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BMJ Open

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

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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

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For peer review only

1 **Abstract**

2 **Introduction**

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

9 **Methods and Analysis**

10 This longitudinal cohort study will analyse 125 participants undergoing usual care for
11 first time RCR. Data will be collected 1 to 21 days preoperatively (T1), 11 to 14 weeks
12 (T2) and 12 to 14 months (T3) postoperatively. We will use mixed-effects linear
13 regression to identify relationships between potential prognostic factors and our
14 primary outcome measure – the Western Ontario Rotator Cuff Index. Secondary
15 outcome measures that will be assessed against prognostic indicators include: The
16 Constant-Score and Subjective Shoulder Value; Maximal Pain (Numeric Rating
17 Scale); and Quality of Life (European Quality of Life 5 Dimensions 5 Levels – EQ-5D-
18 5L). Our potential prognostic factors include: four psychosocial variables — pain
19 catastrophizing, perceived stress, injury perceptions and patients' expectations for
20 RCR; one lifestyle factor — sleep; and four factors related to central pain processing
21 — central sensitisation inventory, temporal summation, thermal hyperalgesia and
22 pressure pain threshold. The potential prognostic factors will be assessed for
23 correlations with our primary and secondary outcomes. Interaction effects will be

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3 24 assessed to determine the strength of relationships between all potential prognostic
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5 25 indicators.
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9 26 **Ethics and Dissemination**
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11 27 The results of the study will be disseminated at conferences (e.g. European Pain
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13 Congress (EFIC)). One or more manuscripts will be published in peer reviewed SCI-
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15 ranked journals. Findings will be reported in accordance with the STROBE statement.
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18 29 Results will be presented with full disclosure. Ethical approval is granted by the Ethical
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20 commission of Canton of Zurich, Switzerland, No: ID_2018-02089.
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25 32 **Registration**
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29 33 Registered at ClinicalTrials.gov, registration number: NCT04946149
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33 35 **Funding**
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35

36 36 This work is supported by the Swiss physiotherapy association *physioswiss* through a
37
38 financial research prize.
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40 38
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42 39 **Keywords**
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44 40 Rotator cuff tears, prognostic factors psychosocial factors, expectations, central
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46 sensitisation, quantitative sensory testing, sleep
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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 lifetime 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 $\geq 270'000$ 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)

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2 RCR seems to reduce this interplay between shoulder pain and sleep disturbances as
3 findings demonstrate an overall post RCR improvement of sleep quality.(14, 33) Yet,
4 41% of RCR patients still demonstrate sleep disturbances at 24 months follow up.(31)
5 Investigations of sleep disturbance in relation to shoulder pain and RCR are
6 incomplete with multiple factors affecting the relationship.(34) This implies that further
7 exploration is needed.
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18 Altered central pain processing (CPP) such as measures of central sensitisation
19 demonstrate conflicting evidence with regards to its presence in musculoskeletal
20 shoulder pain. CPP is almost absent in studies of patients undergoing RCR.(20, 21,
21 25)
22 Two trials (36, 37) investigated the role of central sensitisation, measured with
23 quantitative sensory testing (QST) on outcome (pain and disability) after different
24 shoulder surgeries (RCR, superior labrum from anterior to posterior (SLAP) repair,
25 shoulder arthroscopy (SA) and subacromial decompression). Both studies found small
26 effects of CPP on post-operative outcomes. If a high amount of CPP was present pre-
27 operatively, it was related to a worse outcome 3 months post-subacromial
28 decompression.(36) In contrast, if a small amount of CPP was present 3 months
29 postoperatively (RCR, SLAP-Repair, SA) it was associated to better functioning at 6
30 months post-surgery.(37)

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

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3 postoperatively (T2) and 12-14 months postoperatively (T3). Data from July 2019
4 onwards will be considered. Data collection including 12months follow-up is estimated
5 to be complete in Summer 2022.
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10 See table 1 for overview of measurement points.
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15 Participants

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17 The population of interest includes adult patients undergoing elective RCR, for tears
18 of traumatic and non-traumatic origin.
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24 Eligibility Criteria

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26 *Inclusion criteria:*

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- 28 - Adult men or women ≥ 18 years of age;
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 - 30 - Scheduled for elective arthroscopic RCR;
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 - 32 - First time RCR on the target shoulder
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38 *Exclusion criteria:*

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- 40 - Changes of intra operative procedure (e.g. anything but RCR)
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 - 42 - Re-repair of tendon;
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 - 44 - No surgery;
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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 BMJ Open	T1: Baseline 3weeks pre RCR	36/36 Ramppen-2021-058803 on 4 August 2022 Erasmus University Rotterdam For personal use only Downloaded from http://bmjopen.bmjjournals.org/ on May 12, 2025 at Department GEZ-LTA	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)	<p>Positive evidence for 5 psychometric properties:</p> <ul style="list-style-type: none"> internal consistency, reliability, content validity, hypothesis testing and responsiveness(42, 43) <p>German version showed satisfactory construct validity, internal consistency, test-retest reliability. No specific testing for responsiveness.(42)</p> <p>The minimal important difference (MID) is calculated at $\geq 300\text{mm}$.(44)</p>	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)	<p>Validated in different shoulder diseases and recommended for rotator cuff and osteoarthritis patients due to highest responsiveness in these groups.(46)</p> <p>Reliability was moderately rated with ICCs > 0.8. Results about content and structural validity seem to be lacking.(43)</p>	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						
<i>Psychosocial factors</i>						
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					

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	3) and 4) into "control" and end up with 6 subscales for illness perceptions and one for causes. 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 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(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				

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	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 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 number should only be given if the sensation was burning, stabbing, pulling or gnawing.		x	x	x
Thermal hyperalgesia (TH) cold	<i>Ice pack</i>	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 simulating ice 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 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 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)	<i>Wagner Instruments</i>	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	<i>Body Chart</i>		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				

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1	Sex	Female / male				
2	Cause of tear	Traumatic vs. non-traumatic /				
3	Insurance type	Health care insurance vs accident insurance				
4	Body Mass Index (BMI)	Kg and cm				
5	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				
6	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				
7	Self-reported measures of change					
8	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
9	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, 2 questions ask about repetition of surgery and recommendation for others and 1 question asks from total shoulder arthroplasty research(71) and is modified to RCR. It is clear and simple to administer.	question asks for quality of life improvement, timing of the surgery. The survey originates from total shoulder arthroplasty.	EuroQol, GRoC = Global Rating of Change, EuroPain, EuroPain Pressure Pain Threshold, PROM = Patient Related Outcome Measure, PSS = Perceived Stress Scale, PT = Physiotherapist, QST = Quantitative Sensory Testing, SS = Subjective Shoulder Value, TS = Temporal Summation, WORC = Western Ontario Rotator Cuff Index	EuroQol, GRoC = Global Rating of Change, EuroPain, EuroPain Pressure Pain Threshold, PROM = Patient Related Outcome Measure, PSS = Perceived Stress Scale, PT = Physiotherapist, QST = Quantitative Sensory Testing, SS = Subjective Shoulder Value, TS = Temporal Summation, WORC = Western Ontario Rotator Cuff Index
CPP = Central Pain Processing, CSI = Central Sensitisation Inventory, CSS = Central Sensitivity Symptoms EQ-5D-5L IPQ-R = Illness Perception Questionnaire – Revised, NRS = Numeric Rating Scale, PCS = Pain Catastrophising Scale, PROM = Patient Rated Outcome Measure, PSS = Perceived Stress Scale, PT = Physiotherapist, QST = Quantitative Sensory Testing, SS = 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 $\alpha=0.5$, (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)

1 2 3 Data security and management 4

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

20 21 22 23 24 Study Monitoring 25 26

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

30 31 32 33 34 35 36 37 38 Ethics and dissemination 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60

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

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References

1. Klintberg IH, Cools AMJ, Holmgren TM, et al. Consensus for physiotherapy for
2 shoulder pain. International Orthopaedics. 2014;39(4):715-20.
3. Rodeghero JR, Cleland JA, Mintken PE, Cook CE. Risk stratification of patients with
4 shoulder pain seen in physical therapy practice. J Eval Clin Pract. 2017;23(2):257-63.
5. Bury J, Littlewood C. Rotator cuff disorders: a survey of current (2016) UK
6 physiotherapy practice. Shoulder Elbow. 2018;10(1):52-61.
7. Vincent K, Leboeuf-Yde C, Gagey O. Are degenerative rotator cuff disorders a cause
8 of shoulder pain? Comparison of prevalence of degenerative rotator cuff disease to
9 prevalence of nontraumatic shoulder pain through three systematic and critical reviews. J
10 Shoulder Elbow Surg. 2017;26(5):766-73.
11. Littlewood C, Malliaras P, Bateman M, Stace R, May S, Walters S. The central nervous
12 system--an additional consideration in 'rotator cuff tendinopathy' and a potential basis for
13 understanding response to loaded therapeutic exercise. Man Ther. 2013;18(6):468-72.
14. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are Psychosocial Factors
15 Associated With Patient-reported Outcome Measures in Patients With Rotator Cuff Tears? A
16 Systematic Review. Clin Orthop Relat Res. 2018;476(4):810-29.
17. Littlewood C, Rangan A, Beard DJ, Wade J, Cookson T, Foster NE. The enigma of
18 rotator cuff tears and the case for uncertainty. Br J Sports Med. 2018;52(19):1222.
19. Saltzman BM, Zuke WA, Go B, et al. Does early motion lead to a higher failure rate or
20 better outcomes after arthroscopic rotator cuff repair? A systematic review of overlapping
21 meta-analyses. Journal of Shoulder and Elbow Surgery. 2017;26(9):1681-91.
22. Jain NB, Higgins L. D., Losina, E., Collins, J., Blazar, P. E., and Katz, J. . Epidemiology of
23 musculoskeletal upper extremity ambulatory surgery in the United States. BMC
24 Musculoskeletal Disorders. 2014;15:1471-2474.
25. Paloneva J, Lepola V, Aarimaa V, Joukainen A, Ylinen J, Mattila VM. Increasing
26 incidence of rotator cuff repairs--A nationwide registry study in Finland. BMC Musculoskeletal
27 Disorders. 2015;16:189.
28. Novoa-Boldo A, Gulotta LV. Expectations Following Rotator Cuff Surgery. Curr Rev
29 Musculoskelet Med. 2018;11(1):162-6.
30. Henn RF, 3rd, Kang L, Tashjian RZ, Green A. Patients' preoperative expectations
31 predict the outcome of rotator cuff repair. J Bone Joint Surg Am. 2007;89(9):1913-9.
32. Lambers Heerspink FO, Dorrestijn O, van Raay JJ, Diercks RL. Specific patient-related
33 prognostic factors for rotator cuff repair: a systematic review. J Shoulder Elbow Surg.
34 2014;23(7):1073-80.
35. Cho CH, Song KS, Hwang I, Warner JJ. Does Rotator Cuff Repair Improve Psychologic
36 Status and Quality of Life in Patients With Rotator Cuff Tear? Clin Orthop Relat Res.
37 2015;473(11):3494-500.
38. Ring D. CORR Insights(R): Are Psychosocial Factors Associated With Patient-reported
39 Outcome Measures in Patients With Rotator Cuff Tears? A Systematic Review. Clin Orthop
40 Relat Res. 2018;476(4):830-1.
41. Fermont AJ, Wolterbeek N, Wessel RN, Baeyens JP, de Bie RA. Prognostic factors for
42 successful recovery after arthroscopic rotator cuff repair: a systematic literature review. J
43 Orthop Sports Phys Ther. 2014;44(3):153-63.

