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Promising PROMIS

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2020

document version

Publisher's PDF, also known as Version of record

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citation for published version (APA)

Crins, M. H. P. (2020). *Promising PROMIS: Psychometric properties of the Dutch-Flemish PROMIS Pain Behavior, Pain Interference and Physical Function item banks*. [PhD-Thesis - Research and graduation internal, Vrije Universiteit Amsterdam].

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Summary

Measurement of health as perceived by patients has become more and more important within healthcare. Patient-Reported Outcomes (PROs) are outcomes that reflect the self-perceived status of the patient's health without interpretation by a clinician or anyone else. Examples of PROs are constructs (or domains) like physical function, pain, fatigue, anxiety, and depression. Patient-Reported Outcome Measures (PROMs) are questionnaires used to measure PROs.

Many traditional PROMs are not without shortcomings. They are burdensome to patients, since patients have to answer all questions while not all questions are always relevant for them, have large measurement error and the scores are often difficult to interpret and cannot be compared between the many existing PROMs.

PROMs based on Item Response Theory (IRT) have the potential to overcome most of these shortcomings of traditional PROMs. Measures developed using IRT methods consist of item banks, a set of items (questions) measuring one construct (domain). Items can be selected from an item bank to be administered as short forms (fixed length subsets of items out of the item bank) or highly efficient computer adaptive test (CAT). A CAT is a computer-administered measure in which, after the first item, successive items are selected by a computer algorithm based on persons' responses to previous items.

The Patient-Reported Outcomes Measurement Information System (PROMIS®) is the largest currently available system of IRT-based item banks, short forms and CATs for measuring PROs. Advantages of PROMIS are that it has been developed using a comprehensive framework, that PROMIS instruments are generic instead of disease specific, that PROMIS instruments already showed to have better content validity and smaller measurement error than traditional disease specific PROMs, and that PROMIS scores are easy to interpret and can be used to compare (sub)groups within and between populations. PROMIS has been developed in the United States (US) and has already been translated into several languages, including Dutch-Flemish.

Chapter 1 provides a general introduction to the research of this thesis and describes which steps are required to apply PROMIS in the Netherlands and Flanders. The scope and outline of the thesis are given and the main aim of this thesis is to perform a first exploration whether PROMIS can be applied to measure health in Dutch-Flemish populations.

Chapters 2-6 present the validation of the Dutch-Flemish PROMIS Pain Behavior (v1.1), Pain Interference (v1.1) and Physical Function (v1.2) item banks in multiple Dutch and Flemish patient populations. All three PROMIS item banks show good psychometric properties in Dutch patients with chronic pain (**Chapters 2, 3 and 4**, respectively). Furthermore, the Dutch-Flemish PROMIS Pain Behavior and Pain Interference item banks show good psychometric properties in Dutch and Flemish patients with

rheumatoid arthritis as well (**Chapter 5**). The Dutch-Flemish PROMIS Physical Function item bank shows also good psychometric properties in Dutch patients receiving physical therapy (**Chapter 6**). All three item banks meet the IRT-model assumptions and show good IRT-model fit. The item banks show good cross-cultural validity (no Differential Item Functioning (DIF) for language; Dutch-Flemish vs. English and Dutch vs. Flemish), absence of other measurement variance (no DIF for age, gender, administration mode and/or disease activity), good construct validity, high reliability in the range of the patient samples, and absence of floor and ceiling effects.

In addition to the studies addressing the psychometric properties and in order to investigate the validity of comparisons across populations, the item parameters of the Dutch-Flemish PROMIS Pain Behavior, Pain Interference and Physical Function item banks are compared across several clinical samples with different musculoskeletal disorders and a general population sample (**Chapter 7**). The results show some items with DIF between some of these samples, but the impact of DIF on PROMIS T-scores is negligible. This study provides evidence for the universal applicability of the three item banks. The item banks and their scores can be used for valid comparisons across clinical samples with different musculoskeletal disorders and the general population.

Although it is the current PROMIS recommendation to use a single set of item parameters (current recommendation are the US item parameters) in the scoring of PROMIS instruments and in the PROMIS CAT algorithms across the world, there might be reasons to consider country-specific parameters in non-English speaking countries, like in the Netherlands or Flanders. Non-English PROMIS researchers may argue that the most accurate way to measure a certain population is to use item parameters obtained in a large sample of the population at issue. However, it is important from an international point of view, to obtain scores that are internationally comparable. In **Chapter 8**, a simulation study illustrates the consequences of choosing different sets of item parameters in PROMIS CATs in non-English speaking countries. Four options were examined that reflect different decisions around the retention or rescaling (to the US PROMIS metric) of country-specific IRT parameters. Based on the study results, the conclusion is that no evidence was found for changing the current PROMIS recommendations for group level comparisons. CAT T-scores obtained with US item parameters for DIF-free items and country-specific item parameters, rescaled to the US PROMIS metric, for DIF items, or CAT T-scores obtained with country-specific item parameters for all items, rescaled to the US PROMIS metric, are comparable to CAT T-scores obtained using the US item parameters on group level. However, the choice of item parameters can be consequential for individual patient scores. Using US or country-specific item parameters both have advantages and disadvantages. The PROMIS Health Organization (PHO) should decide upon preferred and allowed strategies for choosing item parameter sets outside of the US, to ensure consistency of reporting of PROMIS T-scores across populations and countries.

Chapter 9 presents the general discussion of this thesis, shows what this thesis brought forth and provides some recommendations for future research. Issues relevant

for the implementation of PROMIS in the Netherlands and Flanders are addressed, and several examples of implementations of PROMIS CATs in daily clinical practice are given.

This thesis is an important step for the use of PROMIS in the Netherlands and Flanders. It is part of a large national PROMIS initiative. The current thesis contributes to the evidence that PROMIS consists of a set of standardized high quality PROMs. It shows good psychometric quality of PROMIS item banks in multiple patient samples. The three investigated Dutch-Flemish PROMIS item banks are appropriate and ready for the use in the Netherlands and Flanders according to the PROMIS requirements for the release of PROMIS instruments in languages other than English and in countries other than the US. PROMIS can be applied well in the Netherlands and Flanders. Worldwide, great efforts are made to implement PROMIS in daily clinical practice and in research. Because of this, health can be measured efficiently and patient-friendly.