

Translation and validation of the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale of Kinesiophobia Shoulder Instability (TSK-SI) into German

Study Type:	Other Clinical Trial according to ClinO, Chapter 4
Risk Categorisation:	A
Study Registration:	clinicaltrials.gov SNCTP
Sponsor:	Schulthess Klinik Zürich Lengghalde 2 8008 Zürich
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Investigated Intervention:	Usage of the Shoulder Instability Return to Sports Index and Tampa Scale of Kinesiophobia Shoulder Instability Questionnaire
Protocol ID:	OE-236 SIRSI Validation
Version and Date:	Version 2 (dated 09/07/2024)

Confidentiality Statement:

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PROTOCOL SIGNATURE FORM

Study Title *Translation and validation of the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale of Kinesiophobia Shoulder Instability (TSK-SI) into German*

The project leader has approved the protocol version 02 (dated 09.07.2024) and confirms hereby to conduct the project according to the protocol, the Swiss legal requirements (Bundesrat, 2013; Eidgenossenschaft, 2011), current version of the World Medical Association Declaration of Helsinki (World-Medical-Association, 2018) and the principles and procedures for integrity in scientific research involving human beings.

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Name: Dr. Asimina Lazaridou, PhD

Date: _____

Signature: _____

Sponsor:

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GLOSSARY OF ABBREVIATIONS

<i>ACL-RSI</i>	<i>Anterior Cruciate Ligament – Return to Sports Index</i>
<i>ADL</i>	<i>Activities of Daily Living</i>
<i>BASEC</i>	<i>Business Administration System for Ethical Committees</i>
<i>CI</i>	<i>Confidence Interval</i>
<i>CRF</i>	<i>Case report form</i>
<i>eCRF</i>	<i>Electronic Case Report Form</i>
<i>HRA</i>	<i>Human Research Act</i>
<i>HRO</i>	<i>Ordinance on Human Research Ordinance</i>
<i>ICC</i>	<i>Intraclass Correlation Coefficient</i>
<i>PI</i>	<i>Principal Investigator</i>
<i>PROM</i>	<i>Patient Reported Outcome Measure</i>
<i>REDCap</i>	<i>Research Electronic Data Capture System</i>
<i>RTS</i>	<i>Return to Sports</i>
<i>SIR</i>	<i>Shoulder Instability Registry</i>
<i>SIRSI</i>	<i>Shoulder Instability Return to Sport Index</i>
<i>SIRSI-D</i>	<i>Shoulder Instability Return to Sport Index - Deutsch</i>
<i>sSSV</i>	<i>Sport Subjective Shoulder Value</i>
<i>SSV</i>	<i>Subjective Shoulder Value</i>
<i>WOSI</i>	<i>Western Ontario Shoulder Instability Index</i>

1 STUDY SYNOPSIS

Sponsor / Sponsor-Investigator	Dr. Asimina Lazaridou, PhD Head of Research Group Upper Extremities and Hand Teaching, Research & Development Lengghalde 2 8008 Zürich +41 44 385 79 77 Asimina.lazaridou@kws.ch
Study Title	Translation and validation of the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale of Kinesiophobia Shoulder Instability (TSK-SI) into German
Short Title / Study ID	OE-236 SIRSI TSK-SI Validation
Protocol Version and Date	Version 2 (dated 09/07/2024)
Study Registration	Clinicaltrials.gov SNCTP
Study Category and Rationale	Risk Category A
Background and Rationale	Return to Sports (RTS) is an important outcome measure after shoulder instability treatment. The concept of Return to Sport is multifactorial consisting of physical, psychological, and social/contextual factors in an interplay with sociodemographic and injury factors. The Shoulder Instability Return to Sport Index (SIRSI) measures psychological readiness to return to sports in the shoulder instability. Similarly the Tampa Scale for Kinesiophobia (TSK) has been invented to measure an excessive fear of movement due to painful injury in chronic low back pain. The Scale was then adapted to the shoulder instability cohort. However, both questionnaires are currently not available in German and therefore not scientifically available for a German speaking population,
Risk / Benefit Assessment	Risk / benefit assessment
Objective(s)	The aim of the project is to translate the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale of Kinesiophobia Shoulder Instability (TSK-SI) into a German version and assess its validity in a Swiss-German population of patients with shoulder instability treated conservatively or surgically and planning to return to sports.
Endpoint(s)	Shoulder Instability Return to Sports Index (SIRSI) Tampa Scale of Kinesiophobia – Shoulder Instability (TSK-SI) Western Ontario Shoulder Instability Index (WOSI) Subjective Shoulder Value (SSV) Sport Subjective Shoulder Value (sSSV) Return to Sports Level
Study Design	single centre cross sectional confirmatory analysis to validate a patient reported outcome measure.
Statistical Considerations	Internal consistency, which measures the extent to which items within the questionnaire are correlated with one another, will be assessed using Cronbach's alpha coefficient. Test-retest reliability will be examined by administering the questionnaire to participants on two different timepoints one week apart and calculating the correlation between their scores. Content validity will be established by ensuring that the items in the questionnaire adequately cover all relevant aspects of the constructs. Construct validity will be evaluated through factor analysis to confirm the underlying factor structure of the questionnaire and assess its convergent and divergent validity with other related measures. Criterion validity will be examined through concurrent validity by comparing the scores of the SIRSI questionnaire with SSV and WOSI. All statistical analyses are conducted in R.
Inclusion- / Exclusion Criteria	Inclusion Criteria Had an instability event* within last year Provided general consent for local shoulder instability register Under the age of 18 years Exclusion Criteria Are at least three months after surgery or instability event Must endeavor to return to their sport

