

Beyond just words: Ensuring cultural appropriateness in Patient-Reported Outcomes (PROs) *A design protocol*



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Introduction

Giving voice to patients, strengthens research, by bringing healthcare delivery closer to patient's needs. The introduction of patient-reported outcome measures (PROMs) are bridging this gap. The cultural adaptation and linguistic validation of PROMs are essential steps for ensuring conceptually and culturally equivalent measurements across different populations. That is essential not only in care delivery but also for health-related data collected in multinational clinical trials(1).

The Functional Assessment of Chronic Illness Therapy (FACIT) methodology is a rigorous internationally recognized and well-established translation approach. As it ensures conceptual and semantic equivalence across languages and cultures while maintaining strong psychometric properties, supporting the validity, reliability, and cross-cultural comparability(2, 3).

The Patient-Reported Outcomes Measurement Information System (PROMIS) entails several measurements helpful in diverse settings. And they are also internationally recognized because this system is developed using state-of-the-art item response theory and large, diverse normative samples, allowing for precise, efficient, and comparable assessment of health outcomes across populations, conditions, and languages, while reducing respondent burden through short forms and computerized adaptive testing(4).

Objectives

This protocol aims to develop finalized European Portuguese versions that demonstrate high conceptual fidelity to the original English sources of the PROMIS measurements:

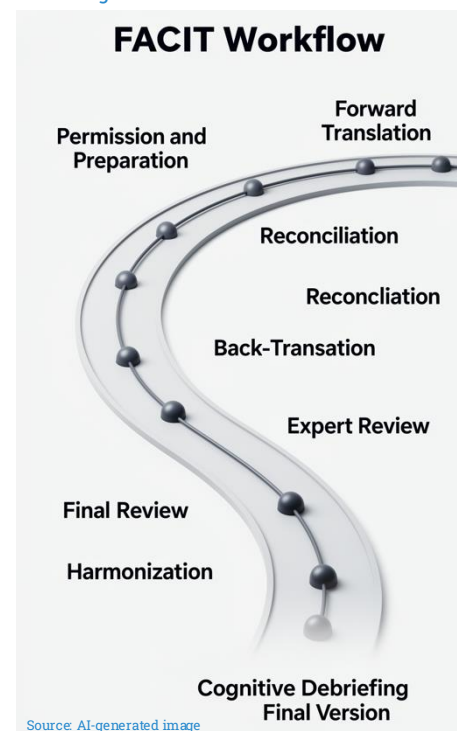
- ✓ PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a
- ✓ PROMIS Short Form v1.0 – Illness Burden 6a
- ✓ PROMIS Short Form v2.0 - Social Isolation 8a

Methods

The FACIT methodology will be used for cultural adaptation of the measurements. Entailing several steps as shown in the chart (Figure1)(5).

In the Forward Translation: Two independent native Portuguese speakers translate the instruments and instructions, focusing on conceptual equivalence rather than word-for-word translation. Following that a reconciler merges the two translations into a single version. The reconciled version is then back translated by a native English speaker, blinded to the original source documents, independently translate the reconciled Portuguese version back into English. Next these versions are compared to the original English source to identify any deviations in conceptual fidelity. In the expert review, a multidisciplinary expert panel reviews the pre-final version, to ensure cultural relevance, medical accuracy, and a suitable reading level. This review panel comments will be assessed in a pre-finalization review, for potential problems identification. The finalization is performed by a Portuguese native, that reviews all measurement translating history. Harmonization and quality assurance tasks are to be performed by Northwestern University, in agreement with PROMIS license agreement. Once finalized the measurements are formatted for release. In a final cultural validation step CDIs are conducted, for this task Ethics approval was requested. For the interviews participants will be recruited from general population and must be adults (>18Y) living in Portugal and be native Portuguese speakers. Each round requires up to 5 participants, continuing rounds until saturation is reached. The final stage includes professional proofreading, layout checks, and formatting to produce the finalized version and a translation report.

Figure 1 – FACIT Method Workflow



Source: AI-generated image

Results

It is expected that several measurable outcomes for Portuguese language persons will emerge.

COSMIN reporting guidelines will be used.

CDI's results will assess seven domains: comprehension, recall, relevance, wording and comprehension, response options, cultural appropriateness, and burdensomeness.

The final product will be a linguistically valid set of measures, supported by a detailed audit trail.

Conclusions

This protocol provides a rigorous and standardized framework for the cultural adaptation of PROMs for use within the Portuguese population. By adhering to the FACIT methodology—which is considered superior to single translation or translation by committee—the study ensures that the resulting instruments are reliable, valid, and responsive for use in clinical research and practice. The inclusion of cognitive debriefing ensures the "patient voice" is captured, affirming that the translated items are understood as intended by the original developers. Ultimately, this process facilitates the use of these tools in international clinical trials, allowing for robust cross-cultural data comparison and the potential for label claims based on patient-reported outcomes.

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