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German translation and cultural adaptation of the Patient Reported Impact of Spasticity Measure (PRISM) to measure the impact of spasticity after spinal cord injury on quality of life.

Submission date 28/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/11/2023	**Overall study status** Completed	
Last Edited 16/02/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Spasticity is a common issue in 60-80% of people with spinal cord injuries. It can be a big challenge, affecting daily activities. Interestingly, some patients find spasticity helpful for tasks like maintaining balance during transfers.

To understand how spasticity affects the quality of life, we use patient-reported outcome measures (PROMs). These help us evaluate the impact and effectiveness of treatments. An expert group recommends two PROMs for measuring quality of life in people with spasticity after a spinal cord injury: the Patient Reported Impact of Spasticity Measure (PRISM) and the Spinal Cord Injury - Spasticity Evaluation Tool (SCI-SET). These tools have been carefully chosen and are backed by solid research.

SCI-SET has been translated into German. The PRISM is in the process of being translated. What's great about the PRISM is that it can be used not only for spinal cord injuries but also for other conditions like multiple sclerosis.

The PRISM is easy to use, takes about 10 minutes, and is free. We need it in German to understand how spasticity affects patients' lives and evaluate treatments better. We follow international guidelines for the translation and cultural adaptation. This study aims to make sure the German version is clear and reliable, with input from patients. This version will help assess spasticity interventions and their effects in daily life for German-speaking individuals.

Who can participate?
Patients with spinal cord injuries in the AUVA rehabilitation centers Weißer Hof and Tobelbad (Austria)

What does the study involve?
The translation process includes a personal comprehensibility test. The patients receive the pre-final version in printed form and fill it out. In the course of a semi-structured interview, they are asked about comprehensibility in order to find out which terms might be problematic. The distribution of the answers is examined for missing items.

What are the possible benefits and risks of participating?
It is not expected that the study participants will derive any personal health benefit from their participation, but they can contribute to the further development of a standardized measurement procedure and further on to the improvement of the quality of care. After completion of the German version of the PRISM, the patients' view of the impact of spasticity on quality of life can also be recorded in German-speaking countries. This will allow to better investigate the effectiveness of interventions and to adapt the selection of interventions for spasticity reduction. Subsequent patients with the same disease will benefit in terms of goal-oriented physiotherapeutic treatment.
No risks for the study participants are to be expected. However, it must be taken into account that the content of the questionnaire confronts the study participants with the limitations in daily life due to the spinal cord injury.

Where is the study run from?
Danube University Krems (Austria)

When is the study starting and how long is it expected to run for?
May 2023 to August 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Anja Largler, anja.largler@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number
LA 41

Study information

Scientific Title
Semi-structured interviews with patients with spinal cord injury to test the comprehensibility of the PRISM questionnaire.

Study objectives
The aim of this study is to provide an authorized, German-language version of the PATIENT REPORTED IMPACT OF SPASTICITY MEASURE (PRISM).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 10/01/2024, Ethics commitee for the hospitals of the AUVA (Wienerbergstraße 11, Wien, 1100, Austria; +43 59320805; ethikkommission@auva.at), ref: 03/2024

2. approved 12/12/2023, Ethics Commission of the province of Lower Austria (Landhausplatz 1, Haus 15B, St. Pölten, 3109, Austria; +43 2742900513367; post.ethikkommission@noel.gv.at), ref: GS1-EK-4/880-2023

Study design
Multicenter qualitative study

Primary study design
Observational

Study type(s)
Quality of life, Screening

Health condition(s) or problem(s) studied
Measuring the impact of spasticity after spinal cord Injury on quality of life.

Interventions
After obtaining informed consent, the pre-final version of the PRISM questionnaire in German is presented to the patients for completion and a semi-structured interview is conducted to assess the comprehensibility of the questionnaire items. The distribution of responses will be examined for missing items. The study participants will incur a one-time additional time expenditure of approximately 1 hour as a result of the measure.

Intervention Type
Other

Primary outcome(s)

Qualitative semi-structured interviews to test the comprehensibility of the translated version of the "Patient reported impact of spasticity measure" for measuring the impact of spasticity after spinal cord injury on quality of life.
Qualitative analysis of the interviews: Content analysis according to Mayring

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Patients with clinically confirmed spinal cord injury of traumatic, nontraumatic, or congenital origin.
2. Patients from 3 months after the spinal cord lesion onwards.
3. Patients with existing spasticity symptoms
4. Age ≥ 18 years
5. Good knowledge of written and spoken German
6. Signed voluntary informed consent for study participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
Decreased cognitive and language abilities

Date of first enrolment
01/03/2024

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
Austria

Study participating centre
AUVA Rehabilitationszentrum Weißer Hof
Holzgasse 350
Klosterneuburg
Austria
3400

Study participating centre
AUVA Rehabilitationszentrum Tobelbad
Dr.-Georg-Neubauer-Straße 6
8144
Austria
8144

Sponsor information

Organisation
Universität für Weiterbildung Krems

ROR
https://ror.org/03ef4a036

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Anja Largler, anja.largler@gmail.com

IPD sharing plan summary

Available on request