	<p>Have another physical or psychological disorder not related to shoulder instability compromising return to sports</p> <p>Have a language barrier to complete the questionnaires in German</p> <p>Are legally incapable of participating in research studies</p>
Number of Participants with Rationale	The Sample Size was calculated to N=135. This leads to a satisfying precision for the aforementioned estimates and includes a 15% dropout rate.
Study Intervention	Usage of the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale of Kinesiophobia Shoulder Instability (TSK-SI)
Control Intervention	Not applicable
Study procedures	<p>Upon identification in the local instability register at the Schulthess Klinik Zürich, patients receive an email with a link to the eCRF containing the German version of the SIRSI the TSK-SI, the WOSI, the SSV and sSSV, information on the RTS status and demographic and clinical information. Entering the link from the eCRF in the email is considered consent to the study which is explicitly explained. Upon completion of the first round eCRF a second round eCRF is sent automatically after seven days containing the German version of the SIRSI. The Data is stored within the REDCap database.</p>
Study Duration and Schedule	<p>Planned 01/07/2024 of First-Participant-In</p> <p>Planned 31/07/2025 of Last-Participant-Out</p>
Investigator(s)	<p>Dr. Asimina Lazaridou, PhD Head of Research Group Upper Extremities and Hand Teaching, Research & Development Lengghalde 2 8008 Zürich +41 44 385 79 77 Asimina.lazaridou@kws.ch</p> <p>Jan Schätz, M.Sc. PT Research Assistant Teaching, Research & Development Lengghalde 2 8008 Zürich +41 44 385 7583 Jan.schaetz@kws.ch</p>
Study Center(s)	Schulthess Klinik Zürich, Lengghalde 2, 8008 Zürich, Switzerland
Data privacy	<p>Project data will be handled with utmost discretion and is only accessible to authorized GCP trained personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number. A participant identification list will be managed and stored by a designated project staff at Schulthess Klinik. The project leader affirms and upholds the principle of the patients' right to privacy and that they shall comply with applicable privacy laws. Exported files will not contain any patient personal data and are pseudo-anonymized. The IT Department of the Schulthess Klinik will perform systematic data backup to prevent data loss or misuse.</p> <p>All materials pertaining to the study, including patient questionnaires, will be documented into a Trial Master File by the study coordinator, sorted and kept in closed archives at the teaching, research and development department at Schulthess Klinik. All study data must be archived for a minimum of 10 years after termination or premature termination of the project.</p>
Ethical consideration	There is currently no tool available for the German speaking population, hence this part of treatment is left to subjective interpretation or related measures like strength, range of motion or anamnesis. Once the SIRSI is culturally adapted to the German population meaning Switzerland, Germany and Austria, it will help clinicians and researcher to objectively estimate the ability to RTS. For patients this means a safer RTS and potentially reduces the risk of re-injury. No vulnerable patients are planned to be enrolled in this study.
GCP Statement	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as other locally relevant legal and

regulatory requirements. A clinical trial covered by ClinO Chapter 4 may be conducted in accordance with other rules than ICH-GCP guidelines, provided that such rules are recognised in the specialty in question and the protection of participants and data quality and security are guaranteed (ClinO Art. 5, Abs 2). If the clinical trial is not conducted according to ICH-GCP guidelines, the paragraph above must be adapted accordingly.
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2 BACKGROUND AND PROJECT RATIONALE

Return to Sports (RTS) is an important outcome measure after shoulder instability treatment (Abdul-Rassoul et al., 2019). While the definition of returning to sport is not clear (Doege et al., 2021), efforts have been made to provide consensus (Ardern et al., 2016). The concept of Return to Sport is multifactorial consisting of physical, psychological, and social/contextual factors in an interplay with sociodemographic and injury factors. Furthermore, different stages of RTS have been defined (Ardern et al., 2016). To take all factors into account, outcome measures like the ACL-RSI for anterior cruciate ligament ruptures have been invented (Webster et al., 2008). To provide such a measure for the shoulder instability cohort have adapted the ACL-RSI to a shoulder instability population and named it the Shoulder Instability Return to Sport Index (SIRSI)(Gerometta et al., 2018). Since then, this outcome has been frequently used to determine psychological readiness to RTS (Rossi et al., 2022). Despite an available German translation, published by a German insurance company ([Return-to-Competition Schulter: Shoulder Instability-Return to Sport after Injury \(SIRSI\)-Skala \(vbg.de\)](#), accessed 23.01.2024), the SIRSI is not scientifically available for a German speaking population, because this version has never been officially translated and validated. Similarly the Tampa Scale for Kinesiophobia (TSK) has been invented to measure an excessive fear of movement due to painful injury in chronic low back pain(Miller et al., 1991). The Scale was then adapted to the shoulder instability cohort(van Iersel et al., 2023). However, it is currently not available in German. Therefore, this project seeks to translate the SIRSI and TSK-SI into a German version and validate them in a German speaking population in Switzerland.

3 PROJECT OBJECTIVES AND DESIGN

3.1 Primary objective

The aim of the project is to translate the Shoulder Instability Return to Sports Index (SIRSI) and Tampa Scale for Kinesiophobia – Shoulder Instability (TSK-SI) into a German version and assess its validity in a Swiss-German population of patients with shoulder instability treated conservatively or surgically and planning to return to sports.

3.2 Primary endpoints

The primary outcomes of interest are the SIRSI and the TSK-SI. The SIRSI has been adapted to the shoulder instability cohort from the Anterior Cruciate Ligament Return to Sport Index (ACL-RSI) by (Gerometta et al., 2018). It is composed of twelve items that are rated on a zero to ten. The single total score is calculated by multiplying the sum of each item and dividing it by 120. The worst score then is zero indicating no psychological readiness to RTS and 100 the best, indicating full psychological readiness to RTS. The TSK-SI is composed of 18 questions scored on a 4 point Likert-Scale from "Strongly agree" to "Strongly disagree". The lowest score is 18, indicating no kinesiophobia and 72, indicating

highest level of kinesiophobia. The outcomes will be assessed electronically between three months and two years after surgery or instability event.

3.3 Secondary endpoints

As a secondary outcome the Western Ontario Shoulder Instability Index (WOSI) was developed by Kirkley (2003) and is the most prominent PROM in clinic and research for shoulder instability. The WOSI consists of 21 items and four domains: Physical symptoms (10 items), Sports, recreation, and work (4 items), lifestyle (4 items) and emotions (3 items). The scale for each item ranges from 0 to 100, allowing for a total score of 0 (best) to 2100 (worst). A transformed value ranging from 0 to 100 may be calculated by dividing the total score by 21 and subtracting it from 100. This allows for the common scale of 0 (worst) to 100 (best).

The subjective shoulder value (SSV) was introduced by Gilbert and Gerber (2007) and provides a simple measure to represent shoulder functionality during activities of daily living (ADL). The patients are asked "What is the overall percent value of your shoulder if a completely normal shoulder represents 100%?" if difficulties emerge with estimating a percentage another possibility is to ask "A completely normal shoulder would cost you €1000. How much would you be willing to pay for yours?" (Gilbert & Gerber, 2007). Because the standard SSV might lack sport specific context Descamps et al (2023) suggested the sport subjective shoulder value (sSSV) with the question "Regarding sports practice, what is the overall percent value of your shoulder, if a completely normal shoulder represents 100% and a non-functional shoulder represents 0%?". Both scales result in a value between zero and 100, where zero means no subjective functionality during ADL or Sport respectively (Descamps et al., 2023).

