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Standardizing Prurigo Control Assessment Globally: Linguistic Validation and Cross-cultural Adaptation of Prurigo Control Test in 18 Languages

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Chronic prurigo (CPG), including prurigo nodularis (PN), is a neuroimmune-inflammatory skin condition characterized by persistent itching and fibrotic lesions. PN commonly affects older adults (>55 years) and imposes substantial disease burden, necessitating effective disease control. Prurigo Control Test (PCT) is the first validated, patient-reported, disease control assessment test for PN/CPG. To ensure broad accessibility and utility, cultural and linguistic adaptation of PCT is essential. We present the first comprehensive translation initiative of PCT into 18 widely spoken languages, beyond its original German and English versions: Arabic/Chinese (Simplified)/Chinese (Traditional)/Czech/Danish/Dutch/Finnish/French/Hebrew/Icelandic/Italian/Japanese/Korean/Norwegian/Portuguese/Spanish/Swedish/Turkish.

We followed best translation practices recommended by ISPOR, EMA and FDA – conceptual analysis, forward/backward translation, author review, cognitive interviews, proofreading and finalization. The availability of PCT in multiple languages facilitates its global applicability and empowers physicians/caregivers/patients to assess the PN/CPG control using PCT in their preferred language, thereby enhancing implementation of this test across diverse clinical and cultural settings. The goal of translating this academically developed test while ensuring broader demographic representation (ages 18–80, diverse educational and occupational backgrounds) is to facilitate meaningful conversations between physicians and patients and optimize treatment decisions while transcending language barriers. To our knowledge, PCT is the first disease control assessment test specifically designed for PN/CPG to undergo such extensive linguistic adaptation, contributing to the advancement of global dermatological assessment.

Key words: linguistic validation; patient reported outcome; prurigo; Prurigo Control Test; translation.

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SIGNIFICANCE

Prurigo nodularis/chronic prurigo is a neuroimmune skin disease marked by intense itching and nodular lesions predominantly affecting older adults. The Prurigo Control Test is the first validated, patient-reported test for assessing Prurigo nodularis/chronic prurigo control. To ensure accessibility across diverse populations, we translated Prurigo Control Test into 18 widely spoken languages. The multilingual availability of Prurigo Control Test will enable physicians/patients to use the test confidently in their preferred language, fostering clear communication and informed treatment decisions in diverse clinical and cultural settings. Standardized use of the Prurigo Control Test across cultures will support reliable data collection with enhanced cross-cultural comparability.

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Chronic prurigo, including prurigo nodularis, is a chronic, neuroimmune-mediated, inflammatory skin disease characterized by intense pruritus (lasting >6 weeks), prolonged scratching and pruriginous lesions including papules and/or nodules and/or plaques (1–3). This difficult-to-treat disease can occur in all ages, with the highest prevalence observed among those aged 50–60 years (4, 5). It is associated with intense frequent itching and burning sensation involving the papulonodular lesions, and the internodular skin, predominantly affecting the upper and lower limbs, trunk, and back – especially where scratching is accessible (1, 6).

Poorly controlled PN/CPG significantly diminishes patient quality of life (QoL). Individuals with PN/CPG are more likely to develop other dermatological conditions, psychiatric, cardiovascular and renal disorders, and systemic diseases including diabetes (5–7). Greater disease severity drives increased burden and decreased treatment satisfaction and patient QoL (7–9). Patients with PN/CPG are reported to have the highest itch burden among chronic inflammatory skin diseases (10) and incur a higher degree of

healthcare utilization, with a preference for dermatology clinics over primary care among patients (6). Until 2022, there were no approved biological therapies for PN/CPG (11, 12). The treatment guidelines, therefore, recommend a wide range of therapies based on limited therapeutic evidence. A multimodal approach is generally employed, including strategies to control pruritus, treat concomitant diseases and manage pruriginous lesions (3). To date, there is no consensus on a treat-to-target approach for patients with PN/CPG; and until recently, no patient reported outcome (PRO) to assess disease control.

