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Validation of the PROMIS Physical Function Measures in a Diverse U.S. Population-Based Cohort of Cancer Patients

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Abstract

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Purpose—To evaluate the validity of the Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function measures in a diverse, population-based cancer sample.

Methods—Cancer patients 6–13 months post diagnosis (n=4,840) were recruited for the Measuring Your Health (MY-Health) study. Participants were diagnosed between 2010–2013 with non-Hodgkin lymphoma or cancers of the colorectum, lung, breast, uterus, cervix, or prostate. Four PROMIS Physical Function short forms (4a, 6b, 10a, and 16) were evaluated for validity and reliability across age and race-ethnicity groups. Covariates included gender, marital status, education level, cancer site and stage, comorbidities, and functional status.

Results—PROMIS Physical Function short forms showed high internal consistency (Cronbach's $\alpha = 0.92 - 0.96$), convergent validity (Fatigue, Pain Interference, FACT Physical Well-Being all r 0.68) and discriminant validity (unrelated domains all r 0.3) across survey short forms, age, and race-ethnicity. Known group differences by demographic, clinical, and functional characteristics performed as hypothesized. Ceiling effects for higher-functioning individuals were identified on most forms.

Conclusions—This study provides strong evidence that PROMIS Physical Function measures are valid and reliable in multiple race-ethnicity and age groups. Researchers selecting specific PROMIS short forms should consider the degree of functional disability in their patient population to ensure that length and content are tailored to limit response burden.

Keywords

Patient-Reported Outcomes; Oncology; Validation Studies; Physical Function

Introduction

Over half of cancer survivors are likely to experience significant physical limitations [1]. Decline in physical function is often associated with a cancer diagnosis and the ensuing initial treatment [2; 3], and such decline can have long-lasting effects extending past treatment and is associated with lower quality of life and increased risk of mortality [4].

Physical Function is a key patient-reported outcome (PRO) used to characterize and better understand overall health, level of physical disability and general well-being. Physical function is a foundation for many commonly-used general and cancer-specific (e.g., SF-36 and FACT-G, respectively) PRO measures [5; 6] and the Patient-Reported Outcomes Measurement Information System[®] (PROMIS[®]) [7–9]. These measures provide a systematic report of functional well-being, similar to physician-rated performance status measures that are known to have low inter-rater reliability [10]. Physical function PROs offer a comprehensive assessment of body function, impact of disability on physical participation, activity level, and environmental and personal characteristics [11; 12] and incorporate the patient perspective.

PROMIS, a U.S. National Institutes of Health Common Fund initiative, has developed an extensive item response theory (IRT)-calibrated item bank, a collection of self-administered questions, and multiple short form questionnaires available to measure physical function. This physical function domain was developed to measure a full range of function on one

common standardized scale, minimizing ceiling and floor effects where the score is higher or lower than the survey can identify [12; 13], and has demonstrated conceptual validity and reliability [8; 14]. Initial validation of this domain in rheumatoid arthritis and osteoarthritis populations and normal aging cohorts showed that PROMIS physical function measures outperformed legacy instruments (i.e., the Health Assessment Questionnaire [HAQ]) [15]. Subsequent work validated this PROMIS physical function item bank in a more diverse general population sample [16]. The item banks were designed to allow customized short forms of variable length and item content to be created, yet yield comparable, standardized scores across the short forms [17]. However, the comparability of PROMIS Physical Function short forms in a community-based sample encompassing a broad range of age, disability level, and race-ethnicity has not been extensively tested.

Our study objectives were to evaluate (1) the applicability of the PROMIS physical function measures for a diverse sample of cancer patients, and (2) the psychometric performance of commonly-used PROMIS physical function short forms.

Methods

Recruitment

The Measuring Your Health (MY-Health) study recruited a population-based sample of cancer patients from four Surveillance, Epidemiology, and End Results (SEER) Program cancer registries (The Greater Bay Area Cancer Registry covering the San Francisco Bay and surrounding area, the Cancer Registry of Greater California covering the rest of the state except Los Angeles County, the Louisiana Tumor Registry, and the New Jersey State Cancer Registry). We stratified sampling by 4 race-ethnicity groups (Non-Hispanic White [NHW], Hispanic, Non-Hispanic Black [Black], Non-Hispanic Asian [Asian]) and 3 age groups (21–49, 50–64, 65–84), based on base incidence rates at each registry. The study was approved by Institutional Review Boards at all participating institutions.

