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
Prinicpal 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
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:

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.

Principal Investigator:

Site: *Schulthess Klinik Zürich, Lengghalde 2, 8008 Zürich*

Name: Dr. Asimina Lazaridou, PhD

Date: _____ Signature: _____

Sponsor:

Site: *Schulthess Klinik Zürich, Lengghalde 2, 8008 Zürich*

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GLOSSARY OF ABBREVATIONS

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

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

	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
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	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.
Study Duration and Schedule	Planned 01/07/2024 of First-Participant-In Planned 31/07/2025 of Last-Participant-Out
Investigator(s)	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 Jan Schätz, M.Sc. PT Research Assistant Teaching, Research & Development Lengghalde 2 8008 Zürich +41 44 385 7583 Jan.schaetz@kws.ch
Study Center(s)	Schulthess Klinik Zürich, Lengghalde 2, 8008 Zürich, Switzerland
Data privacy	Project data will be handled with uttermost 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. 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.
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.

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 Shoulderinstability 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 Gilbart 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?" (Gilbart & 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).
Ardern 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 (Ardern 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
1. Had an instability event within last year 2. Provided general consent for local shoulder instability register 3. Adult patients aged 18 or older	1. Are at least three months after surgery or instability event 2. Must endeavor to return to their sport 3. Have another physical or psychological disorder not related to shoulder instability compromising return to sports 4. Have a language barrier to complete the questionnaires in German 5. 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
```

```
     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. 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.

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), 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-Dwas 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 expose 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, *i*nsufficient 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

The Email contains German language, which is not accepted on clinicaltrials.gov therefore this part is deleted, and may be requested by the authors.