Assessment tools for PN/CPG are sparingly utilized with limited integration into clinical practice. Recently, the Worst Itch Numeric Rating Scale (13) and the Sleep Disturbance Numerical Rating Scale have been validated for patients with PN/CPG (14). The Investigator Global Assessment score (15) and the Prurigo Activity and Severity (PAS) score (16) have been validated for measuring lesion improvements, whereas the Dermatology Life Quality Index (DLQI) has been validated for assessing patient QoL. The psychometric validation of these instruments was done using the PRIME and PRIME-2 clinical trials (17). Other tools, such as the Generalized Anxiety Disorder-7 and the Patient Health Questionnaire-9, have been used to evaluate the burden and impact of psychosocial comorbidities but are not validated for PN/CPG (18, 19). None of these tools, however, evaluate PN/CPG control.

Disease control is an important treatment goal in chronic inflammatory diseases, in order to avoid disease progression and a cumulative diminishing QoL. Due to lack of standardized diagnostic and therapeutic guidelines, as well as high disease burden, disease control in PN/CPG is often compromised (3, 20). Prioritizing patients' disease control by addressing their needs, perceptions and concerns is crucial to determine whether the current treatments for PN/CPG are adequate, or further treatment modifications are required to reduce burden and optimize outcomes (21, 22). Notably, control tests/tools are established for atopic dermatitis (Atopic Dermatitis Control Test) (23), chronic spontaneous urticaria (Urticaria Control Test) (24) and asthma (Asthma Control Test) (25). Therefore, monitoring and ensuring disease control should be considered an important treatment goal in PN/CPG as well.

Prurigo control test

The PCT (Appendix S1) is the first PRO-based test specifically designed to evaluate PN/CPG control from patients' perspectives (21). It is a validated, retrospective and quantifiable test that allows comprehensive evaluation and multidimensional monitoring of disease control (21). The PCT is an independent, academically developed assessment tool, created through collaboration between Charité - Universitätsmedizin Berlin and Münster University Hospital, with its development conducted without any commercial interest or involvement.

The test consists of 5 concise questions, each scored on a 5-point scale ranging from 0 to 4, resulting in a maximum total score of 20 points. Patients are required to answer all 5 questions by selecting the most appropriate answer based on a 2-week recall period. The cut-off value is set at 10 points, which distinguishes between patients with poorly controlled disease (≤9) and well-controlled disease (≥10).

Development of PCT

The PCT was developed using a 3-step process: item generation, reduction and validation. In the generation phase, 19 patients with PN/CPG were interviewed about their disease experience, QoL impact, symptoms, daily activities and treatment effects. Along with literature review and expert input, an initial list of 69 potential items was created. During the item reduction step, based on relevance, frequency and importance of the items as rated by 65 patients, the list was narrowed to 5 items based on impact scores, floor/ceiling effects, missing data and content validity. Finally, a validation survey was performed on 95 patients across PN/CPG subtypes. For further details on the development of PCT, please refer to Metz M et al. (21).

Need for translation and validation of PCT in different languages. It is important to apply cultural tailoring to PCT in clinical and research settings to ensure that all PN/CPG patients, caregivers and physicians, independent of diverse linguistic and cultural backgrounds, can understand and confidently use this test to assess the disease control. Therefore, it is crucial to translate and validate PCT in different languages to allow patients to better understand the test and comprehend its questions as intended. Moreover, this will ensure the test's comparability across various countries, and the data collected from the test will be reliable, maintaining linguistic equivalence and cultural appropriateness.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommends standards for translating PRO measures (26). Additionally, both the United States Food and Drug Administration (USFDA) and European Medicines Agency (EMA) emphasize the importance of evaluating the translation process of PRO measures to ensure the test's content validity across all languages (27, 28). Although there is no "gold standard" for the linguistic validation of PRO measures (29), a generally accepted step-by-step process has been established to translate and validate PRO measures, utilizing the best practices