- 1
2
3 17. Raman JW, D.; MacDermid, J. C.; Athwal, G. Predictors of outcomes after rotator
4 cuff repairdA meta-analysis. *Journal of Hand Therapy*. 2017.
- 5 18. Riley RD, Hayden JA, Steyerberg EW, et al. Prognosis Research Strategy (PROGRESS)
6 2: prognostic factor research. *PLoS medicine*. 2013;10(2):e1001380.
- 7 19. Clark GM, Zborowski DM, Culbertson JL, et al. Clinical utility of epidermal growth
8 factor receptor expression for selecting patients with advanced non-small cell lung cancer
9 for treatment with erlotinib. *Journal of Thoracic Oncology*. 2006;1(8):837-46.
- 10 20. Noten S, Struyf F, Lluch E, D'Hoore M, Van Looveren E, Meeus M. Central Pain
11 Processing in Patients with Shoulder Pain: A Review of the Literature. *Pain Pract*.
12 2017;17(2):267-80.
- 13 21. Sanchis MN, Lluch E, Nijs J, Struyf F, Kangasperko M. The role of central sensitization
14 in shoulder pain: A systematic literature review. *Semin Arthritis Rheum*. 2015;44(6):710-6.
- 15 22. Martinez-Calderon J, Meeus M, Struyf F, Miguel Morales-Asencio J, Gijon-Nogueron
16 G, Luque-Suarez A. The role of psychological factors in the perpetuation of pain intensity
17 and disability in people with chronic shoulder pain: a systematic review. *BMJ Open*.
18 2018;8(4):e020703.
- 19 23. Struyf F, Geraets, J., Noten, S., Meeus, M., Nijs, J. . A Multivariable Prediction Model
20 for the Chronification of Non-traumatic Shoulder PAin: A Systematic Review. *Pain Physician*.
21 2016(19):1-10.
- 22 24. Thorpe AM, O'Sullivan PB, Mitchell T, et al. Are Psychologic Factors Associated With
23 Shoulder Scores After Rotator Cuff Surgery? *Clin Orthop Relat Res*. 2018;476(10):2062-73.
- 24 25. Ravindra A, Barlow JD, Jones GL, Bishop JY. A prospective evaluation of predictors of
25 pain after arthroscopic rotator cuff repair: psychosocial factors have a stronger association
26 than structural factors. *J Shoulder Elbow Surg*. 2018;27(10):1824-9.
- 27 26. Barlow JD, Bishop JY, Dunn WR, Kuhn JE, Group MS. What factors are predictors of
28 emotional health in patients with full-thickness rotator cuff tears? *J Shoulder Elbow Surg*.
29 2016;25(11):1769-73.
- 30 27. Flammer A. Self-efficacy. Elsevier Science Ltd. 2001.
- 31 28. Potter MQ, Wylie JD, Greis PE, Burks RT, Tashjian RZ. Psychological Distress
32 Negatively Affects Self-assessment of Shoulder Function in Patients With Rotator Cuff Tears.
33 Clinical Orthopaedics and Related Research®. 2014;472(12):3926-32.
- 34 29. Oh JH, Yoon JP, Kim JY, Kim SH. Effect of expectations and concerns in rotator cuff
35 disorders and correlations with preoperative patient characteristics. *J Shoulder Elbow Surg*.
36 2012;21(6):715-21.
- 37 30. Gillespie MA, A MC, Wassinger CA, Sole G. Rotator cuff-related pain: Patients'
38 understanding and experiences. *Musculoskelet Sci Pract*. 2017;30:64-71.
- 39 31. Kunze KN, Movasagghi K, Rossi DM, et al. Systematic Review of Sleep Quality Before
40 and After Arthroscopic Rotator Cuff Repair: Are Improvements Experienced and
41 Maintained? *Orthop J Sports Med*. 2020;8(12):2325967120969224.
- 42 32. Cho CH, Jung SW, Park JY, Song KS, Yu KI. Is shoulder pain for three months or longer
43 correlated with depression, anxiety, and sleep disturbance? *J Shoulder Elbow Surg*.
44 2013;22(2):222-8.
- 45 33. Austin L, Pepe M, Tucker B, et al. Sleep disturbance associated with rotator cuff tear:
46 correction with arthroscopic rotator cuff repair. *Am J Sports Med*. 2015;43(6):1455-9.
- 47 34. Longo UG, Facchinetti G, Marchetti A, et al. Sleep Disturbance and Rotator Cuff
48 Tears: A Systematic Review. *Medicina (Kaunas)*. 2019;55(8).
- 49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 35. Nijs J, George SZ, Clauw DJ, et al. Central sensitisation in chronic pain conditions:
4 latest discoveries and their potential for precision medicine. *The Lancet Rheumatology*.
5 2021.
- 6 36. Gwilym SE, Oag, H. C. L., Tracey, I. and Carr A. J. . Evidence that central sensitisation
7 is present in patients with shoulder impingement syndrome and influences the outcome
8 after surgery. *The Journal of Bone & Joint Surgery*. 2011;93-B:498-502.
- 9 37. Valencia C, Fillingim RB, Bishop M, et al. Investigation of central pain processing in
10 postoperative shoulder pain and disability. *Clin J Pain*. 2014;30(9):775-86.
- 11 38. Rees JD, Stride M, Scott A. Tendons--time to revisit inflammation. *Br J Sports Med*.
12 2014;48(21):1553-7.
- 13 39. Lewis J, O'Sullivan P. Is it time to reframe how we care for people with non-traumatic
14 musculoskeletal pain? *British Journal of Sports Medicine*. 2018.
- 15 40. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandebroucke JP. The
16 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement:
17 guidelines for reporting observational studies. *Annals of internal medicine*. 2007;147(8):573-
18 7.
- 19 41. Buchbinder R, Page MJ, Huang H, et al. A Preliminary Core Domain Set for Clinical
20 Trials of Shoulder Disorders: A Report from the OMERACT 2016 Shoulder Core Outcome Set
21 Special Interest Group. *J Rheumatol*. 2017;44(12):1880-3.
- 22 42. Huber W, Hofstaetter JG, Hanslik-Schnabel B, Posch M, Wurnig C. [Translation and
23 psychometric testing of the Western Ontario Rotator Cuff Index (WORC) for use in
24 Germany]. *Z Orthop Ihre Grenzgeb*. 2005;143(4):453-60.
- 25 43. Huang H, Grant JA, Miller BS, Mirza FM, Gagnier JJ. A Systematic Review of the
26 Psychometric Properties of Patient-Reported Outcome Instruments for Use in Patients With
27 Rotator Cuff Disease. *Am J Sports Med*. 2015;43(10):2572-82.
- 28 44. Braun C, Handoll HH. Estimating the Minimal Important Difference for the Western
29 Ontario Rotator Cuff Index (WORC) in adults with shoulder pain associated with partial-
30 thickness rotator cuff tears. *Musculoskelet Sci Pract*. 2018;35:30-3.
- 31 45. MacDermid JC, Drosdowech D, Faber K. Responsiveness of self-report scales in
32 patients recovering from rotator cuff surgery. *J Shoulder Elbow Surg*. 2006;15(4):407-14.
- 33 46. Gilbart MK, Gerber C. Comparison of the subjective shoulder value and the Constant
34 score. *J Shoulder Elbow Surg*. 2007;16(6):717-21.
- 35 47. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales.
36 *Journal of clinical Nursing* 2004;14:798 - 804.
- 37 48. Nahman-Averbuch H, Yarnitsky D, Granovsky Y, et al. Pronociceptive pain
38 modulation in patients with painful chemotherapy-induced polyneuropathy. *J Pain
39 Symptom Manage*. 2011;42(2):229-38.
- 40 49. Ludwig K, Graf von der Schulenburg JM, Greiner W. German Value Set for the EQ-5D-
51 5L. *Pharmacoeconomics*. 2018;36(6):663-74.
- 52 50. Group TE. EuroQol-a new facility for the measurement of health-related quality of
53 life. *Health policy*. 1990;16(3):199-208.
- 54 51. Meyer K SH, Manion AF. Cross-cultural adaptation, reliability and validity of the
55 German version of the Pain Catastrophizing Scale. *Journal of Psychosomatic Research*.
56 2008;64(5):469-478.
- 57 52. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and
58 validation. *Psychological assessment*. 1995;7(4):524.
- 59
60

- 1
2
3 53. Klein EM, Brahler E, Dreier M, et al. The German version of the Perceived Stress Scale
4 - psychometric characteristics in a representative German community sample. *BMC*
5 *Psychiatry*. 2016;16:159.
- 6 54. Leysen M, Nijs J, Meeus M, et al. Clinimetric properties of illness perception
7 questionnaire revised (IPQ-R) and brief illness perception questionnaire (Brief IPQ) in
8 patients with musculoskeletal disorders: A systematic review. *Man Ther*. 2015;20(1):10-7.
- 9 55. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised
10 Illness Perception Questionnaire (IPQ-R). *Psychology & Health*. 2002;17(1):1-16.
- 11 56. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception
12 questionnaire. *J Psychosom Res*. 2006;60(6):631-7.
- 13 57. Lau RR, Hartman KA. Common sense representations of common illnesses. *Health*
14 psychology. 1983;2(2):167.
- 15 58. Broadbent E, Wilkes C, Koschwanez H, Weinman J, Norton S, Petrie KJ. A systematic
16 review and meta-analysis of the Brief Illness Perception Questionnaire. *Psychol Health*.
17 2015;30(11):1361-85.
- 18 59. Jo Nijs OM, Daniel Neu, Laurence Leysen, Lieven Danneels,, Barbara Cagnie MM,
19 Maarten Moens, Kelly Ickmans, Dorien Goubert. sleep disturbances in chronic pain
20 neurobiology assessment and treatment in physical therapy. 2018.
- 21 60. Scerbo T, Colasurdo J, Dunn S, Unger J, Nijs J, Cook C. Measurement Properties of the
22 Central Sensitization Inventory: A Systematic Review. *Pain Pract*. 2018;18(4):544-54.
- 23 61. Mayer TG, Neblett R, Cohen H, et al. The development and psychometric validation
24 of the central sensitization inventory. *Pain Pract*. 2012;12(4):276-85.
- 25 62. Kuppens K, Hans G, Roussel N, et al. Sensory processing and central pain modulation
26 in patients with chronic shoulder pain: A case-control study. *Scand J Med Sci Sports*.
27 2018;28(3):1183-92.
- 28 63. Rebbeck T, Moloney, N., Azoory, R., Hübscher, M., Waller, R., Gibbons, R., Beales,
29 D., Clinical ratings of pain sensitivity correlate with qust in people with chronic neck pain
30 and healthy controls cross sectional study. *Physical Therapy*. 2015;95(11).
- 31 64. Staud R, Robinson ME, Vierck CJ, Cannon RC, Mauderli AP, Price DD. Ratings of
32 experimental pain and pain-related negative affect predict clinical pain in patients with
33 fibromyalgia syndrome. *Pain*. 2003;105(1):215-22.
- 34 65. Edwards RR, Mensing G, Cahalan C, et al. Alteration in pain modulation in women
35 with persistent pain after lumpectomy: influence of catastrophizing. *J Pain Symptom*
36 *Manage*. 2013;46(1):30-42.
- 37 66. Moloney N. An investigation of somatosensory profiles in wook related upper limb
38 disorders a case control obervational study protocol. 2010.
- 39 67. Maxwell S, Sterling M. An investigation of the use of a numeric pain rating scale with
40 ice application to the neck to determine cold hyperalgesia. *Man Ther*. 2013;18(2):172-4.
- 41 68. Walton DM, Macdermid JC, Nielson W, Teasell RW, Reese H, Levesque L. Pressure
42 pain threshold testing demonstrates predictive ability in people with acute whiplash. *J*
43 *Orthop Sports Phys Ther*. 2011;41(9):658-65.
- 44 69. Klyne DM, Schmid AB, Moseley GL, Sterling M, Hodges PW. Effect of types and
45 anatomic arrangement of painful stimuli on conditioned pain modulation. *J Pain*.
46 2015;16(2):176-85.
- 47 70. Steven J Kamper CoGM, Grant Mackay,. Global Rating of change Scales: A review of
48 strenghts and weaknesses and considerations for design. 2009.

- 1
2
3 71. I. Swarup CMH, J. T. Nguyen, D. M. Dines, E. V. Craig, R. F. Warren, L. V. Gulotta, R. F.
4 Henn III Effect of pre-operative expectations on the outcomes following total shoulder
5 arthroplasty. 2017.
- 6 72. Kirkley A. ACaGS. The Development and Evaluation of a Disease-specific Quality-of-
7 Life Questionnaire for Disorders of the Rotator Cuff_ The Western Ontario Rotator Cuff
8 Index. Clinical Journal of Sport Medicine. 2003;13:84–92.
- 9 73. Faul F, Erdfelder, E., Lang, A.-G., & Buchner, A. . G Power 3- A flexible statistical
10 power analysis program for the social, behavioral, and biomedical sciences. Behavior
11 Research Methods. 2007.
- 12 74. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power
13 3.1: tests for correlation and regression analyses. Behav Res Methods. 2009;41(4):1149-60.
- 14 75. Singer JD, Willett JB, Willett JB. Applied longitudinal data analysis: Modeling change
15 and event occurrence: Oxford university press; 2003.
- 16 76. Blackwell E, de Leon CF, Miller GE. Applying mixed regression models to the analysis
17 of repeated-measures data in psychosomatic medicine. Psychosom Med. 2006;68(6):870-8.
- 18 77. Edland S. Which MRI measure is best for Alzheimer's disease prevention trials.
19 Statistical considerations of power and sample size Jt Stat Meet Proc. 2009:4996-9.
- 20 78. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an
21 international community of software platform partners. Journal of biomedical informatics.
22 2019;95:103208.
- 23 79. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic
24 data capture (REDCap)—a metadata-driven methodology and workflow process for
25 providing translational research informatics support. Journal of biomedical informatics.
26 2009;42(2):377-81.
- 27
28
29
30
31
32
33
34
35
36
37
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1 2 3 Appendix

4 5 1. Baseline Assessment

6 7 Quantitativ Sensorische Testung - QS

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9 Datum:betr. Seite:

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11 Schmerzgebiet 1 :.....

12 Patientenkennzeichen:

13 14 Temporal summation (TS) 15 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						

24 25 Gerät: Lokalisation:	26 27 Monofilament 30g. 28 Schmerzhafte Stelle/n UND Tibialis anterior kontralaterale Seite.
29 30 Pressure 31 Pain 32 Threshold 33 (PPT)	34 Links
35	36 1. Messung 2. Messung Durchschnittswert
Deltoides p. acromialis	
Trapezius p. descendens	
Tibialis anterior	

37 Durchführung: Monofilament muss sich **immer maximal beugen**. 1. Berührung 0-10/10 NRS, danach

38 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?

39 Auf einer Skala von 0-10, wie stark schmerzt diese Berührung (bohren, ziehen,

40 Anweisung an den Patienten: stechen oder brennen)

41 Auswertung: Differenz: letzte Zahl minus erste Zahl

46 Gerät:
47 Lokalisation:
48 FORCE Ten FDX50. Immer im 90° Winkel zum Muskelbauch halten.
49 Deltoides p. acromialis: 2cm Kaudal des Acromions, Muskelbauch; Trapezius
descendens: Muskelbauch zwischen lat. Drittel Klavikula und C7; Tibialis anterior:
Muskelbauch.

50 Durchführung: ca. 5N/Sek. Druck steigern, Display nach unten halten, 30Sek Pause zwischen
51 JEDER Messung, 2 Messungen pro Lokalisaiton, IMMER bilateral Schulter messen,
nur kontralateral Tib. Ant. messen
52 Durchschnittswert nehmen.

53 Auswertung:
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		

15 **Gerät:**

Coldpack aus Tiefkühler, vor jeder Messung neu.