Arder et al (2016) defined *RTS* as that the athlete has returned to his previous sport but not necessarily at the same performance level and differentiated it to *return to participation* and *return to performance*. This spectrum will be assessed using custom build questions to determine the RTS level (Arder et al., 2016).

3.4 Study Design

This study is a single centre cross sectional confirmatory analysis to validate two patient reported outcome measures.

4 PROJECT POPULATION AND STUDY PROCEDURES

4.1 Project population

The targeted population to sample from comprises patients with conservative or operative treatment of anterior shoulder instability, who wish to return to sports after a shoulder instability event.

An instability event is defined as a complete dislocation of the glenohumeral joint that needs to be repositioned by a health care professional or repositioned itself spontaneously, or a subluxation where the shoulder almost dislocates however not completely. Not an instability event are voluntarily dislocations or subluxations that can be provoked by the patient.

4.2 Inclusion criteria

Patients are included if they had a shoulder instability event within last year, where an instability event is defined as a) a complete dislocation of the glenohumeral joint that had to be reduced by a clinician or reduced itself spontaneously or b) a subluxation that suddenly almost dislocated but not completely. Dislocations or subluxations that can be induced by patients voluntarily are not considered an instability event. Patients must be above the age of 18 years. Furthermore, they must have signed a general consent for the use of data in scope of the local shoulder instability register at the Schulthess Klinik Zürich.

4.3 Exclusion criteria

Patients are excluded if they are not at least three months after the last instability event or a surgery for shoulder instability, if they do not endeavor to return to their sport, have another physical or psychological disorder not related to shoulder instability that compromises return to sport, have a language barrier to complete the questionnaires in German or are legally incapable of participating in this study.

Table 1: Overview over the inclusion and exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ol style="list-style-type: none"> Had an instability event within last year Provided general consent for local shoulder instability register Adult patients aged 18 or older 	<ol style="list-style-type: none"> Are at least three months after surgery or instability event Must endeavor to return to their sport Have another physical or psychological disorder not related to shoulder instability compromising return to sports Have a language barrier to complete the questionnaires in German Are legally incapable of participating in research studies

4.4 Sample Size

According to the estimates that Gerometta et al (2018) provided in their validation study on the development of the SIRSI, the sample size to detect a Cronbach's alpha of 0.96 with a 95%-CI width of 0.1 is 9 patients. To detect a Pearson correlation coefficient of 0.71 with a CI-width of 0.2 a sample size of 99 is warranted and to detect a difference in means of 22.8 with a CI-width of 20 a sample size of 117 is necessary. To account for a dropout rate of 15% in this cohort a final sample size of 135 is needed to perform the below-mentioned analysis with a satisfying precision. As the TSK-SI is relatively new, no data is available to estimate the mean and standard deviations of the TSK-SI. Therefore, to validate the TSK-SI the sample size calculated for the SIRSI is considered sufficient. Sample size calculations have been conducted with the help of the presize package (Haynes et al., 2021) and the congruent web based application (<https://shiny.ctu.unibe.ch/presize/>, accessed on 03.04.2023).

sample size for Cronbach's alpha						
calpha	k	n	conf.width	conf.level	lwr	upr

1	0.96	12	9	0.1	0.95	0.88588	0.9892657
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sample size for pearson 's correlation coefficient							
r	n	conf.width	conf.level	lwr	upr		
1	0.71	99	0.2	0.95	0.5961453	0.7958619	

sample size for mean difference with equal variance									
delta	sd1	sd2	n1	n2	conf.width	conf.level	lwr	upr	
1	22.8	26.6	26.6	71.82715	45.2511	20	0.95	12.8	32.8

4.5 Recruitment, screening and informed consent procedure

The recruiting takes place at the Schulthess Klinik Zürich. Patients who provided consent for the further use of health-related personal data for research purposes and were included in the local shoulder instability registry (SIR) (BASEC: 2020-01091), are screened for the inclusion criteria 1, 2 and 3.

Those patients will be contacted by email. In the email the study purpose, inclusion- and exclusion criteria are explained and a link to the eCRF is provided, as well as a study information attached. Furthermore, it is explained, that filling out the eCRF is considered as an agreement to participate in this study similar to a written consent. This procedure is valid according to the human research ordinance (HRO) Chapter 2 Article 9, when a study of risk category A with an adult capable of judgement and a disproportionate effort of providing a written informed consent is present. The ethics committee then has to be informed of this procedure and the burden of re-sending the written informed consent can so be reduced. The Email can be found in Appendix 1. Patients will not receive any compensation for participating.

4.6 Study procedures

Upon return of written consent, patients receive an email with a link to the eCRF. This is composed in REDCap and contains a final check on the inclusion and exclusion criteria, the German version of the SIRSI, the German Version of the TSK-SI, the German Version of the WOSI, the SSV and sSSV, information on the RTS status and demographic and clinical information. If not completed reminders are sent every week for four times. A table of the items is provided below (Table 2). Upon completion of the first round eCRF (T1) a second round eCRF (T2) is sent automatically after seven days containing another check on exclusion criteria and the German version of the SIRSI. If not completed three reminders are sent daily therefore a maximum time of ten days between measures (T1 and T2) is not exceeded. The duration to fill out the first round of questionnaires should take around 15 minutes and the second round around five minutes. The Data is stored within the REDCap database.