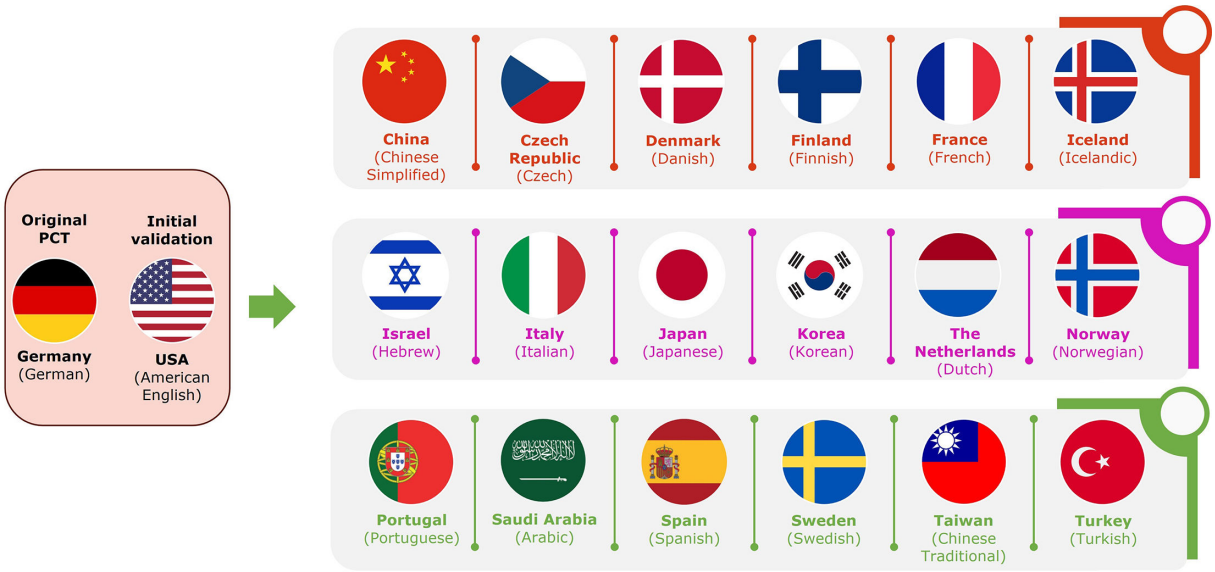

Fig. 1. Prurigo Control Test translation languages.

recommended by these organizations, primarily ISPOR (26, 30).

We looked at validating the linguistic translation of PCT to several languages that would benefit from a local linguistic translation. Eighteen different languages were identified to represent key global and widely spoken languages, with the objective to ensure that the PCT is assessed as equivalent in all selected languages, allowing adaptation of this test for local roll-out in various countries; henceforth, demonstrating its robustness and cross-cultural applicability.

Translation and linguistic validation of PCT into 18 different languages. PCT was originally developed in the German language and was subsequently translated into US American English. For the English translation, 2 different German to English translations were developed, and both translations were reviewed and edited by a US PN expert. A back-translation into the German language was performed to ensure that the translation was consistent with the original test without any misinterpretation of the concepts. The test was linguistically validated through cognitive interviews with 7 US patients with PN/CPG at Johns Hopkins University, Baltimore, MD, USA (21).

Followed by its US-American English translation, PCT was translated into 18 different languages (**Fig. 1**) following a comprehensive methodology (**Fig. 2**). The English version of PCT was used as the source test, and further linguistic validation process was performed in the target country by ICON Clinical Research Limited. The step-by-step linguistic validation process of the PCT is as follows (31).

