C5	Zufall oder Pech					
C6	Schlechte medizinische Versorgung in der Vergangenheit					
C7	Umweltverschmutzung bzw. Umweltgifte					
C8	Mein eigenes Verhalten					
C9	Meine Einstellung, z. B. negatives Denken über das Leben					
C10	Familienprobleme oder Sorgen verursachten meine Krankheit					

C11	Überarbeitung					
C12	Mein emotionales Befinden, z. B. sich bedrückt, einsam, ängstlich, leer fühlen					
C13	Alterungsprozess					
C14	Alkohol					
C15	Rauchen					
C16	Unfall oder Kranheit					
C17	Meine Persönlichkeit					
C18	Verändertes Immunsystem					
	Stimmt überhaupt nicht = 1, stimmt voll und ganz = 5, ausser mit * dort umgekehrt				Total:	

BMJ Open

Can modifiable psychosocial factors, sleep related variables or measures of central pain processing be used to predict outcomes following rotator cuff repair? A protocol for a prospective longitudinal cohort study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058803.R1
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Date Submitted by the Author:	01-Mar-2022
Complete List of Authors:	Schwank, Ariane; University of Antwerp, Department of Rehabilitation Sciences and Physiotherapy (REVAKI); Kantonsspital Winterthur, Institute for Therapy and Rehabilitation Struyf, Thomas; Katholieke Universiteit Leuven, Department of Public Health and Primary Care Struyf, Filip; Universiteit Antwerpen Campus Drie Eiken, REHABILITATION SCIENCES Blazey, Paul; The University of British Columbia, Centre for Hip Health and Mobility Mertens, Michel; University of Antwerp Faculty of Medicine and Health Sciences, Rehabilitation Sciences and Physiotherapy Gisi, David; KSW Kantonsspital Winterthur, Institute for Therapy and Rehabilitation Pisan, Markus; Kantonsspital Winterthur, Surgery / Orthopaedics and Traumatology / Shoulder and Elbow Unit; Gelenkzentrum Winterthur , - Meeus, Mira; Universiteit Antwerpen Campus Drie Eiken; University of Ghent, Department of Rehabilitation Sciences
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Rehabilitation medicine, Medical education and training
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, PAIN MANAGEMENT, PSYCHIATRY, REHABILITATION MEDICINE, SLEEP MEDICINE, NEUROPHYSIOLOGY

Study Protocol

Title

Can modifiable psychosocial factors, sleep related variables or measures of central pain processing be used to predict outcomes following rotator cuff repair? A protocol for a prospective longitudinal cohort study.

Corresponding and first author:

Ariane Schwank[1,2,3]: ariane.schwank@student.uantwerpen.be, ariane.schwank@ksw.ch

Co-Authors:

Second author: Thomas Struyf [4], thomas.struyf@kuleuven.be

Third author: Prof. Dr. Filip Struyf [1], filip.struyf@uantwerpen.be

Fourth author: Paul Blazey [5, 6], paul.blazey@ubc.ca

Fifth author: Michel GCAM Mertens [1,3], michel.mertens@uantwerpen.be

Sixth author: David Gisi [2], david.gisi@ksw.ch

Seventh author: Dr. med. Markus Pisan [7], markus.pisan@gzw.ch

Last author: Prof. Dr. Mira Meeus [1,3,8], mira.meeus@uantwerpen.be

[1]MOVANT research group, Department of Rehabilitation Sciences and Physiotherapy (REVAKI), University of Antwerp Wilrijk, Belgium

[2]Institute for Therapy and Rehabilitation, Kantonsspital Winterthur, Switzerland

[3]Pain in Motion, International research group, www.paininmotion.be

[4]Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium

[5]Centre for Hip Health and Mobility, University of British Columbia, Vancouver, Canada

[6]Department of Physical Therapy, Faculty of Medicine, University of British Columbia, Vancouver, Canada.

[7]Former Head of Shoulder and Elbow Surgery Unit, Clinic of Orthopaedics and Traumatology Kantonsspital Winterthur, Switzerland

[8]Department of Rehabilitation Sciences, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

Abstract

Introduction

Prognosis following surgical rotator cuff repair (RCR) is often established through the assessment of non-modifiable biomedical factors such as tear size. This understates the complex nature of recovery following RCR. There is a need to identify potential modifiable psychosocial factors and sleep related variables, and to find out whether alterations to central pain processing influence prognosis after RCR. This will improve our knowledge on how to optimize recovery, using a holistic rehabilitation approach.

Methods and Analysis

This longitudinal study will analyse 141 participants undergoing usual care for first time RCR. Data will be collected 1 to 21 days preoperatively (T1), 11 to 14 weeks (T2) and 12 to 14 months (T3) postoperatively. We will use mixed-effects linear regression to identify correlations between potential prognostic factors and our primary outcome measure – the Western Ontario Rotator Cuff Index. Secondary outcome measures assessed against prognostic indicators include: The Constant-Score and Subjective Shoulder Value; Maximal Pain (Numeric Rating Scale); and Quality of Life (EQ-5D-5L). Potential prognostic factors include: four psychosocial variables; pain catastrophizing, perceived stress, injury perceptions and patients' expectations for RCR; sleep; and four factors related to central pain processing; central sensitisation inventory, temporal summation, cold hyperalgesia and pressure pain threshold. Intercorrelations will be assessed to determine the strength of relationships between all potential prognostic indicators.

Our aim is to identify potential modifiable psychosocial factors, sleep related variables, and to assess to which extent central pain processing correlate to outcome pre and post RCR.

Ethics and Dissemination

The results of the study will be disseminated at conferences (e.g. European Pain Congress). One or more manuscripts will be published in peer reviewed SCI-ranked journals. Findings will be reported in accordance with the STROBE statement and PROGRESS framework. Ethical approval is granted by the Ethical commission of Canton of Zurich, Switzerland, No: ID_2018-02089

Registration

Registered at ClinicalTrials.gov, registration number: NCT04946149

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Keywords

Rotator cuff tears, prognostic factors, psychosocial factors, expectations, sleep, central sensitisation, quantitative sensory testing

Article Summary

Strengths of this study

- This will be the first study *adequately* powered to identify modifiable psychosocial factors as potential prognostic factors of outcome after rotator cuff repair (RCR).
- This study will also be the first to assess the complex interplay of psychosocial factors, sleep related variables and central pain processing measures as potential prognostic factors of outcome following RCR
- The prospective longitudinal study design includes 3 measurement points, starting preoperatively, at 12 weeks postoperative and following up for 12-months post RCR.

Limitations of this study

- The questionnaires for sleep and patients' expectations were translated to German for the purposes of this study. Therefore, their validity in our population (German-speakers) has yet to be validated.
- Tear size is a known prognostic indicator of how well recovery will go following RCR. We will not account for tear size in our prognostic model which may bias our results.