Table 2: Items collected via the eCRF at T0 = Enrolment, T1 = first round of questionnaires and T2 = second round of SIRSI

Section	Item Nr.	Item	Response	T0	T1	T2
---------	----------	------	----------	----	----	----

0. Enrolment	0.1	Record ID	Number	X		
	0.2	Email	Text	X		
	0.3	Address for sending the consent	Text	X		
	0.4	Consent received	0 = No 1 = Yes	X		
	0.5	Consent withdrawal	0 = No 1 = Yes	X		
1. Exclusion Criteria	Ein Instabilitätsereignis definiert sich durch ...a) ein komplettes Ausrenken der Schulter welches entweder im Notfall eingerenkt wird oder sich spontan selbstständig wieder einrenkt oder b) eine Subluxation, wobei die Schulter plötzlich beinahe luxiert, jedoch nicht ganz ausrenkt. Kein Instabilitätsereignis sind willkürliches Ausrenken oder willkürliches beinahe Ausrenken welches selbst spontan immer wieder herbeigeführt werden kann.				X	
	1.1	Wann war Ihr letztes Instabilitätsereignis? (d.h. komplettes ausrenken oder plötzliches beinahe ausrenken, siehe Definition oben)	date			
	1.2	War/Ist es Ihr Ziel nach dem Instabilitätsereignis wieder in Ihren Sport zurückzukehren?	0 = Nein 1 = Ja		X	
	1.3	Haben Sie neben der Schulterinstabilität eine andere physische oder psychische Erkrankung, welche die Rückkehr in den Sport einschränken könnte oder derzeit einschränkt?	0 = Nein 1 = Ja		X	
	1.4	Können Sie Deutsch problemlos lesen, verstehen und schreiben?	0 = Nein 1 = Ja		X	
	1.5	Hatten Sie seit der letzten Befragung ein erneutes Instabilitätsereignis oder eine Verletzung, welche ihre Rückkehr in den Sport beeinträchtigt hat?	0 = Nein 1 = Ja			X
	1.6	Haben Sie seit der letzten Befragung neben der Schulterinstabilität eine neue physische oder psychische Erkrankung, welche die Rückkehr in den Sport einschränken könnte?	0 = Nein 1 = Ja			X
2. SIRSI German Version	Shoulder Instability Return to Sport Index Anleitung: Bitte beantworten Sie die Fragen in Bezug auf Ihre primäre Sportart vor der Verletzung. Beantworten Sie jede Frage, indem Sie auf der Skala das Kästchen ankreuzen <input checked="" type="checkbox"/> , welches Ihr aktuelles Befinden am besten beschreibt.				X	X
	2.1	Sind Sie zuversichtlich, dass Sie Ihren Sport auf dem vorherigen Niveau ausführen können?	NRS 0-10		X	X
	2.2	Halten Sie es für wahrscheinlich, dass Sie sich bei der Ausübung Ihres Sports erneut verletzen?	NRS 0-10		X	X
	2.3	Sind Sie nervös, wenn Sie Ihren Sport ausüben?	NRS 0-10		X	X
	2.4	Sind Sie zuversichtlich, dass Ihre Schulter bei der Ausführung Ihres Sports stabil bleibt?	NRS 0-10		X	X
	2.5	Sind Sie zuversichtlich, dass Sie Ihren Sport ausüben können, ohne sich Sorgen um Ihre Schulter zu machen?	NRS 0-10		X	X
	2.6	Finden Sie es frustrierend, dass Sie Ihre Schulter in Bezug auf Ihren Sport berücksichtigen müssen?	NRS 0-10		X	X
	2.7	Befürchten Sie, dass Sie Ihre Schulter beim Sport wieder verletzen?	NRS 0-10		X	X
	2.8	Sind Sie zuversichtlich, dass Ihre Schulter einer grossen Belastung standhält?	NRS 0-10		X	X
	2.9	Haben Sie Angst, dass Sie Ihre Schulter beim Sport aus Versehen verletzen?	NRS 0-10		X	X
	2.10	Hindern Sie Gedanken an eine erneute Operation und Rehabilitation daran, Ihren Sport auszuüben?	NRS 0-10		X	X
	2.11	Sind Sie zuversichtlich, dass Sie aufgrund Ihrer Fähigkeiten in der Lage sind, in Ihrem Sport gute Leistungen zu erbringen?	NRS 0-10		X	X
	2.12	Fühlen Sie sich entspannt, wenn Sie Ihren Sport ausüben?	NRS 0-10		X	X
	Bitte beantworten Sie die folgenden Fragen und bewerten Sie jede Aussage von " Stimme überhaupt nicht zu" bis " Stimme völlig zu",				X	X

3. TSK-SI German Version	indem sie das entsprechende Kästchen ankreuzen. Der Fragebogen besteht aus 18 Fragen. Wenn Sie das Gefühl haben, dass eine Frage nicht auf Sie zutrifft, wählen Sie bitte die Antwort, welche am ehesten auf Ihre aktuelle Situation zutrifft.					
	3.1	Wenn ich mich sportlich betätige, bin ich besorgt, dass ich meine Schulter schädigen werde.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.2	Wenn ich meine Schulterbeschwerden ignoriere, werden diese sich verschlimmern.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.3	Mein Körper sagt mir, dass die Situation meiner Schulter ernst ist.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.4	Wenn ich mich sportlich betätige, werden meine Schulterbeschwerden wahrscheinlich abnehmen.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.5	Andere verneinen die Ernsthaftigkeit meiner Schulterbeschwerden.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.6	Aufgrund meiner Schulterbeschwerden ist mein Körper für den Rest meines Lebens in Gefahr.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.7	Schmerz ist Zeichen von Schädigung.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.8	Wenn sich meine Schulterbeschwerden verschlimmern, bedeutet das nicht, dass es eine gefährliche Entwicklung ist.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.9	Ich habe Angst, versehentlich Schäden zu verursachen.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
3.10	Ein sicherer Weg meiner Schulter keinen weiteren Schaden zuzuführen ist, unnötige Bewegungen meines Arms einfach zu vermeiden.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu		X		

			4 = Stimme überhaupt nicht zu			
	3.11	Wenn ich keine ernsthaften Probleme mit meiner Schulter hätte, würden meine Beschwerden wahrscheinlich abnehmen.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.12	Obwohl ich Schulterbeschwerden habe, würde sich mein Allgemeinzustand verbessern, wenn ich aktiver wäre.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.13	Meine Schulterbeschwerden weisen mich darauf hin, dass ich meine Übungen einstellen muss, um weitere Schäden zu vermeiden.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.14	Für eine Person mit meiner Art von Schulterbeschwerden ist sportliche Betätigung keine gute Idee.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.15	Ich kann nicht so viel Leistung erbringen wie andere, da ich ein erhöhtes Risiko habe Schäden an meiner Schulter zu verursachen.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.16	Selbst, wenn meine Schulterbeschwerden zunehmen, halte ich das nicht für gefährlich.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.17	Ich sollte mich nicht sportlich betätigen müssen, wenn ich Schulterbeschwerden habe.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
	3.18	Ich mache mir Sorgen, dass ich mir bei Alltagsaktivitäten die Schulter auskugeln werde.	1 = Stimme völlig zu 2= Stimme eher zu 3 = Stimme eher nicht zu 4 = Stimme überhaupt nicht zu		X	X
4. WOSI German Version	I. Teil: 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.				X	
	4.1	Wie stark ist der Schulterschmerz in Ihrer betroffenen Schulter bei Aktivitäten über dem Kopf?	NRS 0-10		X	
	4.2	Wieviel stechende und/oder pochende Schmerzen verspüren Sie in der betroffenen Schulter?	NRS 0-10		X	