16 **Durchführung:**

10sek. Eisapplikation, dann NRS 0-10/10

17 **Anweisung an den Patienten:**

Ist diese Kälteanwendung schmerhaft für Sie? (bohren, ziehen, stechen oder

brennen) NRS 0-10/10

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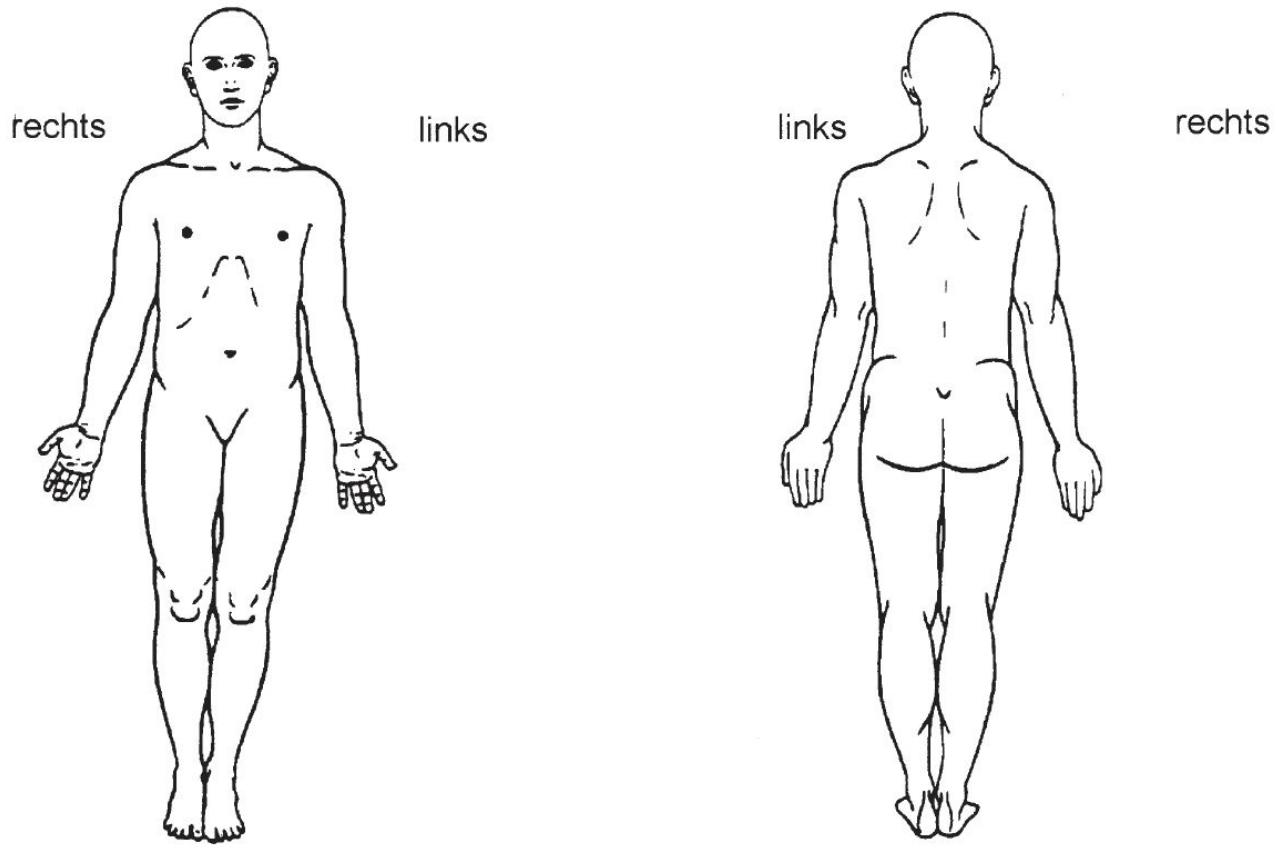
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Datum:.....
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ID:.....

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: _____	Betroffene Schulter: <input type="checkbox"/> re <input type="checkbox"/> li		
Geb.-Datum: _____	Dominanter Arm: <input type="checkbox"/> re <input type="checkbox"/> li		
Untersuchungsdatum: _____			
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.

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Herzlichen Dank
5 **Ihr KSW-Schulter-Team**
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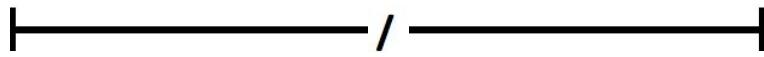
For peer review only

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

Überhaupt nicht	extrem
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6. Wie viel Unbehagen verspüren Sie in Ihrer Nackenmuskulatur?

kein Unbehagen	extremes Unbehagen
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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
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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 schmerhaft 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 Hauthausschlag.	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			

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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

1
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3 Ein wichtiger Faktor rund um die Operation ist Ihre Erwartung. Danach möchten wir
4 Sie hier gerne fragen.
5
6

Erwartungen an die Operation

7
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9 1. Wieviel Prozent (%) **Schulterfunktion** (Beweglichkeit / Kraft / Einsatz
10 des Armes) erwarten Sie zu erreichen durch die Operation?
11
12

13 Zeitpunkte:
14

15 3 Monaten nach der Operation:
16 %
17
18

19 1 Jahr nach der Operation:
20 %
21
22

23 2. Wieviel Prozent (%) **Beschwerden Reduktion** (Schmerzen / Steifigkeit /
24 Schwäche) erwarten Sie zu erreichen durch die Operation?
25
26

27 Zeitpunkte:
28

29 3 Monate nach der Operation:
30 %
31
32

33 1 Jahr nach der Operation:
34 %
35
36

37 3. Welches sind Gründe, warum Sie hohe Erwartungen an die Operation
38 haben?
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47 4. Welches sind Gründe, warum Sie eher mittlere bis tiefe Erwartungen
48 an die Operation haben?
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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: _____

For peer review only

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PSS-DE

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

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

Quelle: Klein, E. M., Brähler, E., Dreier, M., Reinecke, L., Müller, K. W., Schmutzler, 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

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6

7 Bitte kreuzen Sie unter jeder Überschrift DAS Kästchen an, das Ihre Gesundheit
8 HEUTE am besten beschreibt.
9

10 **BEWEGLICHKEIT / MOBILITÄT**

- 11 Ich habe keine Probleme herumzugehen
12 Ich habe leichte Probleme herumzugehen
13 Ich habe mässige Probleme herumzugehen
14 Ich habe grosse Probleme herumzugehen
15 Ich bin nicht in der Lage herumzugehen

16 **FÜR SICH SELBST SORGEN**

- 17 Ich habe keine Probleme, mich selbst zu waschen oder anzuziehen
18 Ich habe leichte Probleme, mich selbst zu waschen oder anzuziehen
19 Ich habe mässige Probleme, mich selbst zu waschen oder anzuziehen
20 Ich habe grosse Probleme, mich selbst zu waschen oder anzuziehen
21 Ich bin nicht in der Lage, mich selbst zu waschen oder anzuziehen

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

- 24 Ich habe keine Probleme, meinen alltäglichen Tätigkeiten
25 nachzugehen
26 Ich habe leichte Probleme, meinen alltäglichen Tätigkeiten
27 nachzugehen
28 Ich habe mässige Probleme, meinen alltäglichen Tätigkeiten
29 nachzugehen
30 Ich habe grosse Probleme, meinen alltäglichen Tätigkeiten
31 nachzugehen
32 Ich bin nicht in der Lage, meinen alltäglichen Tätigkeiten nachzugehen

33 **SCHMERZEN / KÖRPERLICHE BESCHWERDEN**

- 34 Ich habe keine Schmerzen oder Beschwerden
35 Ich habe leichte Schmerzen oder Beschwerden
36 Ich habe mässige Schmerzen oder Beschwerden
37 Ich habe starke Schmerzen oder Beschwerden
38 Ich habe extreme Schmerzen oder Beschwerden

ANGST / NIEDERGESCHLAGENHEIT

Ich bin nicht ängstlich oder deprimiert

Beste
Gesundheit, die
Sie sich
vorstellen können

Ich bin ein wenig ängstlich oder deprimiert

Ich bin mässig ängstlich oder deprimiert

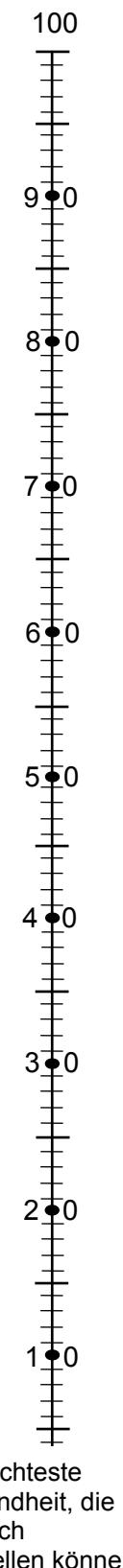
Ich bin sehr ängstlich oder deprimiert

Ich bin extrem ängstlich oder deprimiert

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- 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.

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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 Krankeit						
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.

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Manuscripts

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.

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13 Traumatology Kantonsspital Winterthur, Switzerland
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1 1 **Abstract**

2 2 **Introduction**

3 3 Prognosis following surgical rotator cuff repair (RCR) is often established through the
4 4 assessment of non-modifiable biomedical factors such as tear size. This understates
5 5 the complex nature of recovery following RCR. There is a need to identify potential
6 6 modifiable psychosocial factors and sleep related variables, and to find out whether
7 7 alterations to central pain processing influence prognosis after RCR. This will improve
8 8 our knowledge on how to optimize recovery, using a holistic rehabilitation approach.

9 9 **Methods and Analysis**

10 10 This longitudinal study will analyse 141 participants undergoing usual care for first time
11 11 RCR. Data will be collected 1 to 21 days preoperatively (T1), 11 to 14 weeks (T2) and
12 12 12 to 14 months (T3) postoperatively. We will use mixed-effects linear regression to
13 13 identify correlations between potential prognostic factors and our primary outcome
14 14 measure – the Western Ontario Rotator Cuff Index. Secondary outcome measures
15 15 assessed against prognostic indicators include: The Constant-Score and Subjective
16 16 Shoulder Value; Maximal Pain (Numeric Rating Scale); and Quality of Life (EQ-5D-
17 17 5L). Potential prognostic factors include: four psychosocial variables; pain
18 18 catastrophizing, perceived stress, injury perceptions and patients' expectations for
19 19 RCR; sleep; and four factors related to central pain processing; central sensitisation
20 20 inventory, temporal summation, cold hyperalgesia and pressure pain threshold.
21 21 Intercorrelations will be assessed to determine the strength of relationships between
22 22 all potential prognostic indicators.

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3 23 Our aim is to identify potential modifiable psychosocial factors, sleep related variables,
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5 24 and to assess to which extent central pain processing correlate to outcome pre and
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7 25 post RCR.
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11 26 **Ethics and Dissemination**
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14 27 The results of the study will be disseminated at conferences (e.g. European Pain
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16 28 Congress). One or more manuscripts will be published in peer reviewed SCI-ranked
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18 journals. Findings will be reported in accordance with the STROBE statement and
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20 PROGRESS framework. Ethical approval is granted by the Ethical commission of
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22 Canton of Zurich, Switzerland, No: ID_2018-02089
23
24

25 32 **Registration**
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27

28 33 Registered at ClinicalTrials.gov, registration number: NCT04946149
29
30

31 34 **Funding**
32
33

34 35 This work is supported by the Swiss physiotherapy association *physioswiss* through a
35 financial research prize.
36
37

38 37 **Keywords**
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41 38 Rotator cuff tears, prognostic factors, psychosocial factors, expectations, sleep,
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43 central sensitisation, quantitative sensory testing
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3 41 **Article Summary**
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5 42 **Strengths of this study**
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- 10 44 • This will be the first study *adequately* powered to identify modifiable
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12 45 psychosocial factors as potential prognostic factors of outcome after rotator cuff
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14 46 repair (RCR).
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17 47 • This study will also be the first to assess the complex interplay of psychosocial
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19 48 factors, sleep related variables and central pain processing measures as
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21 49 potential prognostic factors of outcome following RCR
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24 50 • The prospective longitudinal study design includes 3 measurement points,
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26 51 starting preoperatively, at 12 weeks postoperative and following up for 12-
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28 52 months post RCR.
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31 53 **Limitations of this study**
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33 54 • The questionnaires for sleep and patients' expectations were translated to
34
35 55 German for the purposes of this study. Therefore, their validity in our population
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37 56 (German-speakers) has yet to be validated.
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40 57 • Tear size is a known prognostic indicator of how well recovery will go following
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42 58 RCR. We will not account for tear size in our prognostic model which may bias
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44 59 our results.
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1 2 61 **Introduction**

3
4 62 Prognostic factor research most often focuses on biomarkers, including biological,
5 63 clinical or physiological factors. Prognostic factors help us predict the likely outcome
6
7 64 of a patient undergoing a procedure, given the presence of certain behaviours or
8
9 65 characteristics.(1) Prognostic factors for patients undergoing rotator cuff repair (RCR)
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11 66 for shoulder pain often include: fatty infiltration into the rotator cuff muscles (strong
12
13 67 effect); tear size of the tendon and multiple tendon involvement (both moderate
14
15 68 effects); or age and diabetes (both moderate effects).(2) These are all biomedical
16
17 69 markers and are non-modifiable factors with established prediction capabilities for
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19 70 showing worse outcomes for patients following RCR.(2)

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21 71 Despite these biomarkers being well established for RCR, we are still not able to fully
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23 72 predict who will recover successfully. A person's perception of shoulder pain is far
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25 73 more complex than structural changes in the rotator cuff (RC) tendons and we need
26
27 74 to add information towards a more comprehensive picture.(3-7) Yet, the number of
28
29 75 rotator cuff repairs in Europe and the United States of America continues to grow,(4,
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31 76 8-10) in-spite of this lack of knowledge on the odds of success. Current evidence
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33 77 suggests satisfactory outcomes post RCR range from 38% to 95%. This means
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35 78 surgical repair is either very successful or potentially a large waste of resources.(11-
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37 79 14)

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41 81 There is growing evidence that psychosocial factors impact persistent shoulder
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43 82 pain.(4, 15-18) Factors such as: high distress; maladaptive beliefs;(17) the perception
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45 83 of high-demand at work; and a lack of social support (18) can influence whether
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47 84 persistent shoulder pain and disability occur. Patients with existing preoperative
48
49 85 psychological conditions like: depression and anxiety;(14) who exhibit pain

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3 86 catastrophizing and kinesiophobia; (19) or suffer psychological distress (14, 20) may
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5 87 demonstrate greater preoperative shoulder pain.(14, 19) In the reverse, patients who
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7 88 anticipate a good recovery (positive expectations) post RCR show independent and
8
9 89 strong associations with satisfactory outcomes (good prognosis) for pain and disability
10
11 90 measured one-year post surgery.(11, 12, 21) Prior research on psychosocial factors
12
13 91 post RCR has been restricted to: preoperative measures;(19) has lacked statistical
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15 92 power;(14, 20) or has failed to investigate potential psychosocial prognostic factors
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17 93 altogether.(11, 12, 21)