Introduction

Prognostic factor research most often focuses on biomarkers, including biological, clinical or physiological factors. Prognostic factors help us predict the likely outcome of a patient undergoing a procedure, given the presence of certain behaviours or characteristics.(1) Prognostic factors for patients undergoing rotator cuff repair (RCR) for shoulder pain often include: fatty infiltration into the rotator cuff muscles (strong effect); tear size of the tendon and multiple tendon involvement (both moderate effects); or age and diabetes (both moderate effects).(2) These are all biomedical markers and are non-modifiable factors with established prediction capabilities for showing worse outcomes for patients following RCR.(2)

Despite these biomarkers being well established for RCR, we are still not able to fully predict who will recover successfully. A person's perception of shoulder pain is far more complex than structural changes in the rotator cuff (RC) tendons and we need to add information towards a more comprehensive picture.(3-7) Yet, the number of rotator cuff repairs in Europe and the United States of America continues to grow,(4, 8-10) in-spite of this lack of knowledge on the odds of success. Current evidence suggests satisfactory outcomes post RCR range from 38% to 95%. This means surgical repair is either very successful or potentially a large waste of resources.(11-14)

There is growing evidence that psychosocial factors impact persistent shoulder pain.(4, 15-18) Factors such as: high distress; maladaptive beliefs;(17) the perception of high-demand at work; and a lack of social support (18) can influence whether persistent shoulder pain and disability occur. Patients with existing preoperative psychological conditions like: depression and anxiety;(14) who exhibit pain

catastrophizing and kinesiophobia; (19) or suffer psychological distress (14, 20) may demonstrate greater preoperative shoulder pain.(14, 19) In the reverse, patients who anticipate a good recovery (positive expectations) post RCR show independent and strong associations with satisfactory outcomes (good prognosis) for pain and disability measured one-year post surgery.(11, 12, 21) Prior research on psychosocial factors post RCR has been restricted to: preoperative measures;(19) has lacked statistical power;(14, 20) or has failed to investigate potential psychosocial prognostic factors altogether.(11, 12, 21)

Sleep disturbances are also highly prevalent (up to 89%) in patients undergoing RCR, which has been attributed to the presence of shoulder pain.(22-24) RCR seems to reduce this interplay between shoulder pain and sleep disturbances as findings demonstrate an overall post RCR improvement of sleep quality.(14, 25) Yet, 41% of RCR patients still suffer from sleep disturbances at 24 months follow up.(23) Investigations of sleep disturbances in relation to shoulder pain and RCR are incomplete with multiple factors affecting the relationship.(26)

Central pain processing (CPP) changes are measured via assessments for central sensitisation. Assessments of CPP are almost absent in studies of patients undergoing RCR.(15, 16, 27) Two trials (28, 29) investigated the role of central sensitisation, measured with quantitative sensory testing (QST) on outcome (pain and disability) after different shoulder surgeries (RCR, superior labrum from anterior to posterior (SLAP) repair, shoulder arthroscopy (SA) and subacromial decompression). Both studies found small effects of CPP on post-operative outcomes. If a high amount of CPP was present pre-operatively, it was related to a worse outcome 3 months post-

subacromial decompression.(28) In contrast, if a small amount of CPP was present 3 months postoperatively (RCR, SLAP-Repair, SA) it was associated to better functioning at 6 months post-surgery.(29)

Overall, we lack knowledge of potential modifiable prognostic indicators related to psychosocial factors, sleep and CPP and their effects on pain, shoulder function, disability, quality of life and satisfaction following RCR.(4, 19) Neither the local tissue pathology-pain model nor the growing knowledge about local biochemical changes in rotator cuff tendons sufficiently describe the relationship between tissue changes and patients' perceived shoulder pain.(3, 5, 15, 30) Studying the relationship of psychosocial factors, sleep, and central pain processing with RCR would improve our prognosis for outcomes post RCR. This holds the potential to improve treatment selection choices and reduce unnecessary surgical interventions.(3, 4, 16, 20, 31)

This study aims to answer the following questions:

1. Do psychosocial factors such as pain catastrophizing, perceived stress, injury perceptions, patients' expectations of surgery, sleep related variables and measures of CPP obtained pre RCR (baseline), predict post RCR evolution of shoulder function, disability, pain, quality of life and postoperative satisfaction (outcome) at 1year follow-up?
2. Do the potential prognostic factors (psychosocial factors, sleep, CPP) correlate with baseline shoulder function, disability, pain and quality of life (outcome)?
3. How do the potential prognostic factors (psychosocial factors, sleep, CPP) intercorrelate at baseline and over time?

Methods

Study Design and setting

The longitudinal cohort study will be implemented and reported in line with the STROBE statement for observational studies(32) informed and completed by the framework “prognosis research strategy” (PROGRESS).(1, 33)

Data are obtained monocentric in the shoulder and elbow surgery unit in the clinic of orthopaedic surgery and traumatology in alliance with the institute of therapy and rehabilitation of the acute care hospital, canton hospital Winterthur, Switzerland.

The current research project will analyse data from three selected time points in the clinical routine of the RCR management; 1-21 days preoperatively (T1), 11-13 weeks postoperatively (T2) and 12-14 months postoperatively (T3). Data from July 2019 onwards will be considered. Data collection including 12 months follow-up is estimated to be complete in Summer 2022.

See tables 1 and 2 for overview of measurement points.

Participants

The population of interest includes adult patients undergoing elective RCR, for tears of traumatic and non-traumatic origin. To avoid selection bias, we include data from consecutive patient consultations.

Eligibility Criteria

Inclusion criteria:

- Adult men or women ≥18 years of age;
- Scheduled for elective arthroscopic RCR;

- First time RCR on the target shoulder

Exclusion criteria:

- Changes of intra operative procedure (e.g. anything but RCR)
- Re-repair of tendon;
- No surgery;
- No pre-operative data available; e.g. fast track trauma patients

Outcome measures and prognostic factors

Our outcome measures are consistent with those used in the existing literature. We consulted the guidelines from the OMERACT 2016 Shoulder Core Outcome Set Special Interest Group.(34)

Our dependant variables are the *primary outcome measure* Western Ontario Rotator Cuff Index (WORC) for disease-specific function, disability and quality of life. The *secondary outcome measures* are: Constant – Murley – Score (CMS) and Subjective Shoulder Value (SSV) for shoulder function; maximum pain over the last 7 days on Numeric Rating Scale (NRS); European Quality of Life, 5 dimensions, 5 levels (EQ-5D-5L) for quality of life and health status**;** and satisfaction measure developed by Swarup et al.(35)

A detailed description and overview about primary and secondary outcome measures and their psychometric properties is presented in Table 1, which can be found in supplemental material.

Potential prognostic factors for postoperative outcome are; psychosocial factors including 1) pain catastrophizing, 2) perceived stress, 3) injury perceptions and 4) patients' expectations for RCR; 5) sleep related variables; and measures of CPP including 6) the central sensitization inventory (CSI) to assess self-reported somatic and emotional complaints associated to CPP 7) the degree of temporal summation (TS), 8) cold hyperalgesia (CH), 9) pressure pain threshold (PPT) 10) the Douleur Neuropathique - 4 assessment (DN4) to detect the possible presence of neuropathic pain and 11) pain distribution and localisation.

Further potential prognostic factors include patient related characteristics such as; demographics (12) age and 13) sex; 14) trauma vs non-traumatic tendon tear; health status such as 15) body mass index (BMI). These characteristics are handled as potential prognostic factors to ensure a correct approximation of our primary prognostic factors.