	4.3	Wie groß empfinden Sie die Schwäche oder den Mangel an Kraft in Ihrer betroffenen Schulter?	NRS 0-10		X	
	4.4	Wie stark empfinden Sie die Ermüdung oder den Mangel an Ausdauer in Ihrer betroffenen Schulter?	NRS 0-10		X	
	4.5	Wie stark klickt, schnappt oder knackt es in ihrer betroffenen Schulter?	NRS 0-10		X	
	4.6	Wie steif empfinden Sie Ihre Schulter?	NRS 0-10		X	
	4.7	Wie stark sind die Beschwerden im Bereich der Nackenmuskulatur aufgrund Ihrer Schulterproblematik?	NRS 0-10		X	
	4.8	Wie stark ist das Instabilitätsgefühl in Ihrer Schulter?	NRS 0-10		X	
	4.9	Wie stark müssen Sie andere Muskeln benutzen um Ihre eingeschränkte Schulterfunktion auszugleichen?	NRS 0-10		X	
	4.10	Wie groß ist der Verlust des Bewegungsumfanges in Ihrer Schulter?	NRS 0-10		X	
	II. Teil: Sport / Freizeit / Arbeit: In den folgenden Fragen geht es darum wie stark Ihre Schulterproblematik Ihre Arbeit, Sport- und Freizeitgewohnheiten in der letzten Woche beeinflusst hat.				X	
	4.11	Wie stark hat Sie ihre Schulter behindert Sport oder andere Freizeitaktivitäten zu betreiben?	NRS 0-10		X	
	4.12	Wie stark hat Ihre Schulterproblematik spezielle Tätigkeiten in Ihrem Sport und/oder Ihrer Arbeit beeinflusst? (Falls beide Gebiete betroffen sind, bewerten Sie das stärker betroffene)	NRS 0-10		X	
	4.13	Wie groß ist der Drang ihren Arm während einer Aktivität zu schützen?	NRS 0-10		X	
	4.14	Wie schwer fällt es Ihnen, auf Grund Ihrer Schulterproblematik schwere Gegenstände bis auf Schulterhöhe zu heben?	NRS 0-10		X	
	III. Teil: Alltag: In den folgenden Fragen geht es darum wie stark Ihre Schulterproblematik Ihre Lebensweise in der letzten Woche beeinflusst hat.				X	
	4.15	Wie groß ist die Angst auf Ihre betroffene Schulter zu fallen?	NRS 0-10		X	
	4.16	Wie schwierig ist es für Sie, auf Grund Ihrer Schulterprobleme Ihre gewünschte Fitness beizubehalten?	NRS 0-10		X	
	4.17	Wie stark ist Ihr Freizeitvergnügen mit Familie und Freunden eingeschränkt?	NRS 0-10		X	
	4.18	Wie stark beeinträchtigt die Schulter Ihren Schlaf?	NRS 0-10		X	
	IV. Teil: Emotionen: In den folgenden Fragen geht es darum, wie Sie sich in der letzten Woche aufgrund ihrer Schulterproblematik gefühlt haben.				X	
	4.19	Wie bewusst ist Ihnen Ihre Schulterproblematik?	NRS 0-10		X	
	4.20	Wie besorgt sind Sie, dass sich ihre Schulter verschlechtern könnte?	NRS 0-10		X	
	4.21	Wie groß ist Ihre Frustration aufgrund ihrer Schulterproblematik?	NRS 0-10		X	
5. Subjective Shoulder Value (SSV)	5.1	Wie hoch ist der prozentuale Gesamtwert Ihrer Schulter, wenn eine völlig normale Schulter 100 % entspricht?	VAS 0% - 100%		X	
	5.2	Wie hoch ist der prozentuale Gesamtwert Ihrer Schulter in Bezug auf die Sportpraxis, wenn eine völlig normale Schulter 100% und eine nicht funktionierende Schulter 0% entspricht?	VAS 0% - 100%		X	
6. Clinical Information	Ein Instabilitätsevent definiert sich durch ein komplettes Ausrenken der Schulter welches entweder im Notfall reponiert wird <u>oder</u> sich spontan selbstständig wieder einrenkt <u>oder</u> eine Subluxation, wobei die Schulter plötzlich beinahe luxiert, jedoch nicht ganz ausrenkt. <u>Kein</u> Instabilitätsevent sind willkürliches Ausrenken oder willkürliches beinahe Ausrenken welches selbst spontan herbeigeführt werden kann.				X	
	6.1	Wie viele Instabilitätseignisse hatten Sie bereits?	1 = 1x		X	

		(d.h. komplettes ausrenken oder plötzliches beinahe ausrenken, siehe Definition oben)	2 = 2-5x 3 = mehr als 5x			
	6.2	Sind Sie schon einmal an der Schulter aufgrund Ihrer Instabilität operiert worden?	0 = Nein 1 = Ja		X	
	6.3	Wann sind Sie an der Schulter aufgrund Ihrer Instabilität operiert worden?	Datum		X	
	6.4	Welche Seite ist die betroffene/instabile Seite?	1 = rechts 2 = links 3 = beide		X	
	6.5	Haben Sie bereits eine Physiotherapie besucht oder Rehabilitation gemacht?	0 = Nein 1 = Ja		X	
7. Return to Sports Information	7.1	Haben Sie vor der Schulterproblematik regelmässig einen Sport gemacht?	0 = Nein 1 = Ja		X	
	7.2	Wie viele Stunden haben Sie vor der Schulterproblematik pro Woche Sport gemacht?	0 = kein Sport 1 = 1-2 Stunden 2 = 3-4 Stunden 3 = 5-10 Stunden 4 = mehr als 10 Stunden		X	
	7.3	Auf welchem Level haben Sie vor der Schulterproblematik Sport gemacht?	1 = Individueller Freizeitsport für mich 2 = Individueller Freizeitsport auch gegen andere 3 = Mannschaftssport ohne Spiele gegen andere Mannschaften 4 = Mannschaftssport mit Spielen gegen andere Mannschaften 5 = Semiprofessioneller Sport 6 = Professioneller Sport		X	
	7.4	In welchen Sport möchten Sie zurückkehren oder sind Sie zurückgekehrt? (falls sie ihre Sportart nicht finden wählen Sie "Andere")	List of Sports		X	
	7.5	Wie heisst die Sportart, in welche Sie zurückkehren möchten oder Sie zurückgekehrt sind?	Text		X	
	7.6	Beinhaltet ihr Sport typischerweise Überkopfaktivitäten?(wie z.B. beim Volleyball, Speerwurf, Quaterback, Fussballgoalie, ...)	0 = Nein 1 = Ja		X	
	7.7	Ist Ihr Sport ein Kontaktsport? (wie z.B. Fussball, Football, Judo, Turmspringen, ...)	0 = Nein 1 = Ja		X	
	7.8	Ist Ihr Sport ein Kontaktsport? (Fussball, Football, Judo, Turmspringen, ...)	0 = Nein 1 = Ja		X	

