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Clinical validity of PROMIS Depression, Anxiety, and Anger across diverse clinical samples

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Abstract

Objectives: The purpose of this study was to evaluate the responsiveness to change of the PROMIS negative affect measures (depression, anxiety, and anger) using longitudinal data collected in six chronic health conditions.

Study Design and Setting: Individuals with major depressive disorder (MDD), back pain, chronic obstructive pulmonary disease (COPD), chronic heart failure (CHF), and cancer completed PROMIS negative affect instruments as computerized adaptive test or as fixed-length short form at baseline and a clinically relevant follow-up interval. Participants also completed global ratings of health. Linear mixed effects models and standardized response means (SRM) were estimated at baseline and follow-up.

Results: A total of 903 individuals participated (back pain, $n = 218$; cancer, $n = 304$; CHF, $n = 60$; COPD, $n = 125$; MDD, $n = 196$). All three negative affect instruments improved significantly for treatments of depression and pain. Depression improved for CHF patients (anxiety and anger not administered), whereas anxiety improved significantly in COPD groups (stable and exacerbation). Response to treatment was not assessed in cancer. Subgroups of patients reporting better or worse health showed a corresponding positive or negative average SRM for negative affect across samples.

Conclusion: This study provides evidence that the PROMIS negative affect scores are sensitive to change in intervention studies in which negative affect is expected to change. These results inform the estimation of meaningful change and enable comparative effectiveness research.

Keywords: PROMIS; Depression; Anxiety; Anger; Chronic conditions; Item bank

1. Introduction

Researchers and clinicians wishing to assess negative affect in a clinical or community population must choose from among numerous assessment options, many of which purport to measure the same or a similar construct [1–3]. Not all the available instruments meet high levels of instrument development standards for reliability, validity, appropriate reading level, and minimal respondent burden [4,5]. In an effort to improve the existing measures, the Patient-Reported Outcomes Measurement Information System (PROMIS®) used a multistep, mixed-methods approach to develop computerized adaptive tests (CAT) and fixed-length short forms to assess health-related quality of life, including symptoms and functional domains across physical, mental, and social health [6]. Moreover, the goal of PROMIS, as an NIH Roadmap initiative, was to create a system that could standardize the measurement of patient-reported outcome across chronic conditions; thus, enabling comparisons of the burden of disease and the benefits of treatment across these chronic diseases. Included in that system is a set of item banks and short forms for negative affect, specifically depression, anxiety, and anger [7].

This article reports on an important subsequent step in the validation processes for PROMIS measures:

Conflict of interest: D.C. is an unpaid member of the board of directors and officer of the PROMIS Health Organization. All the remaining authors have no conflicts to disclose.

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What is new?

Key findings

- PROMIS negative affect computerized adaptive tests and short-form instruments are predictably responsive in intervention studies that target depression, back pain, and chronic heart failure.

What this adds to what was known?

- A diverse set of clinical groups are differentiated by PROMIS negative affect scores.

What is the implication and what should change now?

- With evidence of responsiveness and the ability to discriminate between clinical groups, PROMIS negative affect instruments are suitable for clinical trials and comparative effectiveness studies.

longitudinal analysis of the PROMIS negative affect scores in adult samples of patients with specified chronic health conditions. These analyses have the potential to deepen the PROMIS validity base, help define anchor-based clinically important differences, and further enable comparative effectiveness research by identifying subpopulation reference values and observed change scores based on receipt of conventional treatment. In the present study, these conditions comprised back pain, cancer, chronic obstructive pulmonary disease (COPD), chronic heart failure (CHF), and major depressive disorder (MDD). Self-reported negative affect may distinguish important features among patients suffering from these medical conditions, including level of risk [8], disability [9–11], or recovery [12].

Although this investigation is an exploratory "test drive" of PROMIS measures, the nature of the clinical groups and interventions allows us to articulate some hypotheses. For each of the PROMIS negative affect measures, we hypothesized that longitudinal improvements would occur during treatment for MDD (psychotropic medications and/or psychotherapy), CHF (heart transplant surgery), back pain (spinal injection), and the resolution of COPD exacerbation. Furthermore, we expected the greatest change on all three negative affect measures for those being treated for MDD relative to those being treated for physical conditions. Given the progressive nature of cancer and the absence of any change in treatment for the COPD-stable subgroup, we did not have a priori hypotheses for longitudinal changes of these groups. Our cross-sample hypotheses were that the MDD sample should have more severe scores on PROMIS depression compared to those with other ailments, whereas patients with COPD exacerbation should have worse negative affect scores compared to the stable group [9,13,14].

Although we have articulated some hypotheses, our ability to develop these more fully is somewhat hampered by the secondary nature of the data analysis. As discussed in the overview article of this series [15], a more thorough validation study developed with an a priori design, analytic approach, and data collection focused on across-study and across-disease validation would be useful and possibly more elegant. It should also be emphasized that the purpose of this report is not to demonstrate treatment effectiveness but to investigate the responsiveness and validity of the PROMIS negative affect instruments.

2. Method

2.1. Measures

2.1.1. PROMIS Depression, Anxiety, and Anger

At the time of this study, there were three PROMIS negative affect item banks, consisting of depression (28 items), anxiety (29 items), and anger (29 items). The items in the PROMIS negative affect banks use a 7-day time frame and a 5-point rating scale that ranges from 1 ("Never") to 5 ("Always") [6,7]. Each item bank was developed using comprehensive mixed (qualitative and quantitative) methods [16,17]. After confirming essential unidimensionality and fit to the graded response model [18], items were calibrated with regard to their location (severity) and discrimination (ability to distinguish people at different levels of distress). This produced a bank of questions that can accurately measure levels of negative affect across its observed continuum and provides the basis for innovative administration strategies such as CAT (in which item administration selection is based on responses to prior items) and short-forms targeted to the particular sample being assessed. Each item bank provided more information than conventional measures across a wider range of severity, ranging from normal to severely distressed [7].

The PROMIS Depression bank focuses on affective and cognitive manifestations of depression rather than somatic symptoms such as appetite, fatigue, and sleep. PROMIS Anxiety content focuses on fear (eg, worry, feelings of panic), anxious misery (eg, dread), hyperarousal (eg, tension, nervousness, restlessness), and somatic symptoms related to arousal (eg, cardiovascular symptoms, dizziness). The anger bank included items that were affective and cognitive but also included indicators of behavioral activation and anger expression [7]. See http://www.healthmeasures.net/measurement-systems/promis for full definitions of these banks.

The administration format of the PROMIS measures differed slightly across the condition and disease groups evaluated in this project. For most studies, the banks were administered via CAT. For the cancer study, however, customized short forms that predated the release of PROMIS short forms (version 1.0) were administered