Charité | Campus Benjamin Franklin | Hindenburgdamm 30 | 12200 Berlin
Department of Psychosomatic Medicine | Prof. Dr. M. Rose

Study Title: „Narcolepsy Patient Assessment Set (NaPAS): Development of a standardized outcome set for patients with narcolepsy for the purpose of implementation in routine care"

Principal Investigator: Dr. Gregor Liegl

Study Information (Delphi Study)

Invitation and Declaration of Voluntariness

Dear participant,
You are invited to participate in a study aimed at developing a core outcome set for narcolepsy. Before you decide for or against participation, we would like to inform you about the study's objectives and procedures. The study was initiated by the H2O Pan European Observatory (PEO, a network that ensures the standardization of patient-reported health parameters and their accessibility for research. The PEO has commissioned the Center for Patient-Centered Outcomes Research (CPCOR) at Charité – University Hospital Berlin to conduct the study.

Your participation is voluntary. You can only be included in the study if you give your consent. If you participate in the study, you agree to the data processing described below and to the data protection declarations. If you do not wish to participate, you will not suffer any disadvantages as a result. You have the right to withdraw your consent to participate or to the further processing of your data at any time and to terminate your participation in the study.

Background and Purpose of the Study

The aim of the study is to identify relevant health parameters ("outcomes") for narcolepsy. This will be done through a consensus process with multiple stakeholders. The health parameters can be self-reported by people with narcolepsy – for example, symptoms or aspects of health-related quality of life – or they can be clinical parameters that can be measured, for instance, through laboratory values. The outcomes can be disease-specific or generic – meaning they do not have to be directly related to narcolepsy and may also apply to other chronic conditions.

The Core Outcome Set is being developed through a consensus process as part of a Delphi study involving all relevant interest groups, including patients, healthcare professionals, scientists, HTA agencies, and industry representatives. The study is part of a larger public-private partnership in the EU called the Health Outcomes Observatory (H2O) (https://health-outcomes-observatory.eu/). H2O's mission is to enable stakeholders to collect standardized health outcomes data and use it to improve treatment and care. The founding and participating countries include Austria, Spain, and the Netherlands. However, representatives from other countries may also be included.

We are interested in your opinion on which patient-reported and clinical outcomes are most important for people with narcolepsy and should be captured in treatment settings.

Study Procedure and Duration

You were recruited through international clinical and research experts or patient representatives who nominated participants from their professional networks. The Delphi study consists of two surveys, which are to be completed approximately four weeks apart. If you are interested in participating, please contact the study coordinator by email (claudia.zensen@charite.de). You will then receive an email with the informed consent form. If you agree with the data processing procedures described in this study information, please return the signed consent form by email. Afterwards, we will send you the link to the survey software. By clicking on the link, you will be redirected to the REDCap website. REDCap is a user-friendly and secure web application that is frequently used at the Charité for surveys and data collection in studies.

The survey takes about 10 minutes to complete. Please complete the questionnaire within two weeks. If you haven't participated after one week, you will receive a reminder. After approximately four weeks, you will be invited to the second round of the survey.

You will be asked to rate the relevance of each health parameter on a 9-point Likert scale ("strongly disagree" to "strongly agree"). In the second round, you will receive feedback comparing your rating with the average of your stakeholder group. This iterative process is the core of the Delphi study and is intended to harmonize the ratings of the outcomes, thereby achieving consensus among the participants, so that only the most relevant parameters are included in the final core outcome set.

To obtain meaningful results during the evaluation, some additional information about you will be collected, such as your age and the duration of the illness.

Potential Risks

There are generally no risks expected from participating in the study. However, you may find answering the questions mentally tiring. You may withdraw from the study at any time without any disadvantage to you.

Potential Benefits

Patients may benefit from reflecting on their illness as part of the survey.

Costs and Compensation

Participation in the study is free of charge. Participants who take part in both rounds of the study will receive a compensation of €50.

Data Protection

The handling of your data is carried out in accordance with the provisions of the EU General Data Protection Regulation (EU GDPR) and the Berlin State Data Protection Act. Your data will be treated confidentially at all times. The legal basis for data processing is your voluntary consent (Art. 6(1)(a), Art. 9(2)(a) GDPR), which you provide by signing the informed consent form.

By participating, you consent to the study leader and his staff collecting and processing your personal data for the purpose of the aforementioned study (legal basis according to Art. 6(1)(a),

Art. 9(2)(a) GDPR). Personal data include, for example, your name or other personal information collected in a purpose-bound manner during your participation in the study.

The study leader is the data controller within the meaning of the EU General Data Protection Regulation. He will use your personal data for the administration and conduct of the study, as well as for research purposes. The research data will be assigned a number, a so-called pseudonym. A separate list linking your identifying data to the pseudonym will be maintained. Only the study leadership and a few specially authorized persons have access to this list. Re-identification will only occur if necessary, for example, if you wish to withdraw from the study.

The study dataset collected from the survey will be stored at Charité for 10 years and will then be deleted without exception. The evaluation and publication of project results will be conducted exclusively in anonymized form, ensuring that no connection to your person can be made.

You have the right to access all personal data about you held by the study leader, including the right to receive a free copy. You also have the right to request the correction of inaccurate personal data. Furthermore, you have the right to withdraw your consent to data processing at any time; in such a case, you may request the deletion of your personal data. In addition, you have the right to restrict the processing of your personal data, especially if the processing is unlawful and you prefer restriction instead of deletion, or while it is disputed whether the processing of personal data is lawful (Art. 18 GDPR). To exercise these rights, please contact the study leader.

You have the right to lodge a complaint with the data protection supervisory authority: Berlin Commissioner for Data Protection and Freedom of Information (Alt-Moabit 59-61, 10555 Berlin, Phone: +49 30 13889-0, Email: mailbox@datenschutz-berlin.de).

You may object to the further processing of your data collected within the scope of the aforementioned study at any time and request their deletion or destruction.

Note on risks associated with data processing: As with any collection, storage, use, and transmission of data, there are confidentiality risks (e.g., the possibility of identifying the affected person) that cannot be completely excluded. We assure you that we will do everything possible according to the state of the art to protect your privacy. Medical risks are not associated with data processing.

Insurance

No special insurance coverage has been arranged for participants. Charité staff are covered under the institution’s liability insurance.

Contact Information

For questions, to withdraw your consent, or for other concerns, contact:

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For data protection concerns, contact:

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