	7.9	In welchem Status bezüglich der Rückkehr in den Sport befinden Sie sich derzeit?	1 = Ich mache Training, Therapie oder Sport aber noch nicht in meinem Sport und auf einem tieferen Level. 2 = Ich trainiere und/oder spiele oder nehme an Wettkämpfen in meinem Sport teil, kann aber noch nicht dieselbe Leistung abrufen wie zuvor. 3 = Ich trainiere und/oder spiele in meinem Sport mit derselben oder besseren Leistung wie zuvor.		X	
	7.10	Sind Sie für Ihr Empfinden erfolgreich in Ihren Sport zurückgekehrt?	0 = Nein 1 = Ja		X	
8. Demographic Information	8.1	Wann sind Sie geboren?	Datum		X	
	8.2	Mit welchem Geschlecht identifizieren Sie sich?	1 = Weiblich 2 = Männlich 3 = Divers		X	
	8.3	Welche ist Ihre Muttersprache?	1 = Deutsch 2 = Englisch 3 = Französisch 4 = Italienisch 5 = Türkisch 6 = andere _____		X	
	8.4	Welche ist Ihre Muttersprache?	Text		X	
	8.5	Haben Sie noch Kommentare, Informationen etc?	Text		X	X

4.7 Withdrawal and discontinuation

The participation in the study is voluntary and all patients have the right to withdraw consent for participation in the study without prejudice. All data collected up to the time of withdrawal will be used in the analysis as appropriate. Should a patient withdraw consent, he or she will be further treated and followed-up according to routine practice in the Schulthess Klinik Zürich. No further project-specific examinations or questionnaires will be performed. Patients are withdrawn from the study, if between T1 and T2 another instability event or other physical or psychological pathology that interferes with the RTS progress occurs. This information is asked for in the beginning of the second round in the eCRF. Lost to follow-up is defined as the subject does not complete questionnaires or follow-up visits but has not “officially” withdrawn from the project. To consider a subject lost to follow-up, the PI should make all reasonable efforts to locate and establish communication with the subject. All attempts should be documented within the source documents, indicating date, time, method, and site personnel. Withdrawal has no positive or negative consequences for the patient. In such cases, the clinical data already collected can continue to be used for regulatory and scientific evaluations.

5 STATISTICS AND METHODOLOGY

5.1 Translation plan

The translation of the SIRSI and TSK-SI into a German follows the guideline of Beaton et al (2000) however little adjustments were made. The original SIRSI was translated into five German versions. Two by two researchers, one with background in occupational therapy and psychology (D.B.) and one with a background in physiotherapy (J.S.). One by a patient with a history of shoulder dislocations, conservative therapy, surgery and return to sports. One online translation by deepl.com (<https://www.deepl.com/translator>, accessed on 20.02.2024) and the available German version by the German insurance company (([Return-to-Competition Schulter: Shoulder Instability-Return to Sport after Injury \(SIRSI\)-Skala \(vbg.de\)](https://www.vbg.de), accessed 23.01.2024). The TSK-SI was translated into four German versions. Two by two researchers, one with background in sport science and data management (T.S.) and one with a background in physiotherapy (J.S.). One by the same patient described above and one again by deepl.com (<https://www.deepl.com/translator>, accessed on 29.05.2024) From these versions a consensus version for the SIRSI was developed by D.B. and J.S. and the TSK-SI by T.S. and J.S.. Then a backtranslation was done by an English native speaker. The resulting English version was compared to the original SIRSI and TSK-SI and the German version was adapted by the respective researchers. Another backtranslation was then done to check for successful adaptations. No further adjustments were made. The German version of the SIRSI was then named SIRSI-D and TSK-SI was named TSK-SI-D. The SIRSI-D and TSK-SI-D was pilot tested on 20 patients each, who attend to outpatient physiotherapy at the Schulthess Klinik. The SIRSI-D will be handed out on paper alongside with a brief feedback sheet. The sheets are returned to the PI and if decided useful by the researchers, the suggestions of the patients are incorporated into the final SIRSI-D or TSK-SI-D version that are used for the further validation process.

5.2 Statistical analysis plan

The reliability and validity of the German version of the Shoulder Instability-Return to Sport after Injury (SIRSI-D) and Tampa Scale of Kinesiophobia-Shoulder Instability (TSK-SI-D) score will be assessed through rigorous psychometric evaluation procedures. Reliability will be evaluated to ensure the consistency and stability of the questionnaire over time.

Internal consistency, which measures the extent to which items within the questionnaire are correlated with one another, will be assessed using Cronbach's alpha coefficient. Test-retest reliability will be examined by administering the questionnaire to participants on two different timepoints one week apart and calculating the correlation between their scores.

Validity will be assessed to determine the extent to which the questionnaire measures the intended constructs of shoulder instability and return to sport after injury.

Content validity will be established by ensuring that the items in the questionnaire adequately cover all relevant aspects of the constructs.

Construct validity will be evaluated through factor analysis to confirm the underlying factor structure of the questionnaire and assess its convergent and divergent validity with other related measures.

Criterion validity will be examined through concurrent validity by comparing the scores of the SIRSI-D and TSK-SI-D questionnaire with SSV and WOSI.

Overall, these psychometric evaluation procedures will ensure that the German version of the SIRSI and TSK-SI-D scores are both reliable and valid for assessing shoulder instability and return to sport after injury in a German-speaking population. All statistical analyses are conducted in R (R Core Team (2022)).