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24 94
25 95 Sleep disturbances are also highly prevalent (up to 89%) in patients undergoing RCR,
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27 96 which has been attributed to the presence of shoulder pain.(22-24) RCR seems to
28
29 97 reduce this interplay between shoulder pain and sleep disturbances as findings
30
31 98 demonstrate an overall post RCR improvement of sleep quality.(14, 25) Yet, 41% of
32
33 99 RCR patients still suffer from sleep disturbances at 24 months follow up.(23)
34
35 100 Investigations of sleep disturbances in relation to shoulder pain and RCR are
36
37 101 incomplete with multiple factors affecting the relationship.(26)

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40 102
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42 103 Central pain processing (CPP) changes are measured via assessments for central
43
44 104 sensitisation. Assessments of CPP are almost absent in studies of patients
45
46 105 undergoing RCR.(15, 16, 27) Two trials (28, 29) investigated the role of central
47
48 106 sensitisation, measured with quantitative sensory testing (QST) on outcome (pain and
49
50 107 disability) after different shoulder surgeries (RCR, superior labrum from anterior to
51
52 108 posterior (SLAP) repair, shoulder arthroscopy (SA) and subacromial decompression).
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54 109 Both studies found small effects of CPP on post-operative outcomes. If a high amount
55
56 110 of CPP was present pre-operatively, it was related to a worse outcome 3 months post-

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3 111 subacromial decompression.(28) In contrast, if a small amount of CPP was present 3
4 112 months postoperatively (RCR, SLAP-Repair, SA) it was associated to better
5 113 functioning at 6 months post-surgery.(29)
6
7 114
8
9 115 Overall, we lack knowledge of potential modifiable prognostic indicators related to
10 116 psychosocial factors, sleep and CPP and their effects on pain, shoulder function,
11 117 disability, quality of life and satisfaction following RCR.(4, 19) Neither the local tissue
12 118 pathology-pain model nor the growing knowledge about local biochemical changes in
13 119 rotator cuff tendons sufficiently describe the relationship between tissue changes and
14 120 patients' perceived shoulder pain.(3, 5, 15, 30) Studying the relationship of
15 121 psychosocial factors, sleep, and central pain processing with RCR would improve our
16 122 prognosis for outcomes post RCR. This holds the potential to improve treatment
17 123 selection choices and reduce unnecessary surgical interventions.(3, 4, 16, 20, 31)
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19 124
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21 125 This study aims to answer the following questions:
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25 127 1. Do psychosocial factors such as pain catastrophizing, perceived stress, injury
26 128 perceptions, patients' expectations of surgery, sleep related variables and
27 129 measures of CPP obtained pre RCR (baseline), predict post RCR evolution of
28 130 shoulder function, disability, pain, quality of life and postoperative satisfaction
29 131 (outcome) at 1year follow-up?
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31 132 2. Do the potential prognostic factors (psychosocial factors, sleep, CPP) correlate
32 133 with baseline shoulder function, disability, pain and quality of life (outcome)?
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34 134 3. How do the potential prognostic factors (psychosocial factors, sleep, CPP)
35 135 intercorrelate at baseline and over time?

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6 137 **Methods**

7 138 **Study Design and setting**

8 139 The longitudinal cohort study will be implemented and reported in line with the
9 140 STROBE statement for observational studies(32) informed and completed by the
10 141 framework “prognosis research strategy” (PROGRESS).(1, 33)

11 142 Data are obtained monocentric in the shoulder and elbow surgery unit in the clinic of
12 143 orthopaedic surgery and traumatology in alliance with the institute of therapy and
13 144 rehabilitation of the acute care hospital, canton hospital Winterthur, Switzerland.

14 145 The current research project will analyse data from three selected time points in the
15 146 clinical routine of the RCR management; 1-21 days preoperatively (T1), 11-13 weeks
16 147 postoperatively (T2) and 12-14 months postoperatively (T3). Data from July 2019
17 onwards will be considered. Data collection including 12 months follow-up is estimated
18 148 to be complete in Summer 2022.

19 149
20 150 See tables 1 and 2 for overview of measurement points.

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24 152 **Participants**

25 153 The population of interest includes adult patients undergoing elective RCR, for tears
26 154 of traumatic and non-traumatic origin. To avoid selection bias, we include data from
27 155 consecutive patient consultations.

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31 157 **Eligibility Criteria**

33 158 *Inclusion criteria:*

- 34 159 - Adult men or women ≥ 18 years of age;
35 160 - Scheduled for elective arthroscopic RCR;

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3 161 - First time RCR on the target shoulder
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7 163 *Exclusion criteria:*
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9 164 - Changes of intra operative procedure (e.g. anything but RCR)
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11 165 - Re-repair of tendon;
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13 166 - No surgery;
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15 167 - No pre-operative data available; e.g. fast track trauma patients
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3 169 **Outcome measures and prognostic factors**
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5 170 Our outcome measures are consistent with those used in the existing literature. We
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7 171 consulted the guidelines from the OMERACT 2016 Shoulder Core Outcome Set
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9 172 Special Interest Group.(34)
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11 173
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14 174 Our dependant variables are the *primary outcome measure* Western Ontario Rotator
15
16 175 Cuff Index (WORC) for disease-specific function, disability and quality of life. The
17
18 176 *secondary outcome measures* are: Constant – Murley – Score (CMS) and Subjective
19
20 177 Shoulder Value (SSV) for shoulder function; maximum pain over the last 7 days on
21
22 178 Numeric Rating Scale (NRS); European Quality of Life, 5 dimensions, 5 levels (EQ-
23
24 179 5D-5L) for quality of life and health status; and satisfaction measure developed by
25
26 180 Swarup et al.(35)
27
28
29 181 A detailed description and overview about primary and secondary outcome measures
30
31 182 and their psychometric properties is presented in Table 1, which can be found in
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33 183 supplemental material.
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40 185 Potential prognostic factors for postoperative outcome are; psychosocial factors
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42 186 including 1) pain catastrophizing, 2) perceived stress, 3) injury perceptions and 4)
43
44 187 patients' expectations for RCR; 5) sleep related variables; and measures of CPP
45
46 188 including 6) the central sensitization inventory (CSI) to assess self-reported somatic
47
48 189 and emotional complaints associated to CPP 7) the degree of temporal summation
49
50 190 (TS), 8) cold hyperalgesia (CH), 9) pressure pain threshold (PPT) 10) the Douleur
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52 191 Neuropathique - 4 assessment (DN4) to detect the possible presence of neuropathic
53
54 192 pain and 11) pain distribution and localisation.

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3 193 Further potential prognostic factors include patient related characteristics such as;
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5 194 demographics (12) age and 13) sex; 14) trauma vs non-traumatic tendon tear; health
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7 195 status such as 15) body mass index (BMI). These characteristics are handled as
8
9 196 potential prognostic factors to ensure a correct approximation of our primary
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11 197 prognostic factors.

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13
14 198 Table 2 presents an overview of the potential prognostic factors including detailed
15
16 199 description of all measurement tools and test methodology

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Potential Prognostic factors

1 Psychosocial factors

3	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
5	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)				
7	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
9			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.			
13	13 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
13	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 2 into "timeline" and dimensions 3) and 4) into "control" and end up with 6subscles 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).				
19	19 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	-	-
21	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.				
24	24 Sleep					
25	25	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
27	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.				

2 Central Pain Processing

30	31 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 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
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3	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.				
4	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
5	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.				
6	18 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
7	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)				
8	19 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
9	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 cm ² (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 tibia 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	20 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
11	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)				
12	21 Pain distribution	Body Chart		x	x	x
13	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)				
14	Additional prognostic factors					
15	32 Age	Date of birth		x	-	-
16	33 Sex	Female / male		x	-	-
17	34 Cause of tear	Traumatic vs. non-traumatic		x	-	-
18	35 Body Mass Index (BMI)	Kg and cm		x	-	-

200
201 TABLE 2: Potential prognostic factors

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3 202 Four (AS, WB, QdG, FM) experienced and especially trained (by the first author AS)
4
5 203 shoulder specialist and physiotherapists perform the measurements (CMS, QST,
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7 204 SSV, NRS Pain). Next to physical skills training, the assessment files incorporate
8
9 205 detailed descriptions with respect to how the assessor should formulate questions and
10
11 206 offer answer suggestions. A detailed description of the prognostic indicators we collect
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13 207 can be found in table 2, further details including the baseline documents can be found
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15 208 in the supplemental file.

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210 **Statistical Methods and Analysis**

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

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

1
2 226 final model, even if it is not significant ($p>0.05$), to ensure correct estimation of other
3 227 (significant) prognostic factors.
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6 228 Descriptive statistics will be performed for comorbidities such as obesity, diabetes,
7 229 depression etc., for insurance status; health care vs. accident insurance, as well as
8 230 for current profession like manual labour (painter, carpenter, locksmith.); construction
9 (e.g. streets, buildings); office work; repetitive work (e.g. supermarket, post office,
10 231 industry, hairdresser); health care practitioner (e.g. nurse, medical doctor, PT, OT);
11 232 pensioner and student.
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16
17 235 **Sample Size (we moved this paragraph to be after the statistical analysis)**
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19 236 We will use a linear mixed-effects regression model for repeated measures. This will
20 have a power of 90% to identify prognostic factors of both interindividual baseline
21 differences in WORC score and a change in WORC score over time that are
22 considered clinically relevant (we assume a standard deviation of 300 points at
23 baseline and a decline in WORC score of at least 15% over time on average) (61), at
24 a confidence level $\alpha=0.5$ (two-tailed). The required total sample size was calculated to
25 be 125 subjects (R, Edland package).(62, 63) To account for an expected attrition rate
26 of 12.5%, the final sample size was set at 141 participants.
27
28 244 The power is set at 90% to minimize the chance of making a type II error.
29
30 245 It is especially difficult to determine a correct sample size for a longitudinal exploratory
31 study, as the final mixed model is likely to contain complex variance and correlation
32 patterns that are not known beforehand. Therefore, we plan an interim analysis after
33 the inclusion of the first 80 participants, to assess the drop-out rate, the achieved
34 power and the potential futility of the *a priori* selected prognostic factors. Mixed models
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3 250 do not require complete datasets to produce accurate results, through correct
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5 251 specification of the likelihood function.(59)
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10 253 **Data security and management**
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12 254 Data generation, transmission, storage and analysis within this project strictly follow
13
14 255 Swiss legal requirements for data protection. The electronic data capture (EDC)
15
16 256 software REDCap (64, 65) will be used for data processing and management.
17
18 257 REDCap was developed by an informatics core at Vanderbilt University in 2004, with
19
20 258 ongoing support from US National Center for Research Resources (NCRR) and US
21
22 259 National Institute of Health (NIH), grants NIH/NCATS UL1 TR000445. REDCap was
23
24 260 specifically developed around HIPAA security guidelines and is Good Clinical
25
26 261 Practice-compliant and fulfils the regulatory requirements regarding the collection of
27
28 262 patient data in clinical trials or non-interventional studies and patient registries and the
29
30 263 EU data protections laws. Appropriate coded identification (e.g. pseudonymisation) is
31
32 264 used in order to enter subject data into the database. The coding list of target data is
33
34 265 saved in a secured folder on the hospital's server. Only the project leader, study
35
36 266 nurses and principal investigator have access to it. Between the members of the
37
38 267 research team only coded and de-identified data will be shared. Safe handling of the
39
40 268 coded data will be covered by the software REDCap.
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53 270 **Study Monitoring**
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271 An audit trail and history of data transmission are provided by REDCap. The steering
272 committee of the research project will oversee all aspects of design, delivery, quality
273 assurance and data analysis according to good clinical practice and local legislation.

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Ethics

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276 The study follows the principles of the Helsinki Declaration. Only data of patients who
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9
10 gave general consent to the hospital or informed written consent to the project will be
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12 considered for analysis. Ethical approval received January 2019 (ID 2018-02089) by
13
14 the Ethical Committee of the Canton of Zurich, Switzerland.
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281 **Dissemination of results**

19
282 The research team is committed to full disclosure of the results of the study. The
20
21 results of the study will be disseminated for research purpose at different conferences
22
23 and as published articles in peer reviewed journals. Findings will be reported in
24
25 accordance to the STROBE statement and we aim to publish in high impact journals.
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287 **Contributorship statement**
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288 AS simultaneously is the project leader, who receives support from FS and MM (last
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37 author) with respect to topic and study design. TS controls the statistical model and
38
39 will support statistical data analysis. MM (fifth author) and PB contribute to the protocol
40
41 by critical reviewing and providing intellectual content. DG and MP support the
42
43 feasibility of the study and access to clinical data from daily routine of the
44
45 physiotherapy and orthopaedic clinic at canton hospital Winterthur, also they support
46
47 data security by providing REDCap software. All authors gave final approval for
48
49 publication of the present protocol version.
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297 **Patient and Public Involvement:**
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3 298 We included patients during our early feasibility study phase. We interviewed patients
4
5 299 about their experience of filling out the questionnaires. Afterwards we fine-tuned our
6
7 300 data collection files; the questionnaire package and the assessment. For example, we
8
9 301 changed the order and the layout of our questionnaire package and we reformulated
10
11 302 introduction for the questionnaires and for the prognostic factor “expectations towards
12
13 303 RCR” we reformulated the questions, so patients understand better what we want to
14
15 304 ask. The data of this feasibility phase from January 2019 until May 2019 are not
16
17 305 included in the study.

18
19 306 Patients were not enrolled for the study but came in for clinical visits, so we did not
20
21 307 have to have support with recruitment. We have not included patient advisers. Study
22
23 308 participants can request the results after publication.

24
25 309

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41
42 317 phase.

43
44 319

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46
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48
49 322 financial research prize to the first author.

