

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/02/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 committee 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

Secondary study design

Qualitative study

Study setting(s)

Other

Study type(s)

Quality of life, Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

18/05/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

30

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

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Sponsor information**Organisation**

Universität für Weiterbildung Krems

Sponsor details

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Sponsor type
Other

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<https://www.donau-uni.ac.at>

ROR
<https://ror.org/03ef4a036>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/03/2026

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