5.3 Handling of missing data

Missing Data is reduced by the "soft required function" in REDCap, where patients are reminded if a question is not filled in but proceeding is possible. The exception are the checks of the inclusion criteria which are mandatory to proceed. This ensures that patients do not drop out completely. In addition, patients will be contacted via mail via a researcher, if an item is missing. In the analysis missing items in the WOSI, TSK-SI-D and SIRSI-D will be imputed by the means, if missing at random and a sensitivity analysis is performed to ensure robustness. Other missing items, not in the WOSI TSK-SI-D or SIRSI-D, will be treated as such. If more than 15% of the sample have incomplete questionnaires even after email contact, the sampling is extended.

5.4 Statistical quality considerations

The statistical analysis plan will be preregistered at clinicaltrials.gov (<https://clinicaltrials.gov/>, accessed at 10.04.2024).

6 REGULATORY ASPECTS AND SAFETY

6.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki (World-Medical-Association, 2018), the principles of Good Clinical Practice, the Human Research Act (HRA) (Eidgenossenschaft, 2011) and the Human Research Ordinance (HRO) (Bundesrat, 2013) as well as other locally relevant regulations. The project leader acknowledges his responsibilities as both the project leader and the Sponsor.

6.2 (Serious) Adverse Events and notification of safety and protective measures

An Adverse Event (AE) is any untoward medical occurrence in a patient or a clinical investigation subject which does not necessarily have a causal relationship with the trial procedure. An AE can therefore be any unfavourable or unintended finding, symptom, or disease temporally associated with a trial procedure, whether or not related to it.

A Serious Adverse Event (SAE) (ClinO, Art. 63) is any untoward medical occurrence that
Results in death or is life-threatening,
Requires in-patient hospitalisation or prolongation of existing hospitalisation,
Results in persistent or significant disability or incapacity, or
Causes a congenital anomaly or birth defect

Both Investigator and Sponsor-Investigator make a causality assessment of the event to the trial intervention (see table below based on the terms given in ICH E2A guidelines). Any event assessed as possibly, probably or definitely related is classified as related to the trial intervention.

Relationship	Description
Definitely	Temporal relationship Improvement after dechallenge* Recurrence after rechallenge (or other proof of drug cause)
Probably	Temporal relationship Improvement after dechallenge No other cause evident
Possibly	Temporal relationship Other cause possible
Unlikely	Any assessable reaction that does not fulfil the above conditions
Not related	Causal relationship can be ruled out
*Improvement after dechallenge only taken into consideration, if applicable to reaction	

Both Investigator and Sponsor-Investigator make a severity assessment of the event as mild, moderate or severe. Mild means the complication is tolerable, moderate means it interferes with daily activities and severe means it renders daily activities impossible.

6.2.1 Reporting of SAEs (see ClinO, Art. 63)

All SAEs are documented and reported immediately (within a maximum of 24 hours) to the Sponsor-Investigator of the study.

If it cannot be excluded that the SAE occurring in Switzerland is attributable to the intervention under investigation, the Investigator reports it to the Ethics Committee via BASEC within 15 days.

Recurrent instability events (as defined above) are a common occurrence in treatment of shoulder surgery and are not considered as due to the intervention of this study (i.e. usage of a questionnaire).

6.2.2 Follow up of (Serious) Adverse Events

Any (S)AEs that occur and prolong over the termination of the study will be followed up via the treating surgeon according to the routine of the clinic. The research team will be in contact with this respective surgeon and evaluate, if the (S)AE interferes with the interpretability of the data

6.2.3 Notification of safety and protective measures (see ClinO, Art 62, b)

If immediate safety and protective measures have to be taken during the conduct of the study, the investigator notifies the Ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

6.3 (Periodic) safety reporting

An annual safety report (ASR) is submitted once a year to the local Ethics Committee by the Investigator (ClinO, Art. 43 Abs 1).

6.4 Radiation

No radiation exposure due to this study is expected.

6.5 Amendments

Substantial changes to the study setup and study organization, the protocol and relevant study documents are submitted to the Ethics Committee for approval before implementation. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior approval of the Ethics Committee. Such deviations shall be documented and reported to the Ethics Committee as soon as possible.

Substantial amendments are changes that affect the safety, health, rights and obligations of participants, changes in the protocol that affect study objective(s) or central research topic, changes of study site(s) or of study leader and sponsor (ClinO, Art. 29).

A list of all non-substantial amendments will be submitted once a year to the competent EC together with the ASR.

6.6 Notification and reporting upon completion, discontinuation or interruption of the study

If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay. The project leader is promptly notified (within 24 hours) if immediate safety and protective measures have to be taken during the conduct of the research project. The Ethics Committee will be notified via BASEC of these measures and of the circumstances necessitating them within 7 days.

The Sponsor-Investigator and any other competent authority may terminate the study prematurely according in case of ethical concerns, insufficient recruitment or when the safety of the participants is doubtful or at risk. Upon premature study termination or study interruption, the Ethics Committee is notified via BASEC within 15 days.

Upon project completion or discontinuation, the Ethics Committee is notified within 90 days. The TMF including the written signed consents are stored in the archives of the Schulthess Klinik Zürich, the project database is stored electronically within the REDCap database. The data will remain coded. The patient identification will be known only at the respective project site by authorized personnel who are bound to confidentiality by contract.

A final report is submitted to the Ethics Committee via BASEC within a year after completion or discontinuation of the study.

6.7 Insurance

Because this is Category A1 with minimal risk, there is no insurance requirement (Art. 12 HRO and insurance is through the clinic's liability).

7 FURTHER ASPECTS

7.1 Overall ethical considerations

The participation of patients is voluntary. Withdrawal is possible without justification at any time without prejudice for further routine treatment and follow-up. This project and related data analyses are conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements of the HFG and HFV. Patients have the right to know any information derived from participating to this project. In this project, we do not foresee any incidental findings that should not be communicated to the concerned patients. Upon agreement by a patient, medical information can be provided to the family doctor, or other treating physicians to ensure his/her well-being. This project complies with the regulatory requirements of the HRA and HRO. The prerequisite for carrying out the research project is the approval of the Cantonal Ethics Committee.

7.2 Risk-Benefit Assessment

Patients provide time effort of approximately 15 minutes and five minutes to complete two rounds of online questionnaires. Health-related risk is negligible. The Patient questionnaires may be perceived long by participants and address issues that could be embarrassing to respond to (e.g. anxiety, unpreparedness, inadequateness).