Table 2 presents an overview of the potential prognostic factors including detailed description of all measurement tools and test methodology

Table 2	Type Mode	Psychometric properties / Clinimetrics	T1: Baseline 2-3weeks pre RCR	T2: 12 – 14 weeks post RCR	T3: 12 - 14 months post RCR
Potential Prognostic factors					
Psychosocial factors					
1 Catastrophic thinking	***Pain Catastrophising Scale (PCS)***	German PCS showed same factor structure like original version and acceptable to good reproducibility.(36) Validated in Low Back Pain Patients.	x	x	x
Description	The Pain Catastrophizing Scale assesses whether or not there is presence of catastrophic thinking about pain. Thirteen items entail aspects about different thoughts and feelings whilst experiencing pain. Items are scored on a 5-point Likert scale. Higher scores indicate more severe catastrophic thinking about pain. There is a total score and a score for three subscales (e.g. helplessness, magnification and rumination).(37)				
2 Perceived distress	***Perceived Stress Scale (PSS)***	The German version showed good psychometric properties like validity and reliability in the general population.(38)	x	x	x
	The Perceived Stress Scale (PSS – 10) includes 10 questions and assesses the degree to which life has been experienced as unpredictable, uncontrollable and overloaded in the past months. The questions are answered by “yes” (1) or “no” (0). The questions are general in nature and therefore the usage for shoulder pain patients undergoing RCR is reasonable.				
3 Perceptions about injury	***Illness Perception Questionnaire – Revised (IPQ-R)***	The clinimetric properties for musculoskeletal pain are reported to be sufficient.(39) For rotator cuff tears and rotator cuff repair, the word “injury” seems to be more matching, therefore we exchanged the word illness (German: Krankheit) with injury (in German Verletzung).	x	x	x
Description	Designed to assess the cognitive and emotional representations of illness. The items are formed by experiences, provided information and interpretation of symptoms. The IPQ-R is not disease specific and may be used in any group of interest.(40) The questionnaire has 9 dimensions of injury perception: 1. Timeline (acute/chronic), 2. Consequences, 3. Personal control, 4. Treatment control 5. Injury coherence, 6. Timeline cyclical, 7. Emotional representations as well as 8. Identity and 9. Causes. We amalgamated dimensions 1. and 6) into “timeline” and dimensions 3) and 4) into “control” and end up with 6subscales for illness perceptions and one for causes. Further it includes 3 domains(41, 42) . The first domain is called illness identity, the second is called the beliefs domain and the third is labelled as the consequence domain.(43) The authors adjusted the questionnaire to the cohort and exchanged illness with injury. The 32 injury perceptions and 18 causes answers are captured on a 5-point Likert scale from “strongly disagree” (1) to “strongly agree” (5)				
4 Expectations	***Study designed, 6 Questions about expectations***	Lack of German translated questionnaires in the field. Consequently, the research team formulated 6 Questions based on literature including the study of the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS).(12, 35)	x	-	-
Description	Patients’ expectations will be assessed using 5 questions: 1) expected shoulder function in percentage at 12 weeks post OP 2) expected shoulder function at 12 month postop 3) expected symptom reduction in percentage at 12 weeks post OP 4) expected symptom reduction in percentage at 12 months post OP 5) & 6) open questions about driver for high (>80%) or low (<80%) expectations for shoulder function and symptom reduction.				
5 Sleep					
	Study designed, 4 Questions about sleep	Due to study feasibility, we formulated 4 questions. Because sleep assessments were not validated in German language, or too long to integrate.	x	x	x
Description	4 Questions regarding sleep quality, sleep efficiency, sleep disturbance, number of awakenings per night. The first question is transformed from the Pittsburgh Sleep Quality Index (PSQI), for sleep quality and is rated on a 4-point Likert Scale. The question 2 to 3 are formulated by suggestion from research(44) and adapted to shoulder pain by the first author.				
Central Pain Processing					
6 Self-reported symptoms of central sensitisation	***Central Sensitisation Inventory (CSI)***	It is a high-quality measurement tool, with high construct validity and test-retest reliability. The defined cut-off point is at 40 points.(45) German version is to be validated by the research group among Laekemann. Contract for their usage.	x	x	x

Description	The original English questionnaire was developed in 2011 (46) to assess key symptoms in relation to central sensitivity symptoms (CSS). It consists of two parts; Part A with 25 items relating to pain, psychosocial aspects, cognitive and functional aspects. Part B with 7 different CSSs, like restless legs, irritable bowel, and multiple chemical sensitivities and 3 disorders like neck pain (whiplash), depression and anxiety or panic attacks.				
7 Temporal summation	***Frey hair filament, 10g calibrated***	No factor analysis available for testing loading of TS for CPP. TS is a common method in research to measure CPP.(47)	x	x	x
Description	Locations for applications will be at two local and one remote site: 1. Local painful site: the most painful site of the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally.(48) The patient is asked to rate the first touch on an NRS from 0 (no pain at all) to 10 (worst imaginable pain). Then the measurement is repeated once per second (1Hz) for 30seconds on a surface of maximum 1cm^2,(49) The standardization of the frequency is important, as wind-up of the C-fibers only arrives if the stimulus is provided at least once every 3 seconds(<0.33Hz).(50) After the 30 seconds application, the patient is asked to rate the last touch on an NRS. The difference between the last and the first rating is calculated. Fifteen seconds after the test, patients need to rate any ongoing pain sensation on NRS again.(51) Patients will be advised that the method does not aim to measure pain tolerance (52) and a number should only be given if the sensation was burning, stabbing, pulling or gnawing.				
8 Cold hyperalgesia (CH)	***Ice pack***	No factor analysis available for testing loading of TH for CPP. CH is a common method in research to measure CPP.(47)	x	x	x
Description	Cold hyperalgesia is measured with a cold pack, kept in the deep freezer which is simulating ice cubes for the ice test.(53) Locations for applications will be at two local and two remote sites: 1. Local painful site: the most painful site of the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally.(48) The cold application is kept for 10 seconds, and the patients will rate the experienced pain on a NRS from 0 (no pain at all) to 10 (worst imaginable pain).(53) Patients will be advised the measure does not aim for pain tolerance and they pain should be reported if a burning, stabbing, pulling or gnawing sensation is felt.(52)				
9 Pressure Pain Threshold (PPT)	***Wagner Instruments***	No factor analysis available for testing loading of PPT for CPP. PPT is a common method in research to measure CPP.(47)	x	x	x
Description	PPT represents a static psychophysical test, which measures the point of pressure evolving into pain. Its report of large to nearly perfect reliability in neck pain patients, demonstrates its great potential as measurement tool also for the present cohort.(54) The measurements will be conducted by digital hand-held pressure algometer with a rubber tip of approximately 1 cm² (FPX 50, FORCE TEN by Wagner Instruments), increasing pressure will be given perpendicular to the skin.(55) Measurements are taken at five standardized sites: 1. Two cm caudal from the acromion at the muscle belly of middle deltoid, bilaterally. 2. At the muscle belly in middle of the upper trapezius, bilaterally. 3. At the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally, as remote site.(48) All measurements will be repeated once and the mean PPT in kilopascals per site will be calculated.				
10 Neuropathic pain differential diagnosis	***Douleur Neuropathique 4 (DN4)***	The DN4 showed more sensitivity and specificity in preselected cohorts with respect of neuropathic pain detection, and it is strongly advised to obtain a thorough clinical assessment when diagnosing neuropathic pain.(56)	x	x	x
Description	Short and easy to administer assessment, which consists of a subjective part, including 7 symptoms (patient-rated) and an objective part including 3 signs (physician-rated). The cut-off point is 4 points, the total of points is 10, indicating that neuropathic pain mechanisms may be involved.(56)				
11 Pain distribution	***Body Chart***		x	x	x
Description	Patients report their pain location and pain distribution. The assessor is painting the body chart. Calculation of pain distribution in percentage of the body surface will be analysed using the Margolis Bodychart scoring system.(57)				
Additional prognostic factors					
12 Age	Date of birth		x	-	-
13 Sex	Female / male		x	-	-
14 Cause of tear	Traumatic vs. non-traumatic		x	-	-
15 Body Mass Index (BMI)	Kg and cm		x	-	-

TABLE 2: Potential prognostic factors

Four (AS, WB, QdG, FM) experienced and especially trained (by the first author AS) shoulder specialist and physiotherapists perform the measurements (CMS, QST, SSV, NRS Pain). Next to physical skills training, the assessment files incorporate detailed descriptions with respect to how the assessor should formulate questions and offer answer suggestions. A detailed description of the prognostic indicators we collect can be found in table 2, further details including the baseline documents can be found in the supplemental file.