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2
3 323 **Competing of Interest**
4

5 324 The authors declare no conflicts of interest.
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7
8 325 **Patients' consent for publication**
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10 326 Obtained
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12 327 **Provenance and peer review**
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14 328 Not commissioned; externally peer reviewed.
15

16 329 **Open access**
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For peer review only

331 References

- 332 1. Riley RD, Hayden JA, Steyerberg EW, et al. Prognosis Research Strategy (PROGRESS)
333 2: prognostic factor research. PLoS Med. 2013;10(2):e1001380.
- 334 2. Raman J, Walton D, MacDermid JC, Athwal GS. Predictors of outcomes after rotator
335 cuff repair-A meta-analysis. J Hand Ther. 2017;30(3):276-92.
- 336 3. Littlewood C, Malliaras P, Bateman M, Stace R, May S, Walters S. The central nervous
337 system--an additional consideration in 'rotator cuff tendinopathy' and a potential basis for
338 understanding response to loaded therapeutic exercise. Man Ther. 2013;18(6):468-72.
- 339 4. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are Psychosocial Factors
340 Associated With Patient-reported Outcome Measures in Patients With Rotator Cuff Tears? A
341 Systematic Review. Clin Orthop Relat Res. 2018;476(4):810-29.
- 342 5. Vincent K, Leboeuf-Yde C, Gagey O. Are degenerative rotator cuff disorders a cause
343 of shoulder pain? Comparison of prevalence of degenerative rotator cuff disease to
344 prevalence of nontraumatic shoulder pain through three systematic and critical reviews. J
345 Shoulder Elbow Surg. 2017;26(5):766-73.
- 346 6. Littlewood C, Rangan A, Beard DJ, Wade J, Cookson T, Foster NE. The enigma of
347 rotator cuff tears and the case for uncertainty. Br J Sports Med. 2018;52(19):1222.
- 348 7. Rodeghero JR, Cleland JA, Mintken PE, Cook CE. Risk stratification of patients with
349 shoulder pain seen in physical therapy practice. J Eval Clin Pract. 2017;23(2):257-63.
- 350 8. Saltzman BM, Zuke WA, Go B, et al. Does early motion lead to a higher failure rate or
351 better outcomes after arthroscopic rotator cuff repair? A systematic review of overlapping
352 meta-analyses. Journal of Shoulder and Elbow Surgery. 2017;26(9):1681-91.
- 353 9. Jain NB, Higgins L. D., Losina, E., Collins, J., Blazar, P. E., and Katz, J. . Epidemiology of
354 musculoskeletal upper extremity ambulatory surgery in the United States. BMC
355 Musculoskeletal Disorders. 2014;15:1471-2474.
- 356 10. Paloneva J, Lepola V, Aarimaa V, Joukainen A, Ylinen J, Mattila VM. Increasing
357 incidence of rotator cuff repairs--A nationwide registry study in Finland. BMC Musculoskelet
358 Disord. 2015;16:189.
- 359 11. Novoa-Boldo A, Gulotta LV. Expectations Following Rotator Cuff Surgery. Curr Rev
360 Musculoskelet Med. 2018;11(1):162-6.
- 361 12. Henn RF, 3rd, Kang L, Tashjian RZ, Green A. Patients' preoperative expectations
362 predict the outcome of rotator cuff repair. J Bone Joint Surg Am. 2007;89(9):1913-9.
- 363 13. Lambers Heerspink FO, Dorrestijn O, van Raay JJ, Diercks RL. Specific patient-related
364 prognostic factors for rotator cuff repair: a systematic review. J Shoulder Elbow Surg.
365 2014;23(7):1073-80.
- 366 14. Cho CH, Song KS, Hwang I, Warner JJ. Does Rotator Cuff Repair Improve Psychologic
367 Status and Quality of Life in Patients With Rotator Cuff Tear? Clin Orthop Relat Res.
368 2015;473(11):3494-500.
- 369 15. Noten S, Struyf F, Lluch E, D'Hoore M, Van Looveren E, Meeus M. Central Pain
370 Processing in Patients with Shoulder Pain: A Review of the Literature. Pain Pract.
371 2017;17(2):267-80.
- 372 16. Sanchis MN, Lluch E, Nijs J, Struyf F, Kangasperko M. The role of central sensitization
373 in shoulder pain: A systematic literature review. Semin Arthritis Rheum. 2015;44(6):710-6.
- 374 17. Martinez-Calderon J, Meeus M, Struyf F, Miguel Morales-Asencio J, Gijon-Nogueron
375 G, Luque-Suarez A. The role of psychological factors in the perpetuation of pain intensity

- 1
2
3 376 and disability in people with chronic shoulder pain: a systematic review. BMJ Open.
4 377 2018;8(4):e020703.
- 5 378 18. Struyf F, Geraets, J., Noten, S., Meeus, M., Nijs, J. . A Multivariable Prediction Model
6 379 for the Chronification of Non-traumatic Shoulder PAin: A Systematic Review. Pain Physician.
7 380 2016(19):1-10.
- 8 381 19. Thorpe AM, O'Sullivan PB, Mitchell T, et al. Are Psychologic Factors Associated With
9 382 Shoulder Scores After Rotator Cuff Surgery? Clin Orthop Relat Res. 2018;476(10):2062-73.
- 10 383 20. Potter MQ, Wylie JD, Greis PE, Burks RT, Tashjian RZ. Psychological Distress
11 384 Negatively Affects Self-assessment of Shoulder Function in Patients With Rotator Cuff Tears.
12 385 Clinical Orthopaedics and Related Research®. 2014;472(12):3926-32.
- 13 386 21. Oh JH, Yoon JP, Kim JY, Kim SH. Effect of expectations and concerns in rotator cuff
14 387 disorders and correlations with preoperative patient characteristics. J Shoulder Elbow Surg.
15 388 2012;21(6):715-21.
- 16 389 22. Gillespie MA, A MC, Wassinger CA, Sole G. Rotator cuff-related pain: Patients'
17 390 understanding and experiences. Musculoskelet Sci Pract. 2017;30:64-71.
- 18 391 23. Kunze KN, Movasagghi K, Rossi DM, et al. Systematic Review of Sleep Quality Before
19 392 and After Arthroscopic Rotator Cuff Repair: Are Improvements Experienced and
20 393 Maintained? Orthop J Sports Med. 2020;8(12):2325967120969224.
- 21 394 24. Cho CH, Jung SW, Park JY, Song KS, Yu KI. Is shoulder pain for three months or longer
22 395 correlated with depression, anxiety, and sleep disturbance? J Shoulder Elbow Surg.
23 396 2013;22(2):222-8.
- 24 397 25. Austin L, Pepe M, Tucker B, et al. Sleep disturbance associated with rotator cuff tear:
25 398 correction with arthroscopic rotator cuff repair. Am J Sports Med. 2015;43(6):1455-9.
- 26 399 26. Longo UG, Facchinetto G, Marchetti A, et al. Sleep Disturbance and Rotator Cuff
27 400 Tears: A Systematic Review. Medicina (Kaunas). 2019;55(8).
- 28 401 27. Nijs J, George SZ, Clauw DJ, et al. Central sensitisation in chronic pain conditions:
29 402 latest discoveries and their potential for precision medicine. The Lancet Rheumatology.
30 403 2021.
- 31 404 28. Gwilym SE, Oag, H. C. L., Tracey, I. and Carr A. J. . Evidence that central sensitisation
32 405 is present in patients with shoulder impingement syndrome and influences the outcome
33 406 after surgery. The Journal of Bone & Joint Surgery. 2011;93-B:498-502.
- 34 407 29. Valencia C, Fillingim RB, Bishop M, et al. Investigation of central pain processing in
35 408 postoperative shoulder pain and disability. Clin J Pain. 2014;30(9):775-86.
- 36 409 30. Rees JD, Stride M, Scott A. Tendons--time to revisit inflammation. Br J Sports Med.
37 410 2014;48(21):1553-7.
- 38 411 31. Lewis J, O'Sullivan P. Is it time to reframe how we care for people with non-traumatic
39 412 musculoskeletal pain? British Journal of Sports Medicine. 2018.
- 40 413 32. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandebroucke JP. The
41 414 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement:
42 415 guidelines for reporting observational studies. Annals of internal medicine. 2007;147(8):573-
43 416 7.
- 44 417 33. Hemingway H, Croft P, Perel P, et al. Prognosis research strategy (PROGRESS) 1: a
45 418 framework for researching clinical outcomes. BMJ. 2013;346:e5595.
- 46 419 34. Buchbinder R, Page MJ, Huang H, et al. A Preliminary Core Domain Set for Clinical
47 420 Trials of Shoulder Disorders: A Report from the OMERACT 2016 Shoulder Core Outcome Set
48 421 Special Interest Group. J Rheumatol. 2017;44(12):1880-3.
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2
3 422 35. I. Swarup CMH, J. T. Nguyen, D. M. Dines, E. V. Craig, R. F. Warren, L. V. Gulotta, R. F.
4 423 Henn III Effect of pre-operative expectations on the outcomes following total shoulder
5 424 arthroplasty. 2017.
- 6 425 36. Meyer K SH, Manion AF. Cross-cultural adaptation, reliability and validity of the
7 426 German version of the Pain Catastrophizing Scale. Journal of Psychosomatic Research.
8 427 2008;64(5):469-478.
- 9 428 37. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and
10 429 validation. Psychological assessment. 1995;7(4):524.
- 11 430 38. Klein EM, Brahler E, Dreier M, et al. The German version of the Perceived Stress Scale
12 431 - psychometric characteristics in a representative German community sample. BMC
13 432 Psychiatry. 2016;16:159.
- 14 433 39. Leysen M, Nijs J, Meeus M, et al. Clinimetric properties of illness perception
15 434 questionnaire revised (IPQ-R) and brief illness perception questionnaire (Brief IPQ) in
16 435 patients with musculoskeletal disorders: A systematic review. Man Ther. 2015;20(1):10-7.
- 17 436 40. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised
18 437 Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.
- 19 438 41. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception
20 439 questionnaire. J Psychosom Res. 2006;60(6):631-7.
- 21 440 42. Lau RR, Hartman KA. Common sense representations of common illnesses. Health
22 441 psychology. 1983;2(2):167.
- 23 442 43. Broadbent E, Wilkes C, Koschwanez H, Weinman J, Norton S, Petrie KJ. A systematic
24 443 review and meta-analysis of the Brief Illness Perception Questionnaire. Psychol Health.
25 444 2015;30(11):1361-85.
- 26 445 44. Jo Nijs OM, Daniel Neu, Laurence Leysen, Lieven Danneels,, Barbara Cagnie MM,
27 446 Maarten Moens, Kelly Ickmans, Dorien Goubert. sleep disturbances in chronic pain
28 447 neurobiology assessment and treatment in physical therapy. 2018.
- 29 448 45. Scerbo T, Colasurdo J, Dunn S, Unger J, Nijs J, Cook C. Measurement Properties of the
30 449 Central Sensitization Inventory: A Systematic Review. Pain Pract. 2018;18(4):544-54.
- 31 450 46. Mayer TG, Neblett R, Cohen H, et al. The development and psychometric validation
32 451 of the central sensitization inventory. Pain Pract. 2012;12(4):276-85.
- 33 452 47. Kuppens K, Hans G, Roussel N, et al. Sensory processing and central pain modulation
34 453 in patients with chronic shoulder pain: A case-control study. Scand J Med Sci Sports.
35 454 2018;28(3):1183-92.
- 36 455 48. Rebbeck T, Moloney, N., Azoory, R., Hübscher, M., Waller, R., Gibbons, R., Beales,
37 456 D., Clinical ratings of pain sensitivity correlate with qust in people with chronic neck pain
38 457 and healthy controls cross sectional study. Physical Therapy. 2015;95(11).
- 39 458 49. Nahman-Averbuch H, Yarnitsky D, Granovsky Y, et al. Pronociceptive pain
40 459 modulation in patients with painful chemotherapy-induced polyneuropathy. J Pain
41 460 Symptom Manage. 2011;42(2):229-38.
- 42 461 50. Staud R, Robinson ME, Vierck CJ, Cannon RC, Mauderli AP, Price DD. Ratings of
43 462 experimental pain and pain-related negative affect predict clinical pain in patients with
44 463 fibromyalgia syndrome. Pain. 2003;105(1):215-22.
- 45 464 51. Edwards RR, Mensing G, Cahalan C, et al. Alteration in pain modulation in women
46 465 with persistent pain after lumpectomy: influence of catastrophizing. J Pain Symptom
47 466 Manage. 2013;46(1):30-42.
- 48 467 52. Moloney N. An investigation of somatosensory profiles in woeck related upper limb
49 468 disorders a case control obervational study protocol. 2010.

- 1
2
3 469 53. Maxwell S, Sterling M. An investigation of the use of a numeric pain rating scale with
4 470 ice application to the neck to determine cold hyperalgesia. *Man Ther.* 2013;18(2):172-4.
5 471 54. Walton DM, Macdermid JC, Nielson W, Teasell RW, Reese H, Levesque L. Pressure
6 472 pain threshold testing demonstrates predictive ability in people with acute whiplash. *J
7 473 Orthop Sports Phys Ther.* 2011;41(9):658-65.
8 474 55. Klyne DM, Schmid AB, Moseley GL, Sterling M, Hodges PW. Effect of types and
9 475 anatomic arrangement of painful stimuli on conditioned pain modulation. *J Pain.*
10 476 2015;16(2):176-85.
11 477 56. Timmerman H, Steegers MAH, Huygen F, et al. Investigating the validity of the DN4
12 478 in a consecutive population of patients with chronic pain. *PLoS One.* 2017;12(11):e0187961.
13 479 57. Margolis R. B. TRCaKSJ. A Rating System For Use with Patient Pain Drawings. *Pain.*
14 480 1986;24:57-65.
15 481 58. Blackwell E, de Leon CF, Miller GE. Applying mixed regression models to the analysis
16 482 of repeated-measures data in psychosomatic medicine. *Psychosom Med.* 2006;68(6):870-8.
17 483 59. Singer JD, Willett JB, Willett JB. Applied longitudinal data analysis: Modeling change
18 484 and event occurrence: Oxford university press; 2003.
19 485 60. Edland S. Which MRI measure is best for Alzheimer's disease prevention trials.
20 486 Statistical considerations of power and sample size *Jt Stat Meet Proc.* 2009:4996-9.
21 487 61. Kirkley A. ACaGS. The Development and Evaluation of a Disease-specific Quality-of-
22 488 Life Questionnaire for Disorders of the Rotator Cuff_ The Western Ontario Rotator Cuff
23 489 Index. *Clinical Journal of Sport Medicine.* 2003;13:84-92.
24 490 62. Faul F, Erdfelder, E., Lang, A.-G., & Buchner, A. . G Power 3- A flexible statistical
25 491 power analysis program for the social, behavioral, and biomedical sciences. *Behavior
26 492 Research Methods.* 2007.
27 493 63. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power
28 494 3.1: tests for correlation and regression analyses. *Behav Res Methods.* 2009;41(4):1149-60.
29 495 64. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an
30 496 international community of software platform partners. *Journal of biomedical informatics.*
31 497 2019;95:103208.
32 498 65. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic
33 499 data capture (REDCap)—a metadata-driven methodology and workflow process for
34 500 providing translational research informatics support. *Journal of biomedical informatics.*
35 501 2009;42(2):377-81.
36 502
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Primary outcome measure

1

2 Shoulder function, disability and
3 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
---	---	---

9 Description

This 21 – items self-reported questionnaire represents a quality of life measure in rotator cuff pathology, 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 VAS at ≥ 300mm).(4)

The WORC measures 5 dimensions (pain, analogue Scale (VAS). Left endpoint equals “no” and right endpoint equals “extreme”. The minimal important difference (MID) is calculated

Secondary outcome measures

14 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. 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.

