Journal of Psychosomatic Research 81 (2016) 9–13

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

Evaluation of the psychometric properties of the PROMIS Cancer Fatigue Short Form with cancer patients

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ARTICLE INFO

Article history:
Received 11 August 2015
Received in revised form 1 December 2015
Accepted 9 December 2015

Keywords:
Cancer
Fatigue
Patient-reported outcomes
PROMIS
Psychometrics

ABSTRACT

Objective: Fatigue is common among cancer patients and adversely impacts quality of life. As such, it is important to measure fatigue accurately in a way that is not burdensome to patients. The 7-item Patient Reported Outcome Measurement Information System (PROMIS) Cancer Fatigue Short Form scale was recently developed using item response theory (IRT). The current study evaluated the psychometric properties of this scale in two samples of cancer patients using classical test theory (CTT).
Methods: Two samples were used: 121 men with prostate cancer and 136 patients scheduled to undergo hematopoietic cell transplantation (HCT) for hematologic cancer. All participants completed the PROMIS Cancer Fatigue Short Form as well as validated measures of fatigue, vitality, and depression. HCT patients also completed measures of anxiety, perceived stress, and a clinical interview designed to identify cases of cancer-related fatigue.
Results: PROMIS Cancer Fatigue Short Form items loaded on a single factor (CFI = 0.948) and the scale demonstrated good internal consistency reliability in both samples (*Cronbach's alphas* > 0.86). Correlations with psychosocial measures were significant (p values < .0001) and in the expected direction, offering evidence for convergent and concurrent validity. PROMIS Fatigue scores were significantly higher in patients who met case definition criteria for cancer-related fatigue ($p < .0001$), demonstrating criterion validity.
Conclusion: The current study provides evidence that the PROMIS Cancer Fatigue Short Form is a reliable and valid measure of fatigue in cancer patients.

Introduction

Research suggests that fatigue is one of the most common and distressing symptoms for cancer patients [1,2]. As such, measurement of fatigue in cancer patients has been the focus of significant research interest. While there are several existing measures of fatigue for cancer patients, few have been developed using item response theory (IRT) [3].

The Patient Reported Outcome Measurement Information System (PROMIS) Fatigue Scale was developed as part of a National Institutes of Health (NIH) funded effort to build and validate item banks using item response theory to measure important health outcomes across clinical and non-clinical populations [4,5]. As part of this effort, item pools were developed from identification of existing items, focus group input, expert item review and revision, and cognitive interviewing [4]. The resulting item banks were further refined and calibrated using IRT, and can be used to create short form measures [6,7].

Assumptions of IRT dictate that the instrument be unidimensional and demonstrate local independence, meaning that the items should load on one factor and not be highly related to each other. Moreover, one of the strengths of instruments developed using IRT is that they are based upon ability scores which are test independent, meaning that the test can be developed to be sensitive across a range of impairment and regardless of the particular choice of test items. This differs from measurement development based upon Classical Test Theory (CTT), which is based upon observed scores and true scores that are test and sample dependent. PROMIS item banks can be administered either uniformly using a defined set of items or interactively using computerized adaptive testing (CAT) [4]. Thus, the PROMIS initiative has the potential to advance measurement of patient-reported outcomes using standardized measures that are easy to administer, adaptable, and allow for comparison across clinical and non-clinical samples.

The measure that is the focus of the current study, the 7-item PROMIS Cancer Fatigue Short Form, was developed from a bank of 95 items [7]. The final set of items was selected so that there was consistency in the response scale options, broad coverage across the fatigue

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http://dx.doi.org/10.1016/j.jpsychores.2015.12.002
0022-3999/

continuum, and good precision of measurement [7]. To the best of our knowledge, only one published study has examined the psychometric properties of the PROMIS Cancer Fatigue Short Form [4]. The study used data collected from a sample that combined a representative U.S. general population with multiple disease populations including people with cancer [4]. The study found that the scale demonstrated good concurrent validity and was highly correlated in the expected direction with the SF-36 Vitality Scale, and the Functional Assessment of Chronic Illness Therapy-Fatigue Scale.

The goal of the current study was to build on this work by examining the reliability and validity of the PROMIS Cancer Fatigue Short Form in two samples of cancer patients, men diagnosed with prostate cancer (Sample 1) and men and women diagnosed with hematologic cancer (Sample 2). It was hypothesized that the measure would be unidimensional as demonstrated by factor analysis, free of locally dependent items as demonstrated by residual correlations, and have strong internal consistency. It was also hypothesized that the measure would demonstrate concurrent, convergent and criterion validity. It was predicted that PROMIS Cancer Fatigue Short Form scores would be significantly correlated with other measures of fatigue as well as measures of vitality, depression, anxiety, and perceived stress, and that PROMIS Cancer Fatigue Short Form scores would be significantly higher in patients meeting the criteria for a case definition of cancer-related fatigue.