Statistical Methods and Analysis

Statistical analyses will be performed using SAS (SAS 9.4, SAS Institute Inc., Cary, NC, USA). Level of significance is set at p = 0.05. Measurements will take place at three time points in the perioperative management, as described above (T1 = at baseline 2-3 weeks prior to RCR, T2 = at 12 weeks post RCR and T3 = at 12 months post RCR as follow-up).

The primary outcome (WORC) will be modelled using mixed-effects linear regression models for repeated (longitudinal) measures, using an unstructured covariance matrix. Dependent variables are the primary and secondary outcomes. Continuous secondary outcomes will be assessed in a similar way to the primary outcome. The models will be developed by stepwise reduction of the *a priori* determined potential prognostic factors (for example psychosocial factors, sleep and CPP). A prognostic factor will be retained in the model if it has a significant effect on the initial outcome or on the outcome over time, or if the fit statistics (Deviance, AIC, BIC and R2) of the model improves after inclusion of the variable, in order to increase the precision of the fixed effects estimates.(58-60) This means that a prognostic factor may be retained in the

final model, even if it is not significant (p>0.05), to ensure correct estimation of other (significant) prognostic factors.

Descriptive statistics will be performed for comorbidities such as obesity, diabetes, depression etc., for insurance status; health care vs. accident insurance, as well as for current profession like manual labour (painter, carpenter, locksmith.); construction (e.g. streets, buildings); office work; repetitive work (e.g. supermarket, post office, industry, hairdresser); health care practitioner (e.g. nurse, medical doctor, PT, OT); pensioner and student.

Sample Size (we moved this paragraph to be after the statistical analysis)

We will use a linear mixed-effects regression model for repeated measures. This will have a power of 90% to identify prognostic factors of both interindividual baseline differences in WORC score and a change in WORC score over time that are considered clinically relevant (we assume a standard deviation of 300 points at baseline and a decline in WORC score of at least 15% over time on average) (61), at a confidence level α=0.5 (two-tailed). The required total sample size was calculated to be 125 subjects (R, Edland package).(62, 63) To account for an expected attrition rate of 12.5%, the final sample size was set at 141 participants.

The power is set at 90% to minimize the chance of making a type II error.

It is especially difficult to determine a correct sample size for a longitudinal exploratory study, as the final mixed model is likely to contain complex variance and correlation patterns that are not known beforehand. Therefore, we plan an interim analysis after the inclusion of the first 80 participants, to assess the drop-out rate, the achieved power and the potential futility of the *a priori* selected prognostic factors. Mixed models

do not require complete datasets to produce accurate results, through correct specification of the likelihood function.(59)

Data security and management

Data generation, transmission, storage and analysis within this project strictly follow Swiss legal requirements for data protection. The electronic data capture (EDC) software REDCap (64, 65) will be used for data processing and management. REDCap was developed by an informatics core at Vanderbilt University in 2004, with ongoing support from US National Center for Research Resources (NCRR) and US National Institute of Health (NIH), grants NIH/NCATS UL1 TR000445. REDCap was specifically developed around HIPAA security guidelines and is Good Clinical Practice-compliant and fulfils the regulatory requirements regarding the collection of patient data in clinical trials or non-interventional studies and patient registries and the EU data protections laws. Appropriate coded identification (e.g. pseudonymisation) is used in order to enter subject data into the database. The coding list of target data is saved in a secured folder on the hospital's server. Only the project leader, study nurses and principal investigator have access to it. Between the members of the research team only coded and de-identified data will be shared. Safe handling of the coded data will be covered by the software REDCap.

Study Monitoring

An audit trail and history of data transmission are provided by REDCap. The steering committee of the research project will oversee all aspects of design, delivery, quality assurance and data analysis according to good clinical practice and local legislation.

Ethics

The study follows the principles of the Helsinki Declaration. Only data of patients who gave general consent to the hospital or informed written consent to the project will be considered for analysis. Ethical approval received January 2019 (ID 2018-02089) by the Ethical Committee of the Canton of Zurich, Switzerland.

Dissemination of results

The research team is committed to full disclosure of the results of the study. The results of the study will be disseminated for research purpose at different conferences and as published articles in peer reviewed journals. Findings will be reported in accordance to the STROBE statement and we aim to publish in high impact journals.

Contributorship statement

AS simultaneously is the project leader, who receives support from FS and MM (last author) with respect to topic and study design. TS controls the statistical model and will support statistical data analysis. MM (fifth author) and PB contribute to the protocol by critical reviewing and providing intellectual content. DG and MP support the feasibility of the study and access to clinical data from daily routine of the physiotherapy and orthopaedic clinic at canton hospital Winterthur, also they support data security by providing REDCap software. All authors gave final approval for publication of the present protocol version.

Patient and Public Involvement:

We included patients during our early feasibility study phase. We interviewed patients about their experience of filling out the questionnaires. Afterwards we fine-tuned our data collection files; the questionnaire package and the assessment. For example, we changed the order and the layout of our questionnaire package and we reformulated introduction for the questionnaires and for the prognostic factor “expectations towards RCR” we reformulated the questions, so patients understand better what we want to ask. The data of this feasibility phase from January 2019 until May 2019 are not included in the study.

Patients were not enrolled for the study but came in for clinical visits, so we did not have to have support with recruitment. We have not included patient advisers. Study participants can request the results after publication.

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Competing of Interest

The authors declare no conflicts of interest.

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Table 1	**Type / Mode**	**Psychometric properties / Clinimetrics**	**T1: Baseline 2-3weeks pre RCR**	**T2: 12 weeks post RCR**	**T3: 12 months post RCR**
Primary outcome measure					
Shoulder function, disability and disease specific quality of life	***Western Ontario Rotator Cuff Index (WORC)***	Positive evidence for 5 psychometric properties: • internal consistency, • reliability, • content validity, • hypothesis testing and • responsiveness.(1, 2) German version showed satisfactory construct validity, internal consistency, test-retest reliability. No specific testing for responsiveness.(1)	x	x	x
Description	This 21 – items self-reported questionnaire represents a quality of life measure in rotator cuff pathology.(3) The WORC measures 5 dimensions (pain, sports/leisure, work, daily living, feelings) with 3-6 questions per domain, measured on a 100mm Visual Analogue Scale (VAS). Left endpoint equals "no" and right endpoint equals "extreme". The total WORC score ranges from 0 (best) to 2100 (worst) (21 items x 100mm). The minimal important difference (MID) is calculated at ≥ 300mm.(4)				
Secondary outcome measures					
Shoulder function	***Constant – Murley Score (CMS)***	Validated in different shoulder diseases and recommended for rotator cuff and osteoarthritis patients due to highest responsiveness in these groups.(2) Reliability was moderately rated with ICCs > 0.8. Results about content and structural validity seem to be lacking.(2)	x	- No strength measure	x
	Subjective Shoulder Value (SSV)	High correlations to Constant-Murley Score, tested in diverse shoulder diseases.			
Description CMS	The Constant-Murley Score assesses shoulder function of which 35 % are subjective variables (maximum pain intensity, work, sport/leisure, sleep, pain free height for light work), and 65% are objective variables (range of motion (ROM) and strength measure). A sum score of 100 represents perfect shoulder function, 0 represents no functionality.(2)				
Description SSV	The SSV is evaluated by one single standardised question:" What is the overall percent value of your shoulder if a completely normal shoulder represents 100%?"(5)				
Max. pain	***Numeric Rating Scale (NRS)***	Reported to be sensitive to measure change of pain level on the 11-point scale. Minimal Clinical important difference is found to be 30-33% of pain reduction.(6)	x	x	x
Description	Patients are asked to indicate the maximum perceived shoulder pain felt in daily life on an NRS from 0 (no pain at all) to 10 (worst imaginable pain).(7)				
Quality of life	***European Quality of Life, 5 Dimensions, 5 Levels (EQ - 5D -5L)***	Adopted and tested in Germany among general population.(8)	x	x	x
Description	The research group EuroQol developed the EQ-5D-5L tool "in order to provide a simple, generic measure of health for clinical and economic appraisal". It contains of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and depression/anxiety and 5 levels ranging from no problems, slight problems, moderate problems, severe problems, and extreme problems.(9)				
Postoperative satisfaction	***Satisfaction questionnaire for postsurgical status***	No validation of this questionnaire in German language available. Forward backward translation with native speakers and expert physiotherapists was best compromise.	-	-	x
Description	Self-rated questionnaire containing 8 questions. Four questions cover current state of satisfaction, 1 question asks for quality of life improvement, 2 questions ask about repetition of surgery and recommendation for others and 1 question asks about timing of the surgery. The survey originates from total shoulder arthroplasty research(10) and is modified to RCR. It is clear and simple to administer.				