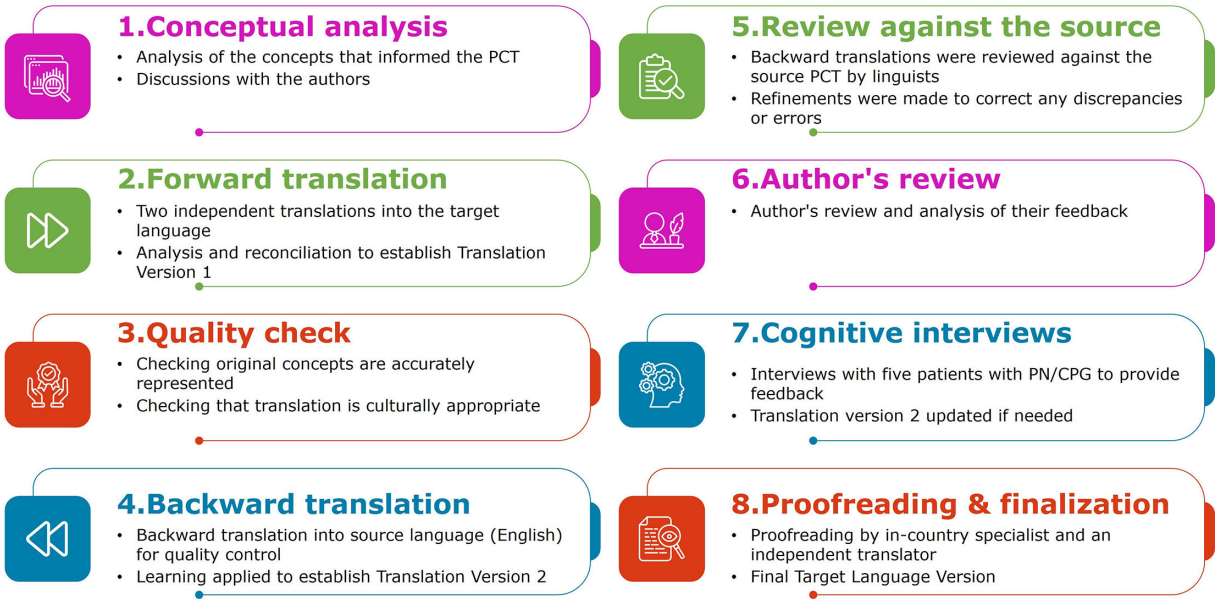

Fig. 2. Methodology for linguistic validation of Prurigo Control Test (PCT).

Conceptual analysis: The instructions and items included in the source PCT (English version) were analysed carefully to clarify the meaning, intent and precise definition of each concept. This analysis was performed to guide the development of translations that convey the intended interpretation of concepts in all languages. The results were discussed and approved by the authors.

Forward translations: Two independent translators, who were native speakers of the target language and blinded to one-another, translated the test into the target language. The in-country consultant analysed and reconciled both versions to generate a single Translation Version 1. A report was prepared summarizing any concerns or issues with the translation, along with the solutions applied to resolve those issues. Translation Version 1 was subjected to quality control to ensure that the original concept was accurately rendered in the translation. This version was checked for its cultural appropriateness.

Backward translation and review against source PCT: A "backward" translation of Translation Version 1 into the source language was generated by a bilingual translator who was a native English speaker and could also speak the target language. The backward translation was compared and analysed against the original test by the in-country consultant to identify any discrepancies in the rendering of concepts, and to ensure that the translation was true to the original test. A Translation Version 2 was established after quality check.

Formatting update and Author review: The existing translation was re-formatted to reflect the required format. The consultant adjusted the wording of the items, if needed, and gave English equivalents of the changes made. The authors reviewed and analysed the Translation Version 2 to confirm the domain specific terminology.

Cognitive interviews: In-depth individual interviews were conducted with 5 anonymous PN patients from the selected countries (Iceland, *n*=3), who were native speakers of the target language, to ascertain their understanding, clarity and acceptability of Translated Version 2. Patients were aged 18–80 years, with approximately 56% of them being female. The patients came from diverse educational backgrounds and held various occupations (**Figs 3 and 4**). Each respondent was asked to complete a copy of the questionnaire and was interrogated with a series of open-ended probing questions about each instruction, question, keyword and response option to assess whether the translation was understood clearly and as intended in the source. The participants commented on their understanding of each item and offered suggestions for better adaptation of problematic concepts. The consultant documented