Method

Participants

Sample 1

Participants were recruited to a larger study examining cognitive functioning and quality of life among men with prostate cancer and included two subsamples: men starting androgen deprivation therapy (ADT) for prostate cancer (ADT+) and men previously treated with surgery for prostate cancer who had not received ADT (ADT−). Participants were eligible if they were greater than 18 years of age, were able to speak and read English, had at least a sixth grade education, had no history of cerebrovascular accident, scored in the normal range (i.e., less than three errors) of mental functioning on the Short Portable Mental Status Questionnaire [8], and were able to provide informed consent. The ADT+ participants were also required to meet the following criteria: they were diagnosed with non-metastatic or asymptomatic metastatic prostate cancer, had not been receiving treatment within the past 12 months for another cancer diagnosis, had no clinical evidence of another diagnosed cancer at the last follow-up visit, had never been diagnosed with primary brain cancer and/or received cranial radiation, and were to be treated with ADT continuously for at least 6 months. The ADT− participants were also required to meet the following criteria: they were diagnosed with non-metastatic prostate cancer, had not been diagnosed with any other form of cancer (except non-melanoma skin cancer), had undergone prostatectomy, had no history of recurrent disease since undergoing prostatectomy, had no history of other forms of prostate cancer treatment, were not scheduled for additional prostate cancer treatment, and were not receiving testosterone supplementation.

Sample 2

Participants were recruited to a larger study examining quality of life and cognitive functioning among patients undergoing hematopoietic cell transplantation (HCT) for hematologic malignancies. Participants were eligible if they were 18 years of age or older, were diagnosed with hematologic cancer; were scheduled to receive an allogeneic HCT with peripheral blood stem cells, had no history of cerebrovascular accident or head trauma with loss of consciousness, had completed six or more years of formal education, were capable of speaking and reading standard English, and were able to provide written informed consent.

Procedure

Sample 1

Following Institutional Review Board (IRB) approval, participants were recruited between September 2008 and July 2012. Participants were compensated $80. Participants were screened for eligibility using medical record review. ADT+ participants were recruited during outpatient appointments at Moffitt Cancer Center or James A. Haley Veterans' Hospital. Potential participants were approached in clinic to verify eligibility and inform them about the study. Those who agreed to participate provided signed informed consent, and were escorted to a private room in the clinic. Patients then had the option of completing the self-report measures that day, or within 1 month of the start of ADT. Potential ADT− participants were recruited by mail and telephone. They were initially mailed a letter and directions for opting out of the study. Those who did not opt out were contacted by phone to have the study explained. Those who were eligible and interested scheduled an appointment to obtain written informed consent and complete the self-report measures. For the larger study, 484 patients were approached for participation; of these, 189 refused, 4 withdrew, 6 were ineligible after consent, 4 failed screening, 63 were unable to be matched, and 218 signed consent and completed the baseline assessment (45% of those contacted). Of those who completed the baseline assessment, PROMIS Cancer Fatigue Short Form was administered to 121 participants. Thus, analyses were conducted on 121 participants with evaluable data.

Sample 2

Following IRB approval, participants were recruited between September 2010 and July 2012. Participants were compensated $20. Potential participants were identified by their transplant physicians and approached during regularly scheduled outpatient visits at Moffitt Cancer Center. All potential participants were informed about the study. Those who wished to participate provided signed informed consent, and were escorted to a private room in the clinic. Participants had the option of completed the self-report measures that day or on another day prior to starting pre-transplant conditioning. For the larger study, 273 patients were approached for participation; of these, 48 refused, and 225 signed consent and completed the baseline assessment (82% of those contacted). Of those who completed the baseline assessment, PROMIS Cancer Fatigue Short Form was administered to 136 participants. Thus, analyses were conducted on 136 participants with evaluable data.

Measures administered to both samples

Demographic and clinical characteristics

Demographic variables (i.e., age, race/ethnicity, marital status and education level) were collected via self-report. Clinical characteristics (i.e., disease type, time since diagnosis) were collected by medical record review at study entry.

Fatigue

The 7-item PROMIS Cancer Fatigue Short Form assesses the frequency of fatigue in the past 7 days [7]. Table 2 presents a list of the items. Items are measured on a five-point scale (1 = never; 5 = always) and summed, after reverse scoring item 7, with higher scores indicating greater fatigue. Raw total scores served as the primary outcome for the purposes of this study. Normalized T-scores were also computed based upon a sample representative of the general U.S. population. The Fatigue Symptom Inventory (FSI) is a 14-item scale that assesses the frequency, severity, and disruptiveness of fatigue [9]. Analyses in the current study focused on average fatigue severity and disruptiveness. Average fatigue severity was measured using an item that asks participants to rate their average fatigue in the past week on an 11-point scale, with higher scores indicating greater fatigue (0 = not at all fatigued; 10 = as fatigued as I could be). Disruptiveness of fatigue