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Are Psychosocial Variables, Sleep Characteristics or Central Pain Processing Prognostic Factors for Outcome Following Rotator Cuff Repair? A Protocol for a Prospective Longitudinal Cohort Study.

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Study Protocol

Title

Are psychosocial variables, sleep characteristics or central pain processing prognostic factors for outcome following rotator cuff repair? A protocol for a prospective longitudinal cohort study.

Corresponding and first author:

Ariane Schwank[1,2,3]: ariane.schwank@student.uantwerpen.be,

ariane.schwank@ksw.ch

Co-Authors:

Second author: Thomas Struyf [4], thomas.struyf@kuleuven.be

Third author: Professor Filip Struyf [1], filip.struyf@uantwerpen.be

Fourth author: Paul Blazey [5, 6], paul.blazey@ubc.ca

Fifth author: Michel GCAM Mertens [1,3], michel.mertens@uantwerpen.be

Sixth author: David Gisi [2], david.gisi@ksw.ch

Seventh author: MD Markus Pisan [7], markus.pisan@gzw.ch

Last author: Professor Mira Meeus [1,3,8], mira.meeus@uantwerpen.be

[1]MOVANT research group, Department of Rehabilitation Sciences and Physiotherapy (REVAKI), University of Antwerp Wilrijk, Belgium

[2]Institute for Therapy and Rehabilitation, Kantonsspital Winterthur, Switzerland

[3]Pain in Motion, International research group, www.paininmotion.be

[4]Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium

[5]Centre for Hip Health and Mobility, University of British Columbia, Vancouver, Canada

[6]Department of Physical Therapy, Faculty of Medicine, University of British Columbia, Vancouver, Canada.

[7]Former Head of Shoulder and Elbow Surgery Unit, Clinic of Orthopaedics and Traumatology Kantonsspital Winterthur, Switzerland

[8]Department of Rehabilitation Sciences, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

Abstract

Introduction

Prognosis following surgical rotator cuff repair (RCR) is often established through the assessment of non-modifiable biomedical factors such as tear size. This understates the complex nature of recovery following RCR. There is a need to identify modifiable psychosocial and sleep related variables, and to find out whether changes in central pain processing influence prognosis after RCR. This will improve our knowledge on how to optimize recovery, using a holistic rehabilitation approach.

Methods and Analysis

This longitudinal study will analyse 141 participants undergoing usual care for first time RCR. Data will be collected 1 to 21 days preoperatively (T1), then 11- to 14-weeks (T2) and 12- to 14-months (T3) postoperatively. We will use mixed-effects linear regression to assess relationships between potential prognostic factors and our primary outcome measure – the Western Ontario Rotator Cuff Index. Secondary outcome measures include: The Constant-Score and Subjective Shoulder Value; Maximal Pain (Numeric Rating Scale); and Quality of Life (EQ-5D-5L). Potential prognostic factors include: four psychosocial variables; pain catastrophizing, perceived stress, injury perceptions and patients' expectations for RCR; sleep; and four factors related to central pain processing (central sensitisation inventory, temporal summation, cold hyperalgesia and pressure pain threshold). Intercorrelations will be assessed to determine the strength of relationships between all potential prognostic indicators.

Our aim is to explore whether modifiable psychosocial factors, sleep related variables and altered central pain processing are associated with outcomes pre- and post-RCR and to identify them as potential prognostic factors.

Ethics and Dissemination

The results of the study will be disseminated at conferences such as the European Pain Congress. One or more manuscripts will be published in a peer-reviewed SCI-ranked journal. Findings will be reported in accordance with the STROBE statement and PROGRESS framework. Ethical approval is granted by the Ethical commission of Canton of Zurich, Switzerland, No: ID_2018-02089

Registration

This trial is registered at ClinicalTrials.gov, registration number: NCT04946149

Funding

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Keywords

Rotator cuff tears, prognostic factors, psychosocial factors, patients' expectations, sleep, central sensitisation, quantitative sensory testing

Article Summary

Strengths of this study

- This will be the first study *adequately* powered to identify modifiable psychosocial factors as potential prognostic factors of outcome after rotator cuff repair (RCR).
- This study will also be the first to assess the complex interplay of psychosocial factors, sleep related variables and central pain processing measures as potential prognostic factors of outcome following RCR
- The prospective longitudinal study design includes 3 measurement points, starting preoperatively, at 12 weeks postoperative, and following up for 12-months post RCR.

Limitations of this study

- The questionnaires for sleep and patients' expectations were translated to German for the purposes of this study. Therefore, their validity in our population (German-speakers) has yet to be validated.
- Tear size is a known prognostic indicator of how well recovery will go following RCR. We will not account for tear size in our prognostic model which may bias our results.

Introduction

Prognostic factor research most often focuses on biomarkers, including biological, clinical or physiological factors. Prognostic factors help us predict the likely outcome of a patient undergoing a procedure, given the presence of certain behaviours or characteristics.(1) For patients undergoing rotator cuff repair (RCR) for shoulder pain, prognostic factors often include: patient's age; fatty infiltration into the rotator cuff muscles; quantified tendon tear size or multiple tendon involvement; and the presence of a confirmed diabetes diagnosis.(2) These are all non-modifiable biomedical markers with established capability to predict worse outcomes for patients following RCR.(2) Despite these biomarkers being recognised prognostic markers for RCR, we are still not able to fully predict who will recover successfully. A person's perception of shoulder pain is far more complex than structural changes in the rotator cuff (RC) tendons. More information is required to gain a comprehensive understanding of all factors that influence recovery.(3-7) Yet, the number of rotator cuff repairs in Europe and the United States of America continues to grow,(4, 8-10) in-spite of this lack of knowledge on the odds of success. Current evidence suggests satisfactory outcomes post RCR range from 38% to 95%. This means surgical repair is either very successful or potentially a large waste of resources.(11-14)

There is growing evidence that psychosocial factors impact persistent shoulder pain.(4, 15-18) Factors such as: high distress; maladaptive beliefs;(17) the perception of high-demand at work; and a lack of social support (18) can influence whether persistent shoulder pain and disability occur. Patients with existing preoperative psychological conditions like: depression and anxiety;(14) who exhibit pain catastrophizing and kinesiophobia; (19) or suffer psychological distress (14, 20) may

demonstrate greater preoperative shoulder pain.(14, 19) In the reverse, patients who anticipate a good recovery (positive expectations) post-RCR show independent and strong associations with satisfactory outcomes (good prognosis) for pain and disability measured one-year post surgery.(11, 12, 21) Prior research on psychosocial factors post RCR has been restricted to: preoperative measures;(19) has lacked statistical power;(14, 20) or has failed to investigate potential psychosocial prognostic factors altogether.(11, 12, 21)