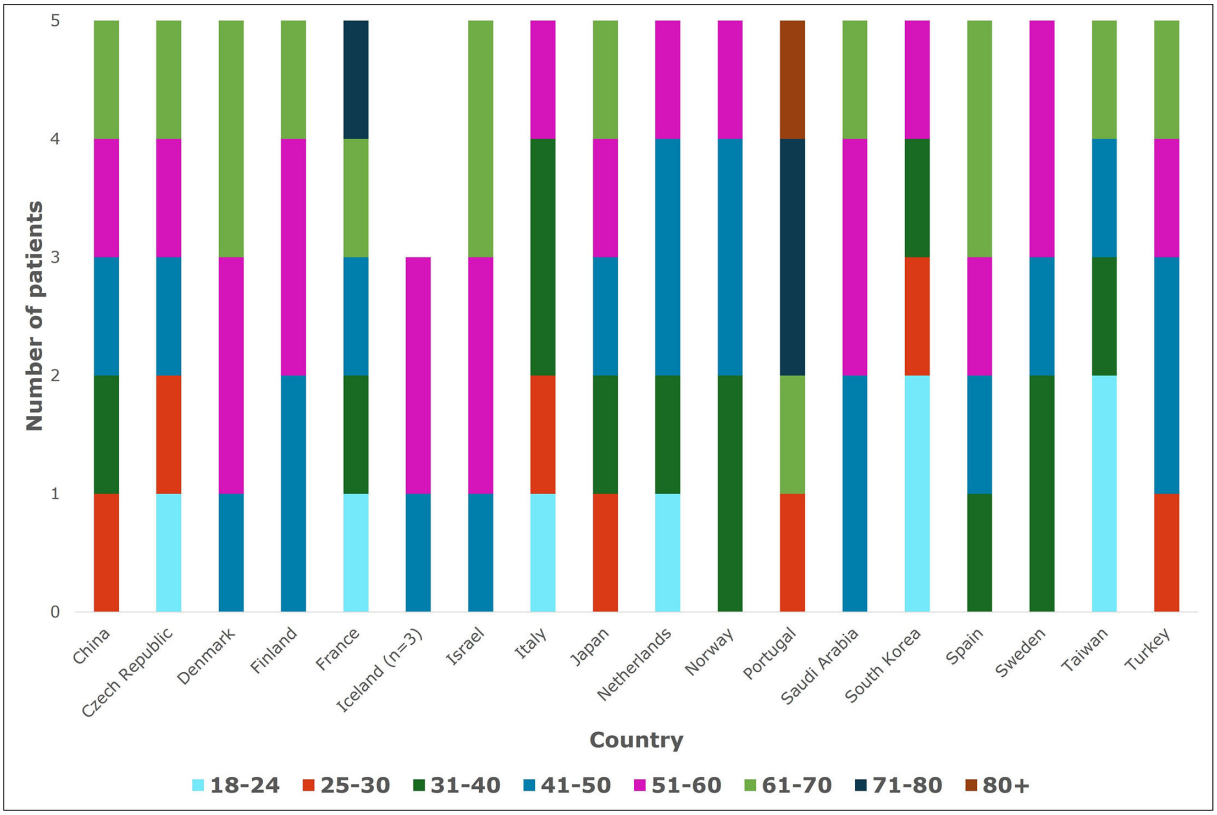

Fig. 3. Country-wise age distribution of patients who participated in cognitive interviews. *N*=5 unless otherwise mentioned.