It is considered that these project-specific procedures provide only minimal risk and discomfort to the patients. There is no clinical risk identified for the participants associated with the data collection described in the protocol.

Confidentiality risk associated with non-anonymized individual data being published is kept to minimum by strict confidentiality rules. No personal individual data will be captured into the project database, except the patients' email address that will be exclusively used to send project questionnaire for electronic data capture. Email addresses will not be exported from the REDCap database and therefore remain protected from unauthorized access.

This study provides a questionnaire to measure psychological readiness to return to sport after shoulder instability and an analysis of its validity and reliability. There is currently no tool available for the German speaking population, hence this part of treatment is left to subjective interpretation or related measures like strength, range of motion or anamnesis. Once the SIRSI is culturally adapted to the German population meaning Switzerland, Germany and Austria, it will help clinicians and researcher to objectively estimate the ability to RTS. For patients this means a safer RTS and potentially reduces the risk of re-injury.

The subjects will not benefit directly/explicitly from the participation in this study.

7.3 Rationale for the inclusion of vulnerable participants

Not applicable. No vulnerable patients will be enrolled in this study.

8 QUALITY CONTROL AND DATA PROTECTION

8.1 Quality measures

The project team will ensure the completeness and consistency of the collected data. For more details, see section 7.2. For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions. All investigators are trained according to the good clinical practice. All patient informed consents will be verified and confirmed. The study TMF will be monitored to ensure completeness of study documentation according to GCP guidelines.

8.2 Data recording and source data

Source data used encompasses the email address which is stored within the clinic information system. All other information can be retrieved from the local instability register, where patients provided signed written consent for (BASEC: 2020-01091). The postal address to sent the informed consent for this study to, is asked for in the invitation email (see Appendix 1). The eCRF encompasses the source and collected data as described in table 2.

8.3 Electronic Data Capture system

Study data will be entered and stored in the REDCap web-based electronic data capture system (Harris et al., 2009; *REDCap web-based Electronic Data Capture system*, 2017) that is hosted on a dedicated server within the protected IT environment of the Schulthess Klinik. This is a cost-effective and user-friendly system that is used worldwide for clinical research. REDCap is designed to limit data entry errors using pop-up menus, pre-specified values where applicable, consistency checks, automatic entry checking for implausible values and non-allowance for closing relevant data fields without entry specifications. REDCap conforms with Good Clinical Practice guidelines providing required features for data protection and integrity e.g. using password-protected access and change tracking.

8.4 Data recording

For this study, questionnaires in the German language were developed to capture all variables described in this protocol and are filled out by the participant him- or herself. Patients will complete their questionnaire electronically after invitation by email.

8.5 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number. A participant identification list will be managed and stored by a designated project staff at Schulthess Klinik. It will be kept in a place (an electronic folder or paper-based form) only accessible to authorized staff. The project leader affirms and upholds the principle of the patients' right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the patients shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. Study data will be exported from the REDCap system into statistical software for statistical analyses. Exported files will not contain any patient personal data and be accessible only to authorized staff. Data transformations and analyses will be primarily

implemented using statistical software and fully documented within programming files. Variables required for the analyses are transformed or created after data transfer into Stata and saved in the final analysis dataset. This final dataset contains only pseudo-anonymous data. The IT Department of the Schulthess Klinik will perform systematic data backup to prevent data loss or misuse. This project does not collect any biological material.

8.6 Retention and destruction of project data

All materials pertaining to the study, including patient questionnaires, will be documented into a Trial Master File by the study coordinator, sorted and kept in closed archives at the teaching, research and development department at Schulthess Klinik.

All study data must be archived for a minimum of 10 years after termination or premature termination of the project.

9 FUNDING / PUBLICATION / DECLARATION OF INTEREST

Study costs are paid by the upper extremities research division of the teaching, development and research department at the Schulthess Klinik. No further funding is available.

9.1 Publication policy

The results of this project will be published in peer-reviewed medical journals, independent of the results. Data analyses will be performed upon clear formulation of clinical questions according to this study protocol.

The authorship is regulated according to the content of the publication and the guidelines of the Swiss Academies of Arts and Sciences.

9.2 Conflict of interest

No conflict of interest in terms of independence, intellectuality, finance and proprietary exist in this project.

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10 APPENDIX

10.1 Appendix 1: Invitation Email

Subject:

Rückkehr in den Sport nach Schulterinstabilität – Eine Umfrage der Schulthess Klinik

Mail:

Sehr geehrte/r Patient/in

Sie haben vor einiger Zeit eine Schulterverletzung erlitten und haben sich bei uns in der Schulthess Klinik vorgestellt und ggf. operieren lassen. Da sie schon der Aufnahme in unser Schulterinstabilitätsregister zugestimmt haben, kontaktieren wir Sie, da sie zusätzlich für eine kurze online Fragebogenstudie in Frage kommen.

Mit der Studie möchten wir zwei Fragebögen testen, wobei einer Ihre Bereitschaft beurteilt, wieder in den Sport einzusteigen und der andere eine eventuelle Angst vor Bewegung misst nachdem Ihre Schulter einmal ausgelenkt war. Bei einer Teilnahme würden sie zweimal einen 12-Fragen und zweimal einen 18-Fragen Fragebogen online zugeschickt bekommen. Bei dem ersten Mal werden diese mit einem weiteren 21-Fragen Fragebogen und ein paar Fragen zu Ihrer Person ergänzt. Der zeitliche Aufwand beträgt einmal 15 Minuten und einmal zehn Minuten.

Für Sie selbst entstehen keine Kosten, Ihre Daten werden verschlüsselt und streng vertraulich behandelt und die Behandlung wird durch die Ergebnisse der Studie in keiner Weise beeinflusst.

Falls Sie Interesse haben uns bei dieser Studie zu unterstützen Gelangen Sie mit folgendem Link zu dem ersten Fragebogenteil:

[\[survey-link\]](#)

Sollte der Link nicht funktionieren, können Sie diese Adresse in Ihren Browser kopieren:

[\[survey-url\]](#)

Wichtig: Ein Ausfüllen des Fragebogens, wird als eine Zustimmung zur Teilnahme an dieser Studie gewertet. Sie finden eine Zusammenfassung sowie detaillierte Studieninformationen im Anhang dieser Mail. Bei Fragen zögern Sie nicht uns zu kontaktieren.

Vielen Dank für Ihre Unterstützung und freundliche Grüsse

Jan Schätz



Jan Schätz

Research Assistant

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Lehre Forschung & Entwicklung

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