Sleep disturbances are also highly prevalent (up to 89%) in patients undergoing RCR. Sleep disturbance has been attributed to the presence of shoulder pain.(22-24) RCR seems to reduce this interplay between shoulder pain and sleep disturbances as findings demonstrate an overall post RCR improvement of sleep quality.(14, 25) Yet, 41% of RCR patients still suffer from sleep disturbances at 24 months follow up.(23) Investigations of sleep disturbances in relation to shoulder pain and RCR are incomplete with multiple factors affecting the relationship.(26)

Central pain processing (CPP) changes are measured via assessments for central sensitisation. Assessments of CPP are almost absent in studies of patients undergoing RCR.(15, 16, 27) Two trials (28, 29) investigated the role of central sensitisation, measured with quantitative sensory testing (QST) on outcome (pain and disability) after different shoulder surgeries (RCR, superior labrum from anterior to posterior (SLAP) repair, shoulder arthroscopy (SA) and subacromial decompression). Both studies found small effects of CPP on post-operative outcomes. If a high amount of CPP was present pre-operatively, it was related to a worse outcome 3 months post-subacromial decompression.(28) In contrast, if a small amount of CPP was present 3

months postoperatively (RCR, SLAP-Repair, SA) it was associated to better functioning at 6 months post-surgery.(29)

The existence of potential modifiable prognostic indicators related to psychosocial factors, sleep and CPP and their effects on, shoulder function, disability, pain, quality of life and satisfaction following RCR require further investigation.(4, 19) Neither the local tissue pathology-pain model nor the growing knowledge about local biochemical changes in rotator cuff tendons sufficiently describe the relationship between tissue changes and patients' perceived shoulder pain.(3, 5, 15, 30) Studying the relationship of psychosocial factors, sleep, and central pain processing with RCR would improve our prognosis for outcomes post RCR. This holds the potential to improve treatment selection choices and reduce unnecessary surgical interventions.(3, 4, 16, 20, 31)

This study aims to answer the following questions:

1. Do psychosocial factors such as pain catastrophizing, perceived stress, injury perceptions, patients' expectations of surgery, sleep related variables and measures of CPP obtained pre RCR (baseline), influence baseline shoulder function, disability, pain and quality of life and their evolution over time (1-year post-surgery)?
2. How do potential prognostic factors: psychosocial indicators; sleep related variables; and CPP intercorrelate at baseline and over time?

Methods

Study Design and setting

The longitudinal cohort study will be implemented and reported in line with the STROBE statement for observational studies(32) informed and completed by the framework "prognosis research strategy" (PROGRESS).(1, 33)

Data will be obtained in a single shoulder and elbow surgery unit in the clinic of orthopaedic surgery and traumatology in alliance with the institute of therapy and rehabilitation of the acute care hospital, canton hospital Winterthur, Switzerland.

The current research project will analyse data from three time points in the routine clinical management post-RCR: 1-21 days preoperatively (T1); 11-13 weeks postoperatively (T2); and 12-14 months postoperatively (T3). Data from July 2019 onwards will be considered. Data collection including 12 months follow-up is estimated to be complete in Summer 2022.

See tables 1 and 2 for overview of measurement points.

Participants

The population of interest includes adult patients undergoing elective RCR, for tears of traumatic and non-traumatic origin. To avoid selection bias, we will include data from consecutive patient consultations.

Eligibility Criteria

Inclusion criteria:

- Adult men or women ≥18 years of age;
- Scheduled for elective arthroscopic RCR;
- First time RCR on the target shoulder

Exclusion criteria:

- Changes of intra-operative procedure (e.g. anything but RCR)
- Re-repair of tendon;
- No surgery;
- No pre-operative data available; e.g. fast track trauma patients

Outcome measures and prognostic factors

Our outcome measures are consistent with those used in the existing literature. We consulted the guidelines from the OMERACT 2016 Shoulder Core Outcome Set Special Interest Group.(34)

Our dependant variables are the *primary outcome measure* Western Ontario Rotator Cuff Index (WORC) for disease-specific function, disability and quality of life. The *secondary outcome measures* are: Constant – Murley – Score (CMS) and Subjective Shoulder Value (SSV) for shoulder function; maximum pain over the last 7 days on Numeric Rating Scale (NRS); European Quality of Life, 5 dimensions, 5 levels (EQ-5D-5L) for quality of life and health status**;** and a satisfaction measure developed by Swarup et al.(35)

A detailed description and overview about primary and secondary outcome measures and their psychometric properties is presented below in Table 1.

Table 1	Type / Mode	Psychometric properties / Clinimetrics	T1: Baseline 2-	T2: 12 weeks post	T3: 12 months post RCR
Primary outcome measure					
Shoulder function, disability and disease specific quality of life	***Western Ontario Rotator Cuff Index (WORC)***	Positive evidence for 5 psychometric properties: • internal consistency, • reliability, • content validity, • hypothesis testing and • responsiveness.(36, 37) German version showed satisfactory construct validity, internal consistency, test-retest reliability. No specific testing for responsiveness.(36)	x		x
Description	This 21 – items self-reported questionnaire represents a quality of life measure in rotator cuff pathology.(38) The WORC measures 5 dimensions (pain, sports/leisure, work, daily living, feelings) with 3-6 questions per domain, measured on a 100mm Visual Analogue Scale (VAS). Left endpoint equals “no” and right endpoint equals “extreme”. The total WORC score ranges from 0 (best) to 2100 (worst) (21 items x 100mm). The minimal important difference (MID) is calculated at ≥ 300mm.(39)				
Secondary outcome measures					
Shoulder function	***Constant – Murley Score (CMS)***	Validated in different shoulder diseases and recommended for rotator cuff and osteoarthritis patients due to highest responsiveness in these groups.(40) Reliability was moderately rated with ICCs > 0.8. Results about content and structural validity seem to be lacking.(37)	x	No strength measure	x
	Subjective Shoulder Value (SSV)	High correlations to Constant-Murley Score, tested in diverse shoulder diseases.			
Description CMS	The Constant-Murley Score assesses shoulder function of which 35 % are subjective variables (maximum pain intensity, work, sport/leisure, sleep, pain free height for light work), and 65% are objective variables (range of motion (ROM) and strength measure). A sum score of 100 represents perfect shoulder function, 0 represents no functionality.(37)				
Description SSV	The SSV is evaluated by one single standardised question:” What is the overall percent value of your shoulder, a completely normal shoulder represents 100%?”(40)				
Max. pain	***Numeric Rating Scale (NRS)***	Reported to be sensitive to measure change of pain level on the 11-point scale. Minimal Clinical important difference is found to be 30-33% of pain reduction.(41)	x		x
Description	Patients are asked to indicate the maximum perceived shoulder pain felt in daily life on an NRS from 0 (no pain at all) to 10 (worst imaginable pain).(42)				
Quality of life	***European Quality of Life, 5 Dimensions, 5 Levels (EQ - 5D -5L)***	Adopted and tested in Germany among general population.(43)	x		x
Description	The research group EuroQol developed the EQ-5D-5L tool “in order to provide a simple, generic measure of health for clinical and economic appraisal”. It contains of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and depression/anxiety and 5 levels ranging from no problems, slight problems, moderate problems, severe problems, and extreme problems.(44)				
Postoperative satisfaction	***Satisfaction questionnaire for postsurgical status***	No validation of this questionnaire in German language available. Forward backward translation with native speakers and expert physiotherapists was best compromise.	-		x
Description	Self-rated questionnaire containing 8 questions. Four questions cover current state of satisfaction, 1 question asks for quality of life improvement, 2 questions ask about repetition of surgery and recommendation for others and 1 question asks about timing of the surgery. The survey originates from total shoulder arthroplasty research(35) and is modified to RCR. It is clear and simple to administer.				