20 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)

22 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)

24 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
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27 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)

29 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
---	---	---

31 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)

33 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
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37 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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1. Huber W, Hofstaetter JG, Hanslik-Schnabel B, Posch M, Wurnig C. [Translation and psychometric testing of the Western Ontario Rotator Cuff Index (WORC) for use in Germany]. *Z Orthop Ihre Grenzgeb.* 2005;143(4):453-60.
2. Huang H, Grant JA, Miller BS, Mirza FM, Gagnier JJ. A Systematic Review of the Psychometric Properties of Patient-Reported Outcome Instruments for Use in Patients With Rotator Cuff Disease. *Am J Sports Med.* 2015;43(10):2572-82.
3. MacDermid JC, Drosdowech D, Faber K. Responsiveness of self-report scales in patients recovering from rotator cuff surgery. *J Shoulder Elbow Surg.* 2006;15(4):407-14.
4. Braun C, Handoll HH. Estimating the Minimal Important Difference for the Western Ontario Rotator Cuff Index (WORC) in adults with shoulder pain associated with partial-thickness rotator cuff tears. *Musculoskelet Sci Pract.* 2018;35:30-3.
5. Gilbart MK, Gerber C. Comparison of the subjective shoulder value and the Constant score. *J Shoulder Elbow Surg.* 2007;16(6):717-21.
6. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *Journal of Clinical Nursing* 2004;14:798 - 804.
7. Nahman-Averbuch H, Yarnitsky D, Granovsky Y, et al. Pronociceptive pain modulation in patients with painful chemotherapy-induced polyneuropathy. *J Pain Symptom Manage.* 2011;42(2):229-38.
8. Ludwig K, Graf von der Schulenburg JM, Greiner W. German Value Set for the EQ-5D-5L. *Pharmacoeconomics.* 2018;36(6):663-74.
9. Group TE. EuroQol-a new facility for the measurement of health-related quality of life. *Health policy.* 1990;16(3):199-208.
10. I. Swarup CMH, J. T. Nguyen, D. M. Dines, E. V. Craig, R. F. Warren, L. V. Gulotta, R. F. Henn III Effect of pre-operative expectations on the outcomes following total shoulder arthroplasty. 2017.

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BMJ Open

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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Manuscripts

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.

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1 1 **Abstract**

2 2 **Introduction**

3 3 Prognosis following surgical rotator cuff repair (RCR) is often established through the
4 4 assessment of non-modifiable biomedical factors such as tear size. This understates
5 5 the complex nature of recovery following RCR. There is a need to identify modifiable
6 6 psychosocial and sleep related variables, and to find out whether changes in central
7 7 pain processing influence prognosis after RCR. This will improve our knowledge on
8 8 how to optimize recovery, using a holistic rehabilitation approach.

9 9 **Methods and Analysis**

10 10 This longitudinal study will analyse 141 participants undergoing usual care for first time
11 11 RCR. Data will be collected 1 to 21 days preoperatively (T1), then 11- to 14-weeks
12 12 (T2) and 12- to 14-months (T3) postoperatively. We will use mixed-effects linear
13 13 regression to assess relationships between potential prognostic factors and our
14 14 primary outcome measure – the Western Ontario Rotator Cuff Index. Secondary
15 15 outcome measures include: The Constant-Score and Subjective Shoulder Value;
16 16 Maximal Pain (Numeric Rating Scale); and Quality of Life (EQ-5D-5L). Potential
17 17 prognostic factors include: four psychosocial variables; pain catastrophizing,
18 18 perceived stress, injury perceptions and patients' expectations for RCR; sleep; and
19 19 four factors related to central pain processing (central sensitisation inventory, temporal
20 20 summation, cold hyperalgesia and pressure pain threshold). Intercorrelations will be
21 21 assessed to determine the strength of relationships between all potential prognostic
22 22 indicators.

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3 23 Our aim is to explore whether modifiable psychosocial factors, sleep related variables
4
5 24 and altered central pain processing are associated with outcomes pre- and post-RCR
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7 25 and to identify them as potential prognostic factors.
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10 26 **Ethics and Dissemination**
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13 27 The results of the study will be disseminated at conferences such as the European
14
15 28 Pain Congress. One or more manuscripts will be published in a peer-reviewed SCI-
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17 29 ranked journal. Findings will be reported in accordance with the STROBE statement
18
19 30 and PROGRESS framework. Ethical approval is granted by the Ethical commission of
20
21 Canton of Zurich, Switzerland, No: ID_2018-02089
22
23

24 32 **Registration**
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27 33 This trial is registered at ClinicalTrials.gov, registration number: NCT04946149
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29

30 34 **Funding**
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32

33 35 This work is supported by the Swiss physiotherapy association *physioswiss* through a
34
36 financial research prize.
37

38 37 **Keywords**
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40

41 38 Rotator cuff tears, prognostic factors, psychosocial factors, patients' expectations,
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45 39 sleep, central sensitisation, quantitative sensory testing
46

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3 41 **Article Summary**
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5 42 **Strengths of this study**
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- 10 44 • This will be the first study *adequately* powered to identify modifiable
11
12 45 psychosocial factors as potential prognostic factors of outcome after rotator cuff
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14 46 repair (RCR).
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17 47 • This study will also be the first to assess the complex interplay of psychosocial
18
19 48 factors, sleep related variables and central pain processing measures as
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21 49 potential prognostic factors of outcome following RCR
22
23
24 50 • The prospective longitudinal study design includes 3 measurement points,
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26 51 starting preoperatively, at 12 weeks postoperative, and following up for 12-
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28 52 months post RCR.

30
31 53 **Limitations of this study**
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34 54 • The questionnaires for sleep and patients' expectations were translated to
35
36 55 German for the purposes of this study. Therefore, their validity in our population
37
38 56 (German-speakers) has yet to be validated.
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41 57 • Tear size is a known prognostic indicator of how well recovery will go following
42
43 58 RCR. We will not account for tear size in our prognostic model which may bias
44
45 59 our results.

61 **Introduction**

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

79
80 There is growing evidence that psychosocial factors impact persistent shoulder
81 pain.(4, 15-18) Factors such as: high distress; maladaptive beliefs;(17) the perception
82 of high-demand at work; and a lack of social support (18) can influence whether
83 persistent shoulder pain and disability occur. Patients with existing preoperative
84 psychological conditions like: depression and anxiety;(14) who exhibit pain
85 catastrophizing and kinesiophobia; (19) or suffer psychological distress (14, 20) may

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3 86 demonstrate greater preoperative shoulder pain.(14, 19) In the reverse, patients who
4 87 anticipate a good recovery (positive expectations) post-RCR show independent and
5 88 strong associations with satisfactory outcomes (good prognosis) for pain and disability
6
7 89 measured one-year post surgery.(11, 12, 21) Prior research on psychosocial factors
8 90 post RCR has been restricted to: preoperative measures;(19) has lacked statistical
9 91 power;(14, 20) or has failed to investigate potential psychosocial prognostic factors
10 92 altogether.(11, 12, 21)

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13 93
14 94 Sleep disturbances are also highly prevalent (up to 89%) in patients undergoing RCR.
15 95 Sleep disturbance has been attributed to the presence of shoulder pain.(22-24) RCR
16 96 seems to reduce this interplay between shoulder pain and sleep disturbances as
17 97 findings demonstrate an overall post RCR improvement of sleep quality.(14, 25) Yet,
18 98 41% of RCR patients still suffer from sleep disturbances at 24 months follow up.(23)
19 99 Investigations of sleep disturbances in relation to shoulder pain and RCR are
20 100 incomplete with multiple factors affecting the relationship.(26)

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22
23 101
24 102 Central pain processing (CPP) changes are measured via assessments for central
25 103 sensitisation. Assessments of CPP are almost absent in studies of patients
26 104 undergoing RCR.(15, 16, 27) Two trials (28, 29) investigated the role of central
27 105 sensitisation, measured with quantitative sensory testing (QST) on outcome (pain and
28 106 disability) after different shoulder surgeries (RCR, superior labrum from anterior to
29 107 posterior (SLAP) repair, shoulder arthroscopy (SA) and subacromial decompression).
30 108 Both studies found small effects of CPP on post-operative outcomes. If a high amount
31 109 of CPP was present pre-operatively, it was related to a worse outcome 3 months post-
32 110 subacromial decompression.(28) In contrast, if a small amount of CPP was present 3

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3 111 months postoperatively (RCR, SLAP-Repair, SA) it was associated to better
4
5 112 functioning at 6 months post-surgery.(29)

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10 114 The existence of potential modifiable prognostic indicators related to psychosocial
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12 115 factors, sleep and CPP and their effects on, shoulder function, disability, pain, quality
13
14 116 of life and satisfaction following RCR require further investigation.(4, 19) Neither the
15
16 117 local tissue pathology-pain model nor the growing knowledge about local biochemical
17
18 118 changes in rotator cuff tendons sufficiently describe the relationship between tissue
19
20 119 changes and patients' perceived shoulder pain.(3, 5, 15, 30) Studying the relationship
21
22 120 of psychosocial factors, sleep, and central pain processing with RCR would improve
23
24 121 our prognosis for outcomes post RCR. This holds the potential to improve treatment
25
26 122 selection choices and reduce unnecessary surgical interventions.(3, 4, 16, 20, 31)

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28 123
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30 124 This study aims to answer the following questions:
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37 126 1. Do psychosocial factors such as pain catastrophizing, perceived stress, injury
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39 127 perceptions, patients' expectations of surgery, sleep related variables and
40
41 128 measures of CPP obtained pre RCR (baseline), influence baseline shoulder
42
43 129 function, disability, pain and quality of life and their evolution over time (1-year
44
45 130 post-surgery)?
46
47
48 131 2. How do potential prognostic factors: psychosocial indicators; sleep related
49
50 132 variables; and CPP intercorrelate at baseline and over time?
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57 134 **Methods**
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59 135 **Study Design and setting**
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3 136 The longitudinal cohort study will be implemented and reported in line with the
4
5 137 STROBE statement for observational studies(32) informed and completed by the
6
7 138 framework “prognosis research strategy” (PROGRESS).(1, 33)
8
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10 139 Data will be obtained in a single shoulder and elbow surgery unit in the clinic of
11
12 140 orthopaedic surgery and traumatology in alliance with the institute of therapy and
13
14 141 rehabilitation of the acute care hospital, canton hospital Winterthur, Switzerland.
15
16
17 142 The current research project will analyse data from three time points in the routine
18
19 143 clinical management post-RCR: 1-21 days preoperatively (T1); 11-13 weeks
20
21 144 postoperatively (T2); and 12-14 months postoperatively (T3). Data from July 2019
22
23 145 onwards will be considered. Data collection including 12 months follow-up is estimated
24
25 146 to be complete in Summer 2022.
26
27
28 147 See tables 1 and 2 for overview of measurement points.
29
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31 148

32 149 **Participants**

33
34 150 The population of interest includes adult patients undergoing elective RCR, for tears
35
36 151 of traumatic and non-traumatic origin. To avoid selection bias, we will include data
37
38 152 from consecutive patient consultations.
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41 153

42 154 **Eligibility Criteria**

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44 155 *Inclusion criteria:*
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46 156 - Adult men or women ≥ 18 years of age;
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48 157 - Scheduled for elective arthroscopic RCR;
49
50 158 - First time RCR on the target shoulder
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60 160 *Exclusion criteria:*

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3 161 - Changes of intra-operative procedure (e.g. anything but RCR)
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5 162 - Re-repair of tendon;
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7 163 - No surgery;
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9
10 164 - No pre-operative data available; e.g. fast track trauma patients
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3 **166 Outcome measures and prognostic factors**

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5 167 Our outcome measures are consistent with those used in the existing literature. We
6
7 168 consulted the guidelines from the OMERACT 2016 Shoulder Core Outcome Set
8
9 169 Special Interest Group.(34)

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14 171 Our dependant variables are the *primary outcome measure* Western Ontario Rotator
15
16 172 Cuff Index (WORC) for disease-specific function, disability and quality of life. The
17
18 173 *secondary outcome measures* are: Constant – Murley – Score (CMS) and Subjective
19
20 174 Shoulder Value (SSV) for shoulder function; maximum pain over the last 7 days on
21
22 175 Numeric Rating Scale (NRS); European Quality of Life, 5 dimensions, 5 levels (EQ-
23
24 176 5D-5L) for quality of life and health status; and a satisfaction measure developed by
25
26 177 Swarup et al.(35)

27
28
29 178 A detailed description and overview about primary and secondary outcome measures
30
31 179 and their psychometric properties is presented below in Table 1.