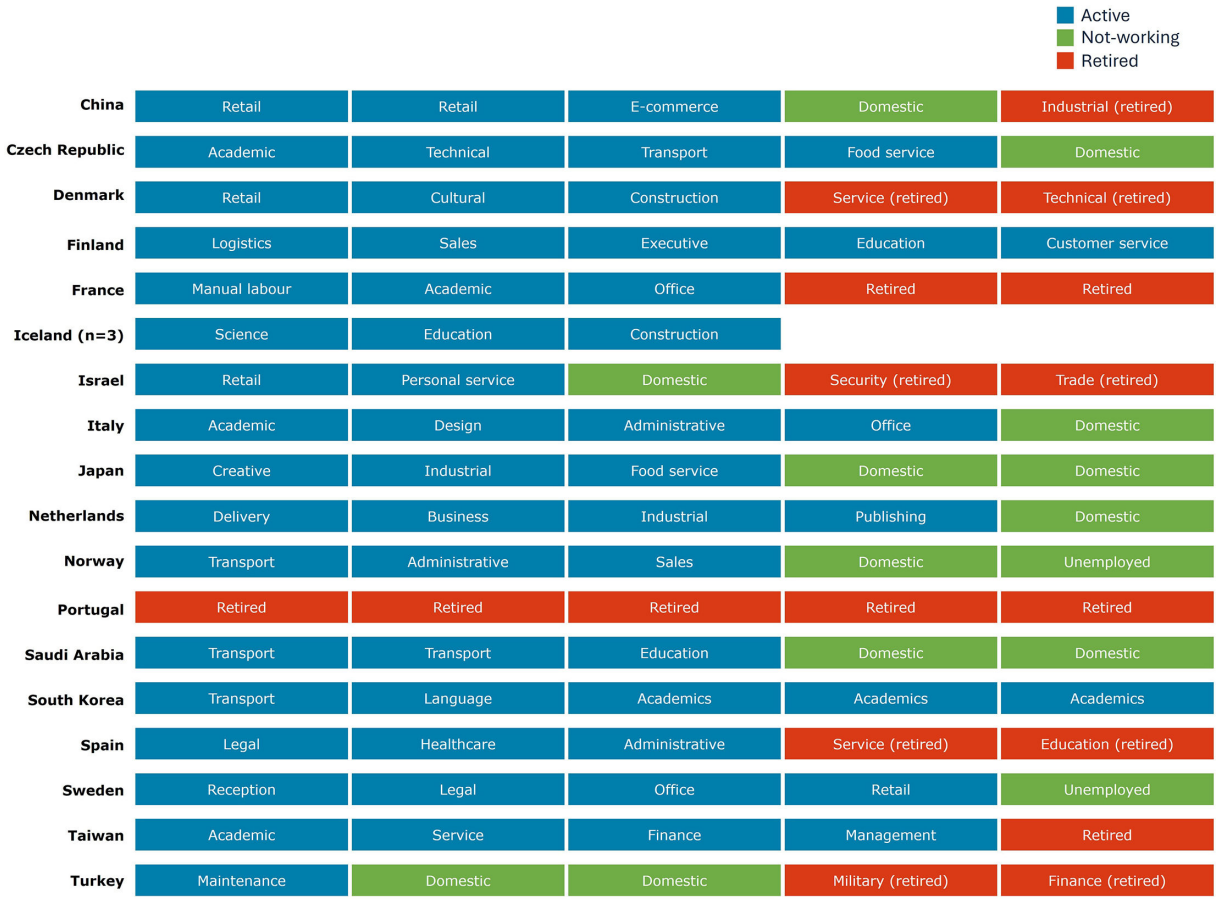

Fig. 4. Country-wise occupational profiles of patients who participated in cognitive interviews. *N*=5 unless otherwise mentioned.

and analysed patients' responses and feedback. After a discussion with authors, the translation was updated as required.

Proofreading and finalization: The translation was finally proofread by an independent translator and the in-country consultant for concept, formatting and typographical or grammatical errors. Modifications were suggested, if any, and Final Target Language Version was established.

Our translation process is completely traceable, with documentation that justifies the decisions made for every word choice in the translated version. During the translation process, we observed that there can be slight differences in the preferred terminology for the same word in different languages. In the Instructions section of the original PCT, the word "itching disease" was used; however, it was translated as "itchy skin condition" in Icelandic, "pruritus" in Chinese (traditional) and Hebrew, and "prurigo" in Dutch. For the first item, the word "skin lesions" was changed to "skin symptoms" in Chinese (traditional) and South Korean; "symptoms" in Japanese; and "afflicted spot on skin" in Czech. For QoL evaluation in the fourth item, "impaired" was translated as "harmed" in Hebrew and Portuguese, "reduced" in Spanish and "decrease" in Turkish. For the fifth item, most backtranslations preferred the term "treatment" over "therapy." The response items were also adjusted, such as in Chinese, where "very severe, severe, somewhat, a little, no skin lesions" became "very severe, severe, moderate, mild, no symptoms." Additionally, date formats and verb tenses were also modified to fit the local language context.

DISCUSSION

PCT is the first PRO measure that provides a real-time evaluation of PN/CPG control. Patients with PN/CPG were intricately involved in the development of this test, which allowed patients to play a crucial part in management of their condition, and thereby enhancing the test's relevance (21). Due to the global prevalence of PN/CPG (32–35), the translation and linguistic validation of this test, including patients from different ages, demographics and cultures, represents a significant advancement in PN/CPG assessment across diverse linguistic and cultural contexts.

A "meaningful translation" ensures that the translation is conceptually equivalent to the original text and culturally and linguistically suitable for the target

country, enabling effective data pooling and comparison (31, 36, 37). The complexity of translating concepts and symptoms into multiple languages requires iterative testing and refinement of the translated PRO measures. Poorly translated instruments can lead to interpatient variability due to patients' poor understanding of the test, thereby jeopardizing the validity and true meaning of the data (26).

In our study, we aimed to adhere to the best practices for translational assessment of PRO measures (26) and followed a structured process including conceptual analysis, forward translation, backward translation, formatting, cognitive interviews and proofreading. We used appropriate terminologies and definitions, and clearly identified concepts involved in PCT during the conceptual analysis stage. Relevant individuals, such as developers, project managers, translators, in-country consultants and PN/CPG patients, were involved at every stage of the translation process as required. The review criteria focused on cultural relevance, semantic accuracy and syntactic correctness to ensure clarity, readability and coherence in the translated items. Consequently, the translations reflected the original measurement's intent, were relevant to the target country and were accepted by the end-users.