TABLE 1: Outcome measures

Potential prognostic factors for postoperative outcome are:

- psychosocial factors

1) pain catastrophizing,

2) perceived stress,

3) injury perceptions and

4) patients' expectations for RCR

5) sleep-related variables

- and measures of CPP

6) the central sensitization inventory (CSI) to assess self-reported somatic and emotional complaints associated to CPP

7) temporal summation (TS),

8) cold hyperalgesia (CH),

9) pressure pain threshold (PPT),

10) the Douleur Neuropathique - 4 assessment (DN4) to detect the possible presence of neuropathic pain and

11 pain distribution and localisation.

Further factors include patient related characteristics such as; demographics: 12) age and 13) sex; 14) trauma vs non-traumatic tendon tear; and health status such as 15) body mass index (BMI). These characteristics are all handled as potential prognostic factors to ensure a correct estimation of our primary prognostic factors.

Table 2 presents an overview of the potential prognostic factors including a detailed description of all measurement tools and test methodology.

Table 2	Type Mode	Psychometric properties / Clinimetrics	T1: Baseline 2-3weeks pre RCR	T2: 12 – 14 weeks post RCR	T3: 12 - 14 months post RCR
Potential Prognostic factors					
Psychosocial factors					
1 Catastrophic thinking	***Pain Catastrophising Scale (PCS)***	German PCS showed same factor structure like original version and acceptable to good reproducibility.(45) Validated in Low Back Pain Patients.	x	x	x
Description	The Pain Catastrophizing Scale assesses whether or not there is presence of catastrophic thinking about pain. Thirteen items entail aspects about different thoughts and feelings whilst experiencing pain. Items are scored on a 5-point Likert scale. Higher scores indicate more severe catastrophic thinking about pain. There is a total score and a score for three subscales (e.g. helplessness, magnification and rumination).(46)				
2 Perceived distress	***Perceived Stress Scale (PSS)***	The German version showed good psychometric properties like validity and reliability in the general population.(47)	x	x	x
	The Perceived Stress Scale (PSS – 10) includes 10 questions and assesses the degree to which life has been experienced as unpredictable, uncontrollable and overloaded in the past months. The questions are answered by “yes” (1) or “no” (0). The questions are general in nature and therefore the usage for shoulder pain patients undergoing RCR is reasonable.				
3 Perceptions about injury	***Illness Perception Questionnaire – Revised (IPQ-R)***	The clinimetric properties for musculoskeletal pain are reported to be sufficient.(48) For rotator cuff tears and rotator cuff repair, the word “injury” seems to be more matching, therefore we exchanged the word illness (German: Krankheit) with injury (in German Verletzung).	x	x	x
Description	Designed to assess the cognitive and emotional representations of illness. The items are formed by experiences, provided information and interpretation of symptoms. The IPQ-R is not disease specific and may be used in any group of interest.(49) The questionnaire has 9 dimensions of injury perception: 1. Timeline (acute/chronic), 2. Consequences, 3. Personal control, 4. Treatment control 5. Injury coherence, 6. Timeline cyclical, 7. Emotional representations as well as 8. Identity and 9. Causes. We amalgamated dimensions 1. and 6) into “timeline” and dimensions 3) and 4) into “control” and end up with 6subscales for illness perceptions and one for causes. Further it includes 3 domains(50, 51) . The first domain is called illness identity, the second is called the beliefs domain and the third is labelled as the consequence domain.(52) The authors adjusted the questionnaire to the cohort and exchanged illness with injury. The 32 injury perceptions and 18 causes answers are captured on a 5-point Likert scale from “strongly disagree” (1) to “strongly agree” (5)				
4 Expectations	***Study designed, 6 Questions about expectations***	Lack of German translated questionnaires in the field. Consequently, the research team formulated 6 Questions based on literature including the study of the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS).(12, 35)	x	-	-
Description	Patients’ expectations will be assessed using 5 questions: 1) expected shoulder function in percentage at 12 weeks post OP 2) expected shoulder function at 12 month postop 3) expected symptom reduction in percentage at 12 weeks post OP 4) expected symptom reduction in percentage at 12 months post OP 5) & 6) open questions about driver for high (>80%) or low (<80%) expectations for shoulder function and symptom reduction.				
5 Sleep					
	Study designed, 4 Questions about sleep	Due to study feasibility, we formulated 4 questions. Because sleep assessments were not validated in German language, or too long to integrate.	x	x	x
Description	4 Questions regarding sleep quality, sleep efficiency, sleep disturbance, number of awakenings per night. The first question is transformed from the Pittsburgh Sleep Quality Index (PSQI), for sleep quality and is rated on a 4-point Likert Scale. The question 2 to 3 are formulated by suggestion from research(53) and adapted to shoulder pain by the first author.				
Central Pain Processing					
6 Self-reported symptoms of central sensitisation	***Central Sensitisation Inventory (CSI)***	It is a high-quality measurement tool, with high construct validity and test-retest reliability. The defined cut-off point is at 40 points.(54) German version is to be validated by the research group among Laekemann. Contract for their usage.	x	x	x

Description	The original English questionnaire was developed in 2011 (55) to assess key symptoms in relation to central sensitivity symptoms (CSS). It consists of two parts; Part A with 25 items relating to pain, psychosocial aspects, cognitive and functional aspects. Part B with 7 different CSSs, like restless legs, irritable bowel, and multiple chemical sensitivities and 3 disorders like neck pain (whiplash), depression and anxiety or panic attacks.				
7 Temporal summation	***Frey hair filament, 10g calibrated***	No factor analysis available for testing loading of TS for CPP. TS is a common method in research to measure CPP.(56)	x	x	x
Description	Locations for applications will be at two local and one remote site: 1. Local painful site: the most painful site of the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally.(57) The patient is asked to rate the first touch on an NRS from 0 (no pain at all) to 10 (worst imaginable pain). Then the measurement is repeated once per second (1Hz) for 30seconds on a surface of maximum 1cm^2,(42) The standardization of the frequency is important, as wind-up of the C-fibers only arrives if the stimulus is provided at least once every 3 seconds(<0.33Hz).(58) After the 30 seconds application, the patient is asked to rate the last touch on an NRS. The difference between the last and the first rating is calculated. Fifteen seconds after the test, patients need to rate any ongoing pain sensation on NRS again.(59) Patients will be advised that the method does not aim to measure pain tolerance (60) and a number should only be given if the sensation was burning, stabbing, pulling or gnawing.				
8 Cold hyperalgesia (CH)	***Ice pack***	No factor analysis available for testing loading of TH for CPP. CH is a common method in research to measure CPP.(56)	x	x	x
Description	Cold hyperalgesia is measured with a cold pack, kept in the deep freezer which is simulating ice cubes for the ice test.(61) Locations for applications will be at two local and two remote sites: 1. Local painful site: the most painful site of the shoulder is marked on the skin with a pen, indicated on a body chart and noted in the assessors' documents, to determine the site for repeated measures. 2. Local standardized site: at ipsilateral upper trapezius muscle at the midpoint between C7 spinous process and the acromion. 3. Remote site is standardized at the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally.(57) The cold application is kept for 10 seconds, and the patients will rate the experienced pain on a NRS from 0 (no pain at all) to 10 (worst imaginable pain).(61) Patients will be advised the measure does not aim for pain tolerance and they pain should be reported if a burning, stabbing, pulling or gnawing sensation is felt.(60)				
9 Pressure Pain Threshold (PPT)	***Wagner Instruments***	No factor analysis available for testing loading of PPT for CPP. PPT is a common method in research to measure CPP.(56)	x	x	x
Description	PPT represents a static psychophysical test, which measures the point of pressure evolving into pain. Its report of large to nearly perfect reliability in neck pain patients, demonstrates its great potential as measurement tool also for the present cohort.(62) The measurements will be conducted by digital hand-held pressure algometer with a rubber tip of approximately 1 cm² (FPX 50, FORCE TEN by Wagner Instruments), increasing pressure will be given perpendicular to the skin.(63) Measurements are taken at five standardized sites: 1. Two cm caudal from the acromion at the muscle belly of middle deltoid, bilaterally. 2. At the muscle belly in middle of the upper trapezius, bilaterally. 3. At the contralateral muscle belly of tibialis anterior at 5cm distal to the tibial tuberosity and 2cm laterally, as remote site.(57) All measurements will be repeated once and the mean PPT in kilopascals per site will be calculated.				
10 Neuropathic pain differential diagnosis	***Douleur Neuropathique 4 (DN4)***	The DN4 showed more sensitivity and specificity in preselected cohorts with respect of neuropathic pain detection, and it is strongly advised to obtain a thorough clinical assessment when diagnosing neuropathic pain.(64)	x	x	x
Description	Short and easy to administer assessment, which consists of a subjective part, including 7 symptoms (patient-rated) and an objective part including 3 signs (physician-rated). The cut-off point is 4 points, the total of points is 10, indicating that neuropathic pain mechanisms may be involved.(64)				
11 Pain distribution	***Body Chart***		x	x	x
Description	Patients report their pain location and pain distribution. The assessor is painting the body chart. Calculation of pain distribution in percentage of the body surface will be analysed using the Margolis Bodychart scoring system.(65)				
Additional prognostic factors					
12 Age	Date of birth		x	-	-
13 Sex	Female / male / other		x	-	-
14 Cause of tear	Traumatic vs. non-traumatic		x	-	-
15 Body Mass Index (BMI)	Kg and cm		x	-	-