Primary outcome measure					
1 Shoulder function, disability 2 and disease specific quality 3 of life 4 5 6 7 8	9 Western Ontario Rotator Cuff Index (WORC)	Positive evidence for 5 psychometric properties: <ul style="list-style-type: none"> 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
9 Description 10 11	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					
12 Shoulder function 13 14 15 16 17	18 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	strength measure	x
19 Description CMS 20 21	22 Subjective Shoulder Value (SSV)	High correlations to Constant-Murley Score, tested in diverse shoulder diseases.			
23 Description SSV 24	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)				
25 Max. pain 26	27 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
28 Description 29	30 European Quality of Life, 5 Dimensions, 5 Levels (EQ - 5D -5L)	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)	x		x
31 Description 32	33 Quality of life	Adopted and tested in Germany among general population.(43)	x		x
34 Postoperative satisfaction 35	36 Satisfaction questionnaire for postsurgical status	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)	-		x
37 Description 38 39	38 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.				

1 TABLE 1: Outcome measures

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2
3 181 Potential prognostic factors for postoperative outcome are:
4
5 182 • psychosocial factors
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7 183 1) pain catastrophizing,
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9 184 2) perceived stress,
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11 185 3) injury perceptions and
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13 186 4) patients' expectations for RCR
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15 187 5) sleep-related variables
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17 188 • and measures of CPP
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19 189 6) the central sensitization inventory (CSI) to assess self-reported
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21 190 somatic and emotional complaints associated to CPP
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23 191 7) temporal summation (TS),
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25 192 8) cold hyperalgesia (CH),
26
27 193 9) pressure pain threshold (PPT),
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29 194 10) the Douleur Neuropathique - 4 assessment (DN4) to detect the
30
31 195 possible presence of neuropathic pain and
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33 196 11 pain distribution and localisation.
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36 197 Further factors include patient related characteristics such as; demographics: 12) age
37
38 198 and 13) sex; 14) trauma vs non-traumatic tendon tear; and health status such as 15)
39
40 199 body mass index (BMI). These characteristics are all handled as potential prognostic
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42 200 factors to ensure a correct estimation of our primary prognostic factors.
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44
45 201 Table 2 presents an overview of the potential prognostic factors including a detailed
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47 202 description of all measurement tools and test methodology.
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			T1: Baseline 2-3weeks pre RCR	T2: 12 – 14 weeks post RCR	T3: 12 - 14 months post RCR
Potential Prognostic factors					
1 Psychosocial factors					
3 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
5 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)				
7 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
9	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.				
13 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
13 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 2 into "timeline" and dimensions 3) and 4) into "control" and end up with 6subscale 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).				
19 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	-	-
21 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.				
24 Sleep					
25	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
27 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.				
29 Central Pain Processing					
31 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 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
32					
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36/bmjopen-2021-05803 on 4 August 2023. Downloaded from http://bmjopen.bmjjournals.org/ on May 12, 2025 at Department GEZ-LTA by copyright, including for web storage, printing, and similar technologies.

3 Description	The original English questionnaire was developed in 2011 (55) to assess key symptoms in relation to central sensitivity symptoms (CSSs). 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
7 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
14 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)			
18 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
20 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 cm ² (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 tibiales 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.			
240 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
27 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)			
28 Pain distribution	Body Chart		x	x
30 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				
32 Age	Date of birth		x	-
33 Sex	Female / male / other		x	-
34 Cause of tear	Traumatic vs. non-traumatic		x	-
35 Body Mass Index (BMI)	Kg and cm		x	-

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204 TABLE 2: Potential prognostic factors

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3 205 Four (AS, WB, QdG, FM) experienced and trained (by the first author AS) shoulder
4 specialists and physiotherapists will perform all the measurements (CMS, QST, SSV,
5 NRS Pain). To support the training, all participant assessment files will incorporate
6 detailed descriptions with respect to how the assessor should formulate questions and
7 offer answer suggestions. A detailed description of the prognostic indicators we collect
8 can be found in table 2.
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19 212 **Statistical Methods and Analysis**
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21 213 Statistical analyses will be performed using SAS (SAS 9.4, SAS Institute Inc., Cary,
22 NC, USA). Level of significance is set at $p = 0.05$. Measurements will take place at
23 three time points in the perioperative management, as described above (T1 = at
24 baseline 2-3 weeks prior to RCR, T2 = at 12 weeks post RCR and T3 = at 12 months
25 post RCR as follow-up).
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33 218 The primary outcome (WORC) will be modelled using mixed-effects linear regression
34 models for repeated (longitudinal) measures, using an unstructured covariance matrix.
35
36
37 220 Dependent variables are the primary and secondary outcomes. Continuous secondary
38 outcomes will be assessed in a similar way to the primary outcome. The models will
39 be developed by stepwise reduction of the *a priori* determined potential prognostic
40 factors (for example psychosocial factors, sleep and CPP). A prognostic factor will be
41 retained in the model if it has a significant effect on the initial outcome or on the
42 outcome over time, or if the fit statistics (Deviance, AIC, BIC and R²) of the model
43 improves after inclusion of the variable, in order to increase the precision of the fixed
44 effects estimates.(66-68) This means that a prognostic factor may be retained in the
45 final model, even if it is not significant ($p>0.05$), to ensure correct estimation of other
46 (significant) prognostic factors.
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3 230 Descriptive statistics will be performed for comorbidities such as: obesity, diabetes,
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5 231 and depression; for insurance status (health care vs. accident insurance); and current
6
7 232 profession divided into categories such as, manual labourer (painter, carpenter,
8
9 233 locksmith.), construction-worker (e.g. streets, buildings), office worker, repetitive work
10
11 234 (e.g. supermarket, post office, industry, hairdresser), health care practitioner (e.g.
12
13 235 nurse, medical doctor, PT, OT), pensioner and student.

14
15 236

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17 237 **Sample Size**

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19 238 We will use a linear mixed-effects regression model for repeated measures. This will
20
21 239 have a power of 90% to identify prognostic factors of both interindividual baseline
22
23 240 differences in WORC score and a change in WORC score over time that are
24
25 241 considered clinically relevant (we assume a standard deviation of 300 points at
26
27 242 baseline and a decline in WORC score of at least 15% over time on average),(69) at
28
29 243 a confidence level $\alpha=0.5$ (two-tailed). The required total sample size was calculated to
30
31 244 be 125 subjects (R, Edland package).(70, 71) To account for an expected attrition rate
32
33 245 of 12.5%, the final sample size was set at 141 participants.

34
35 246 The power is set at 90% to minimize the chance of making a type II error.

36
37 247 It is especially difficult to determine a correct sample size for a longitudinal exploratory
38
39 study, as the final mixed model is likely to contain complex variance and correlation
40
41 248 patterns that are not known beforehand. Therefore, we plan an interim analysis after
42
43 249 the inclusion of the first 80 participants, to assess the drop-out rate, the achieved
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45 250 power and the potential futility of the *a priori* selected prognostic factors. Mixed models
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47 251 do not require complete datasets to produce accurate results, through correct
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49 252 specification of the likelihood function.(67)

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2 **255 Data security and management**

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4 256 Data generation, transmission, storage and analysis within this project strictly follow
5 Swiss legal requirements for data protection. The electronic data capture (EDC)
6
7 257 software REDCap (72, 73) will be used for data processing and management.
8
9 258 REDCap was developed by an informatics core at Vanderbilt University in 2004, with
10 ongoing support from US National Center for Research Resources (NCRR) and US
11
12 259 National Institute of Health (NIH), grants NIH/NCATS UL1 TR000445. REDCap was
13 specifically developed around HIPAA security guidelines and is Good Clinical
14 Practice-compliant and fulfils the regulatory requirements regarding the collection of
15 patient data in clinical trials or non-interventional studies and patient registries and the
16 EU data protections laws. Appropriate coded identification (e.g. pseudonymisation) is
17 used in order to enter subject data into the database. The coding list of target data is
18 saved in a secured folder on the hospital's server. Only the project leader, study
19 nurses and principal investigator have access to it. Between the members of the
20 research team only coded and de-identified data will be shared. Safe handling of the
21 coded data will be covered by the software REDCap.

22
23 271
24 **272 Study Monitoring**

25
26 273 An audit trail and history of data transmission are provided by REDCap. The steering
27 committee of the research project will oversee all aspects of design, delivery, quality
28
29 274 assurance and data analysis according to good clinical practice and local legislation.

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31 276
32 **277 Ethics**

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2
3 278 The study follows the principles of the Helsinki Declaration. Only data of patients who
4
5 279 gave general consent to the hospital or informed written consent to the project will be
6
7 280 considered for analysis. Ethical approval was received in January 2019 (ID 2018-
8
9 281 02089) by the Ethical Committee of the Canton of Zurich, Switzerland.

10 282

11 283 **Dissemination of results**

12 284 The research team is committed to full disclosure of the results of the study. The
13
14 285 results of the study will be disseminated for research purpose at different conferences
15
16 286 and as published articles in peer reviewed journals. Findings will be reported in
17
18 287 accordance to the STROBE statement and we aim to publish in high impact journals.

19 288

20 289 **Contributors statement**

21 290 AS is the project leader, who receives support from FS and MM (last author) with
22
23 291 respect to topic-selection and study design. TS controls the statistical model and will
24
25 292 support statistical data analysis. MM (fifth author) and PB contributed to the protocol
26
27 293 through critical review and intellectual content. DG and MP support the feasibility of
28
29 294 the study and access to clinical data through the physiotherapy and orthopaedic clinic
30
31 295 at canton hospital Winterthur. DG and MP also support data security by providing
32
33 296 REDCap software. All authors gave final approval for publication of the present
34
35 297 protocol version.

36 298

37 299 **Patient and Public Involvement:**

38 300 Between January 2019 and June 2019, we have interviewed patients about their
39
40 301 experience of filling out the questionnaires and about their experience of attending the
41
42 302 clinical consultations at the canton hospital Winterthur. The responses supported the

1
2
3 303 fine tuning of our questionnaires, assessments and organisation processes. In detail
4
5 304 these were:

6
7 305 a) changes in the introduction texts of the different questionnaires;
8
9 306 b) changes of wording for the questions regarding patients' expectations for RCR
10
11 307 (replacement of the word "satisfaction" with the word "expectation");
12
13 308 c) the repeated training of the four physiotherapists to formulate the questions
14
15 during the assessment equally as their peer and always precisely (e.g. "From 0 -
16
17 309 being no pain at all - to 10 - being excruciating pain- what has been your strongest
18
19 310 perceived pain during the last week?") and;
20
21 311 d) improvements of the processes and organisation around the clinical
22
23 312 consultations (e.g. communication between staff and patients regarding
24
25 313 appointments).

26
27 314
28
29 315 Data of this feasibility phase from January 2019 until June 2019 will not be included in
30
31 the study.

32
33 316
34
35 317 Patients attend the clinic in a usual care setting and will be asked for general or
36
37 318 informed consent. There will not be a study specific recruitment and therefore patients
38
39 319 are not needed to be involved in a recruitment procedure.

40
41 320 Study participants can request the results after publication.
42
43 321

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56
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58 328
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2
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7
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9
10 331
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12 332
13
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15
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18
19 335
20
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22
23 337 The authors declare no conflicts of interest.
24
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26 338 **Patients' consent for publication**
27
28 339 Obtained
29
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58
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344 References

- 345 1. Riley RD, Hayden JA, Steyerberg EW, et al. Prognosis Research Strategy (PROGRESS)
346 2: prognostic factor research. PLoS Med. 2013;10(2):e1001380.
- 347 2. Raman J, Walton D, MacDermid JC, Athwal GS. Predictors of outcomes after rotator
348 cuff repair-A meta-analysis. J Hand Ther. 2017;30(3):276-92.
- 349 3. Littlewood C, Malliaras P, Bateman M, Stace R, May S, Walters S. The central nervous
350 system--an additional consideration in 'rotator cuff tendinopathy' and a potential basis for
351 understanding response to loaded therapeutic exercise. Man Ther. 2013;18(6):468-72.
- 352 4. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are Psychosocial Factors
353 Associated With Patient-reported Outcome Measures in Patients With Rotator Cuff Tears? A
354 Systematic Review. Clin Orthop Relat Res. 2018;476(4):810-29.
- 355 5. Vincent K, Leboeuf-Yde C, Gagey O. Are degenerative rotator cuff disorders a cause
356 of shoulder pain? Comparison of prevalence of degenerative rotator cuff disease to
357 prevalence of nontraumatic shoulder pain through three systematic and critical reviews. J
358 Shoulder Elbow Surg. 2017;26(5):766-73.
- 359 6. Littlewood C, Rangan A, Beard DJ, Wade J, Cookson T, Foster NE. The enigma of
360 rotator cuff tears and the case for uncertainty. Br J Sports Med. 2018;52(19):1222.
- 361 7. Rodeghero JR, Cleland JA, Mintken PE, Cook CE. Risk stratification of patients with
362 shoulder pain seen in physical therapy practice. J Eval Clin Pract. 2017;23(2):257-63.
- 363 8. Saltzman BM, Zuke WA, Go B, et al. Does early motion lead to a higher failure rate or
364 better outcomes after arthroscopic rotator cuff repair? A systematic review of overlapping
365 meta-analyses. Journal of Shoulder and Elbow Surgery. 2017;26(9):1681-91.
- 366 9. Jain NB, Higgins L. D., Losina, E., Collins, J., Blazar, P. E., and Katz, J. . Epidemiology of
367 musculoskeletal upper extremity ambulatory surgery in the United States. BMC
368 Musculoskeletal Disorders. 2014;15:1471-2474.
- 369 10. Paloneva J, Lepola V, Aarimaa V, Joukainen A, Ylinen J, Mattila VM. Increasing
370 incidence of rotator cuff repairs--A nationwide registry study in Finland. BMC Musculoskelet
371 Disord. 2015;16:189.
- 372 11. Novoa-Boldo A, Gulotta LV. Expectations Following Rotator Cuff Surgery. Curr Rev
373 Musculoskelet Med. 2018;11(1):162-6.
- 374 12. Henn RF, 3rd, Kang L, Tashjian RZ, Green A. Patients' preoperative expectations
375 predict the outcome of rotator cuff repair. J Bone Joint Surg Am. 2007;89(9):1913-9.
- 376 13. Lambers Heerspink FO, Dorrestijn O, van Raay JJ, Diercks RL. Specific patient-related
377 prognostic factors for rotator cuff repair: a systematic review. J Shoulder Elbow Surg.
378 2014;23(7):1073-80.
- 379 14. Cho CH, Song KS, Hwang I, Warner JJ. Does Rotator Cuff Repair Improve Psychologic
380 Status and Quality of Life in Patients With Rotator Cuff Tear? Clin Orthop Relat Res.
381 2015;473(11):3494-500.
- 382 15. Noten S, Struyf F, Lluch E, D'Hoore M, Van Looveren E, Meeus M. Central Pain
383 Processing in Patients with Shoulder Pain: A Review of the Literature. Pain Pract.
384 2017;17(2):267-80.
- 385 16. Sanchis MN, Lluch E, Nijs J, Struyf F, Kangasperko M. The role of central sensitization
386 in shoulder pain: A systematic literature review. Semin Arthritis Rheum. 2015;44(6):710-6.
- 387 17. Martinez-Calderon J, Meeus M, Struyf F, Miguel Morales-Asencio J, Gijon-Nogueron
388 G, Luque-Suarez A. The role of psychological factors in the perpetuation of pain intensity