The linguistically validated translations of PCT into all the aforementioned 18 languages are available in the Appendix S1. This paper will serve as an essential comprehensive resource for dermatologists and healthcare providers treating diverse patient populations with PN/CPG, who are encouraged to access and download these validated translations of the PCT and practice standardized disease control assessment regardless of language barriers.

Limitations

There are a few concerns and limitations related to translated versions of the PRO measures. It is important to use nontechnical language and ensure cultural relevance in PRO measures so the local population could relate to the questionnaire; however, maintaining concept validity and integrity in this process can be challenging at times (38). The subjective expression of outcome variables presents additional challenges due to differences in linguistic preferences (39). PRO measures usually assess multiple symptoms and/or experiences and their associated levels/gradations, which may not provide a clear distinction between choices. Further translating these concepts may even amplify this ambiguity and patients may not necessarily be able to quantify/grade their symptoms as intended (30). At times, physicians may not agree with the translation and gravitate to the original technical terms to ensure concept accuracy; notably, however, our objective for translation was to make it understandable for patients. The patient's experience with PCT is collected biweekly; while this recall period is intended to average out daily variations, the potential for recall bias exists (27, 40). Limited number of patients in the cognitive interviews – 5 patients from all countries and 3 patients from Iceland (less patients from Iceland due to recruitment difficulties) – may not fully capture the diversity within each linguistic group. Finally, the translations were carried out in only one identified dialect per language; however, variations in the preferred terminology and style may exist even within the same language.

Conclusion

The linguistic validation of the PCT produced a reliable, valid and culturally sensitive test for assessing PN/CPG control across 20 different languages, including German and English. This will enable the local roll-out of the test in various countries, ensuring multilingual harmonization, and comprehensive and comparable data collection globally. The PCT will support better physician–patient shared decision-making and informed treatment decisions to optimize patient outcomes. Looking ahead, integrating the PCT into electronic health records and digital health platforms could streamline the disease control assessment through improved patient engagement, enhancing its accessibility and utility in clinical practice.

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Author's contribution: All the authors interpreted the data and/or reviewed the manuscript. MM, KW, DB, and SW designed the study, with SW supporting the finalization of the manuscript outline. All authors approved the final manuscript.

Data availability: The datasets generated during and/or analyzed during the study are available from the corresponding author on reasonable request.

Conflict of interest: MM: AbbVie, Advanz, ALK-Abello, Allegria, Almirall, Amgen, Argenx, AstraZeneca, Astria, Attovia, Berlin-Chemie, Celldex, Celltrion, DeepApple, Escient, Ga2len, Galderma, GSK, Incyte, Jasper, Lilly, Novartis, Pfizer, Pharvaris, Regeneron, Sanofi, Santa Ana Bio, Septerna, Teva, ThirdHarmonicBio, Vifor – personal fees outside the submitted work. KW: Dr. med. Otto Eppenauer und Lieselotte Gutzeit-Stiftung – grants; Moxie – personal fees outside the submitted work. SST: Celldex Therapeutics, Clexio Biosciences, Dermasence, Galderma, GSK, Incyte, Kiniksa Pharmaceuticals, Menlo Therapeutics, Novartis, Sanofi, Trevi Therapeutics – investigator; AbbVie, Almirall, Beiersdorf, Bellus Health, BenevolentAI, Bionorica, Bristol Myers Squibb,

Cara Therapeutics, Clexio Biosciences, DS Biopharma, Eli Lilly, Escient Pharmaceuticals, Galderma, Incyte, Integrity CE, Grünenthal, Kiniksa Pharmaceuticals, Klirna Biotech, Menlo Therapeutics, Pfizer, Professor Paul Gerson Unna Academy, Sanofi, Touch IME, Trevi Therapeutics, Vanda Pharmaceuticals, Vifor Pharma, WebMD – consultant/advisory board; AbbVie, Almirall, Beiersdorf, Bristol Myers Squibb, Eli Lilly, FOMF, Galderma, LEO Pharma, MEDahead, Menlo Therapeutics, Novartis, Omnicuris, Pfizer, Pierre Fabre, Professor Paul Gerson Unna Academy, Sanofi, UCB, Vifor Pharma – speaker. AN, DB, SW: Sanofi – employees, may hold stock and/or stock options in the company.

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