TABLE 2: Potential prognostic factors

Four (AS, WB, QdG, FM) experienced and trained (by the first author AS) shoulder specialists and physiotherapists will perform all the measurements (CMS, QST, SSV, NRS Pain). To support the training, all participant assessment files will incorporate detailed descriptions with respect to how the assessor should formulate questions and offer answer suggestions. A detailed description of the prognostic indicators we collect can be found in table 2.

Statistical Methods and Analysis

Statistical analyses will be performed using SAS (SAS 9.4, SAS Institute Inc., Cary, NC, USA). Level of significance is set at p = 0.05. Measurements will take place at three time points in the perioperative management, as described above (T1 = at baseline 2-3 weeks prior to RCR, T2 = at 12 weeks post RCR and T3 = at 12 months post RCR as follow-up).

The primary outcome (WORC) will be modelled using mixed-effects linear regression models for repeated (longitudinal) measures, using an unstructured covariance matrix. Dependent variables are the primary and secondary outcomes. Continuous secondary outcomes will be assessed in a similar way to the primary outcome. The models will be developed by stepwise reduction of the *a priori* determined potential prognostic factors (for example psychosocial factors, sleep and CPP). A prognostic factor will be retained in the model if it has a significant effect on the initial outcome or on the outcome over time, or if the fit statistics (Deviance, AIC, BIC and R2) of the model improves after inclusion of the variable, in order to increase the precision of the fixed effects estimates.(66-68) This means that a prognostic factor may be retained in the final model, even if it is not significant (p>0.05), to ensure correct estimation of other (significant) prognostic factors.

Descriptive statistics will be performed for comorbidities such as: obesity, diabetes, and depression; for insurance status (health care vs. accident insurance); and current profession divided into categories such as, manual labourer (painter, carpenter, locksmith.), construction-worker (e.g. streets, buildings), office worker, repetitive work (e.g. supermarket, post office, industry, hairdresser), health care practitioner (e.g. nurse, medical doctor, PT, OT), pensioner and student.

Sample Size

We will use a linear mixed-effects regression model for repeated measures. This will have a power of 90% to identify prognostic factors of both interindividual baseline differences in WORC score and a change in WORC score over time that are considered clinically relevant (we assume a standard deviation of 300 points at baseline and a decline in WORC score of at least 15% over time on average),(69) at a confidence level α=0.5 (two-tailed). The required total sample size was calculated to be 125 subjects (R, Edland package).(70, 71) To account for an expected attrition rate of 12.5%, the final sample size was set at 141 participants.

The power is set at 90% to minimize the chance of making a type II error.

It is especially difficult to determine a correct sample size for a longitudinal exploratory study, as the final mixed model is likely to contain complex variance and correlation patterns that are not known beforehand. Therefore, we plan an interim analysis after the inclusion of the first 80 participants, to assess the drop-out rate, the achieved power and the potential futility of the *a priori* selected prognostic factors. Mixed models do not require complete datasets to produce accurate results, through correct specification of the likelihood function.(67)

Data security and management

Data generation, transmission, storage and analysis within this project strictly follow Swiss legal requirements for data protection. The electronic data capture (EDC) software REDCap (72, 73) will be used for data processing and management. REDCap was developed by an informatics core at Vanderbilt University in 2004, with ongoing support from US National Center for Research Resources (NCRR) and US National Institute of Health (NIH), grants NIH/NCATS UL1 TR000445. REDCap was specifically developed around HIPAA security guidelines and is Good Clinical Practice-compliant and fulfils the regulatory requirements regarding the collection of patient data in clinical trials or non-interventional studies and patient registries and the EU data protections laws. Appropriate coded identification (e.g. pseudonymisation) is used in order to enter subject data into the database. The coding list of target data is saved in a secured folder on the hospital's server. Only the project leader, study nurses and principal investigator have access to it. Between the members of the research team only coded and de-identified data will be shared. Safe handling of the coded data will be covered by the software REDCap.

Study Monitoring

An audit trail and history of data transmission are provided by REDCap. The steering committee of the research project will oversee all aspects of design, delivery, quality assurance and data analysis according to good clinical practice and local legislation.

Ethics

The study follows the principles of the Helsinki Declaration. Only data of patients who gave general consent to the hospital or informed written consent to the project will be considered for analysis. Ethical approval was received in January 2019 (ID 2018-02089) by the Ethical Committee of the Canton of Zurich, Switzerland.

Dissemination of results

The research team is committed to full disclosure of the results of the study. The results of the study will be disseminated for research purpose at different conferences and as published articles in peer reviewed journals. Findings will be reported in accordance to the STROBE statement and we aim to publish in high impact journals.

Contributors statement

AS is the project leader, who receives support from FS and MM (last author) with respect to topic-selection and study design. TS controls the statistical model and will support statistical data analysis. MM (fifth author) and PB contributed to the protocol through critical review and intellectual content. DG and MP support the feasibility of the study and access to clinical data through the physiotherapy and orthopaedic clinic at canton hospital Winterthur. DG and MP also support data security by providing REDCap software. All authors gave final approval for publication of the present protocol version.

Patient and Public Involvement:

Between January 2019 and June 2019, we have interviewed patients about their experience of filling out the questionnaires and about their experience of attending the clinical consultations at the canton hospital Winterthur. The responses supported the

fine tuning of our questionnaires, assessments and organisation processes. In detail these were:

a) changes in the introduction texts of the different questionnaires;

b) changes of wording for the questions regarding patients' expectations for RCR (replacement of the word "satisfaction" with the word "expectation");

c) the repeated training of the four physiotherapists to formulate the questions during the assessment equally as their peer and always precisely (e.g. "From 0 - being no pain at all - to 10 - being excruciating pain- what has been your strongest perceived pain during the last week?") and;

d) improvements of the processes and organisation around the clinical consultations (e.g. communication between staff and patients regarding appointments).

Data of this feasibility phase from January 2019 until June 2019 will not be included in the study.

Patients attend the clinic in a usual care setting and will be asked for general or informed consent. There will not be a study specific recruitment and therefore patients are not needed to be involved in a recruitment procedure.

Study participants can request the results after publication.

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Competing of Interest

The authors declare no conflicts of interest.

Patients' consent for publication

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