- 1
2
3 389 and disability in people with chronic shoulder pain: a systematic review. BMJ Open.
4 390 2018;8(4):e020703.
- 5 391 18. Struyf F, Geraets, J., Noten, S., Meeus, M., Nijs, J. . A Multivariable Prediction Model
6 392 for the Chronification of Non-traumatic Shoulder PAin: A Systematic Review. Pain Physician.
7 393 2016(19):1-10.
- 8 394 19. Thorpe AM, O'Sullivan PB, Mitchell T, et al. Are Psychologic Factors Associated With
9 395 Shoulder Scores After Rotator Cuff Surgery? Clin Orthop Relat Res. 2018;476(10):2062-73.
- 10 396 20. Potter MQ, Wylie JD, Greis PE, Burks RT, Tashjian RZ. Psychological Distress
11 397 Negatively Affects Self-assessment of Shoulder Function in Patients With Rotator Cuff Tears.
12 398 Clinical Orthopaedics and Related Research®. 2014;472(12):3926-32.
- 13 399 21. Oh JH, Yoon JP, Kim JY, Kim SH. Effect of expectations and concerns in rotator cuff
14 400 disorders and correlations with preoperative patient characteristics. J Shoulder Elbow Surg.
15 401 2012;21(6):715-21.
- 16 402 22. Gillespie MA, A MC, Wassinger CA, Sole G. Rotator cuff-related pain: Patients'
17 403 understanding and experiences. Musculoskelet Sci Pract. 2017;30:64-71.
- 18 404 23. Kunze KN, Movasagghi K, Rossi DM, et al. Systematic Review of Sleep Quality Before
19 405 and After Arthroscopic Rotator Cuff Repair: Are Improvements Experienced and
20 406 Maintained? Orthop J Sports Med. 2020;8(12):2325967120969224.
- 21 407 24. Cho CH, Jung SW, Park JY, Song KS, Yu KI. Is shoulder pain for three months or longer
22 408 correlated with depression, anxiety, and sleep disturbance? J Shoulder Elbow Surg.
23 409 2013;22(2):222-8.
- 24 410 25. Austin L, Pepe M, Tucker B, et al. Sleep disturbance associated with rotator cuff tear:
25 411 correction with arthroscopic rotator cuff repair. Am J Sports Med. 2015;43(6):1455-9.
- 26 412 26. Longo UG, Facchinetto G, Marchetti A, et al. Sleep Disturbance and Rotator Cuff
27 413 Tears: A Systematic Review. Medicina (Kaunas). 2019;55(8).
- 28 414 27. Nijs J, George SZ, Clauw DJ, et al. Central sensitisation in chronic pain conditions:
29 415 latest discoveries and their potential for precision medicine. The Lancet Rheumatology.
30 416 2021.
- 31 417 28. Gwilym SE, Oag, H. C. L., Tracey, I. and Carr A. J. . Evidence that central sensitisation
32 418 is present in patients with shoulder impingement syndrome and influences the outcome
33 419 after surgery. The Journal of Bone & Joint Surgery. 2011;93-B:498-502.
- 34 420 29. Valencia C, Fillingim RB, Bishop M, et al. Investigation of central pain processing in
35 421 postoperative shoulder pain and disability. Clin J Pain. 2014;30(9):775-86.
- 36 422 30. Rees JD, Stride M, Scott A. Tendons--time to revisit inflammation. Br J Sports Med.
37 423 2014;48(21):1553-7.
- 38 424 31. Lewis J, O'Sullivan P. Is it time to reframe how we care for people with non-traumatic
39 425 musculoskeletal pain? British Journal of Sports Medicine. 2018.
- 40 426 32. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandebroucke JP. The
41 427 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement:
42 428 guidelines for reporting observational studies. Annals of internal medicine. 2007;147(8):573-
43 429 7.
- 44 430 33. Hemingway H, Croft P, Perel P, et al. Prognosis research strategy (PROGRESS) 1: a
45 431 framework for researching clinical outcomes. BMJ. 2013;346:e5595.
- 46 432 34. Buchbinder R, Page MJ, Huang H, et al. A Preliminary Core Domain Set for Clinical
47 433 Trials of Shoulder Disorders: A Report from the OMERACT 2016 Shoulder Core Outcome Set
48 434 Special Interest Group. J Rheumatol. 2017;44(12):1880-3.

- 1
2
3 435 35. I. Swarup CMH, J. T. Nguyen, D. M. Dines, E. V. Craig, R. F. Warren, L. V. Gulotta, R. F.
4 436 Henn III Effect of pre-operative expectations on the outcomes following total shoulder
5 437 arthroplasty. 2017.
- 6 438 36. Huber W, Hofstaetter JG, Hanslik-Schnabel B, Posch M, Wurnig C. [Translation and
7 439 psychometric testing of the Western Ontario Rotator Cuff Index (WORC) for use in
8 440 Germany]. Z Orthop Ihre Grenzgeb. 2005;143(4):453-60.
- 9 441 37. Huang H, Grant JA, Miller BS, Mirza FM, Gagnier JJ. A Systematic Review of the
10 442 Psychometric Properties of Patient-Reported Outcome Instruments for Use in Patients With
11 443 Rotator Cuff Disease. Am J Sports Med. 2015;43(10):2572-82.
- 12 444 38. MacDermid JC, Drosdowech D, Faber K. Responsiveness of self-report scales in
13 445 patients recovering from rotator cuff surgery. J Shoulder Elbow Surg. 2006;15(4):407-14.
- 14 446 39. Braun C, Handoll HH. Estimating the Minimal Important Difference for the Western
15 447 Ontario Rotator Cuff Index (WORC) in adults with shoulder pain associated with partial-
16 448 thickness rotator cuff tears. Musculoskeletal Sci Pract. 2018;35:30-3.
- 17 449 40. Gilbart MK, Gerber C. Comparison of the subjective shoulder value and the Constant
18 450 score. J Shoulder Elbow Surg. 2007;16(6):717-21.
- 19 451 41. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales.
20 452 Journal of Clinical Nursing 2004;14:798 - 804.
- 21 453 42. Nahman-Averbuch H, Yarnitsky D, Granovsky Y, et al. Pronociceptive pain
22 454 modulation in patients with painful chemotherapy-induced polyneuropathy. J Pain
23 455 Symptom Manage. 2011;42(2):229-38.
- 24 456 43. Ludwig K, Graf von der Schulenburg JM, Greiner W. German Value Set for the EQ-5D-
25 457 5L. Pharmacoeconomics. 2018;36(6):663-74.
- 26 458 44. Group TE. EuroQoL-a new facility for the measurement of health-related quality of
27 459 life. Health policy. 1990;16(3):199-208.
- 28 460 45. Meyer K SH, Manion AF. Cross-cultural adaptation, reliability and validity of the
29 461 German version of the Pain Catastrophizing Scale. Journal of Psychosomatic Research.
30 462 2008;64(5):469-478.
- 31 463 46. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and
32 464 validation. Psychological assessment. 1995;7(4):524.
- 33 465 47. Klein EM, Brahler E, Dreier M, et al. The German version of the Perceived Stress Scale
34 466 - psychometric characteristics in a representative German community sample. BMC
35 467 Psychiatry. 2016;16:159.
- 36 468 48. Leysen M, Nijs J, Meeus M, et al. Clinimetric properties of illness perception
37 469 questionnaire revised (IPQ-R) and brief illness perception questionnaire (Brief IPQ) in
38 470 patients with musculoskeletal disorders: A systematic review. Man Ther. 2015;20(1):10-7.
- 39 471 49. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised
40 472 Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.
- 41 473 50. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception
42 474 questionnaire. J Psychosom Res. 2006;60(6):631-7.
- 43 475 51. Lau RR, Hartman KA. Common sense representations of common illnesses. Health
44 476 psychology. 1983;2(2):167.
- 45 477 52. Broadbent E, Wilkes C, Koschwanez H, Weinman J, Norton S, Petrie KJ. A systematic
46 478 review and meta-analysis of the Brief Illness Perception Questionnaire. Psychol Health.
47 479 2015;30(11):1361-85.

- 1
2
3 480 53. Jo Nijs OM, Daniel Neu, Laurence Leysen, Lieven Danneels,, Barbara Cagnie MM,
4 481 Maarten Moens, Kelly Ickmans, Dorien Goubert. sleep disturbances in chronic pain
5 482 neurobiology assessment and treatment in physical therapy. 2018.
6 483 54. Scerbo T, Colasurdo J, Dunn S, Unger J, Nijs J, Cook C. Measurement Properties of the
7 484 Central Sensitization Inventory: A Systematic Review. *Pain Pract.* 2018;18(4):544-54.
8 485 55. Mayer TG, Neblett R, Cohen H, et al. The development and psychometric validation
9 486 of the central sensitization inventory. *Pain Pract.* 2012;12(4):276-85.
10 487 56. Kuppens K, Hans G, Roussel N, et al. Sensory processing and central pain modulation
11 488 in patients with chronic shoulder pain: A case-control study. *Scand J Med Sci Sports.*
12 489 2018;28(3):1183-92.
13 490 57. Rebbeck T, Moloney, N., Azoory, R., Hübscher, M., Waller, R., Gibbons, R., Beales,
14 491 D.. Clinical ratings of pain sensitivity correlate with qust in people with chronic neck pain
15 492 and healthy controls cross sectional study. *Physical Therapy.* 2015;95(11).
16 493 58. Staud R, Robinson ME, Vierck CJ, Cannon RC, Mauderli AP, Price DD. Ratings of
17 494 experimental pain and pain-related negative affect predict clinical pain in patients with
18 495 fibromyalgia syndrome. *Pain.* 2003;105(1):215-22.
19 496 59. Edwards RR, Mensing G, Cahalan C, et al. Alteration in pain modulation in women
20 497 with persistent pain after lumpectomy: influence of catastrophizing. *J Pain Symptom
21 498 Manage.* 2013;46(1):30-42.
22 499 60. Moloney N. An investigation of somatosensory profiles in woeck related upper limb
23 500 disorders a case control obervational study protocol. 2010.
24 501 61. Maxwell S, Sterling M. An investigation of the use of a numeric pain rating scale with
25 502 ice application to the neck to determine cold hyperalgesia. *Man Ther.* 2013;18(2):172-4.
26 503 62. Walton DM, Macdermid JC, Nielson W, Teasell RW, Reese H, Levesque L. Pressure
27 504 pain threshold testing demonstrates predictive ability in people with acute whiplash. *J
28 505 Orthop Sports Phys Ther.* 2011;41(9):658-65.
29 506 63. Klyne DM, Schmid AB, Moseley GL, Sterling M, Hodges PW. Effect of types and
30 507 anatomic arrangement of painful stimuli on conditioned pain modulation. *J Pain.*
31 508 2015;16(2):176-85.
32 509 64. Timmerman H, Steegers MAH, Huygen F, et al. Investigating the validity of the DN4
33 510 in a consecutive population of patients with chronic pain. *PLoS One.* 2017;12(11):e0187961.
34 511 65. Margolis R. B. TRCaKSJ. A Rating System For Use with Patient Pain Drawings. *Pain.*
35 512 1986;24:57-65.
36 513 66. Blackwell E, de Leon CF, Miller GE. Applying mixed regression models to the analysis
37 514 of repeated-measures data in psychosomatic medicine. *Psychosom Med.* 2006;68(6):870-8.
38 515 67. Singer JD, Willett JB, Willett JB. Applied longitudinal data analysis: Modeling change
39 516 and event occurrence: Oxford university press; 2003.
40 517 68. Edland S. Which MRI measure is best for Alzheimer's disease prevention trials.
41 518 Statistical considerations of power and sample size *Jt Stat Meet Proc.* 2009:4996-9.
42 519 69. Kirkley A. ACaGS. The Development and Evaluation of a Disease-specific Quality-of-
43 520 Life Questionnaire for Disorders of the Rotator Cuff_ The Western Ontario Rotator Cuff
44 521 Index. *Clinical Journal of Sport Medicine.* 2003;13:84–92.
45 522 70. Faul F, Erdfelder, E., Lang, A.-G., & Buchner, A. . G Power 3- A flexible statistical
46 523 power analysis program for the social, behavioral, and biomedical sciences. *Behavior
47 524 Research Methods.* 2007.
48 525 71. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power
49 526 3.1: tests for correlation and regression analyses. *Behav Res Methods.* 2009;41(4):1149-60.

- 1
2
3 527 72. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an
4 528 international community of software platform partners. *Journal of biomedical informatics*.
5 529 2019;95:103208.
6
7 530 73. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic
8 531 data capture (REDCap)—a metadata-driven methodology and workflow process for
9 532 providing translational research informatics support. *Journal of biomedical informatics*.
10 533 2009;42(2):377-81.
11
12 534

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