Population

Participants in this cohort were identified based on the following SEER eligibility criteria: 21–84 years of age at diagnosis; diagnosed with one of seven cancers (prostate, colorectal, non-small cell lung, Non-Hodgkin lymphoma, female breast, uterine or cervical); no prior cancer diagnosis (except non-melanoma skin cancer); currently within 6–13 months of diagnosis and able to read English, Spanish, or Mandarin. Patients without cancer stage information, age, or race-ethnicity information were excluded from this analysis (N=662, figure 1) to ensure all known groups comparisons were done across a single uniform cohort.

MY-Health Survey

Survey items included self-reported sociodemographic characteristics, receipt of recent treatments, comorbidities, patient-reported outcomes and selected health behaviors. Pilot testing was conducted in 35 respondents to identify and correct any errors or unclear language and skip patterns in the survey. The SEER registry sites mailed a survey to eligible participants, with an additional Spanish and Mandarin Chinese translations sent to persons based on surname or made available upon request. Cover letters in the same language as the

survey were sent explaining the reason for the study and requesting participation. Along with a second mailing, phone follow-up was initiated for all non-responders after 3 weeks to encourage return of the survey. When contacted, participants were given the option to complete the survey over the phone in English, Spanish, or Mandarin Chinese. All Spanish and Mandarin translations of PROMIS items followed a strict translation protocol [18] and were done in coordination with the PROMIS Statistical Center at Northwestern University. Participants received a \$30 gift card or check after completing the survey.

Demographic and Clinical Variables

We merged the patient survey data with SEER registry variables. SEER registry variables include: age, sex, date of cancer diagnosis, cancer type, and cancer stage. In addition we included the following self-reported survey variables: receipt of chemotherapy, radiation therapy, or hormonal therapy; surgery, comorbid conditions (number and type); education level; current employment status; annual income; marital status; insurance coverage; and whether the patient was born in the U.S. We used the following self-reported race-ethnicity categories (NHW, Black, Hispanic, Asian), created following U.S. Census (2010) classification algorithms [19]. When self-reported race-ethnicity was missing (<0.4% of patients) SEER registry information was used.

Patient-Reported Outcomes

We evaluated three established PROMIS Physical Function (PF) short form measures (PF 4a, PF 6b, PF 10a, and custom 16-item form). PROMIS PF short forms are fixed assessments, administered either on paper or electronically. Two forms evaluated here (PF 4a, PF 6b) are the physical function sub-scale of the PROMIS Adult Profile 29 v2 and PROMIS Adult Profile 43 v2, respectively [20]. We selected items for inclusion in the MY-Health survey instrument based on either their inclusion in commonly used short forms, or their frequent selection in the online PROMIS Computer Adaptive Testing (CAT) format. We examined CAT item selection for two different patient groups (0.5 and 1.0 SD below the population mean). Convergent and discriminant validity (types of construct validity) were evaluated with respect to the following variables (each showing high internal consistency a in this cohort) [21]: Ability to Participate in Social Roles and Activities v1 (10 items, a=0.98); Emotional Distress – Anxiety (11 items, a=0.97); Emotional Distress-Depression (10 items, α =0.97); Fatigue (14 items, α =0.96); and Pain Interference (11 items, α =0.98). PROMIS measures are reported as T-scores (0–100 scale) with a mean of 50 and SD of 10. All PROMIS measures except Ability to Participate in Social Roles and Activities are normalized to the general US population [7]. High scores for Physical Function and Social Roles and Activity represent better functioning and high scores for the symptoms represent greater symptom burden. To address convergent and discriminant validity, we also administered the 7-item FACT Physical Well-Being (PWB) subscale (a=0.84) [5]. Spirituality, comprised of two sub-domains (faith and peace) measured by the FACIT-SP-12 v4 (α =0.85) [22]; a 5-item financial burden subscale from the PSQ-III (α =0.83) [23]; an 8item acculturation scale for U.S. immigrants (a=0.94) [24]; To address known groups validity, questions on the use of assistive devices, a single-item Patient Self-Report ECOG Performance Status Scale used in cancer clinical trials to assess disease impact on daily living abilities [25], comorbid medical conditions (asthma, COPD, arthritis, and overall

number), physical activity, stage of disease, cancer site, and demographic variables were included. Hypotheses are described below.

Reliability and Validity Testing

We used standard psychometric procedures to evaluate reliability and validity [26] of each PROMIS PF short form across 3 age (21–49, 50–64, 65–84) and 4 race-ethnicity (NHW, Black, Hispanic, Asian) groups. We evaluated overall and item-level performance. We estimated internal consistency using Cronbach's Coefficient alpha, with $\alpha > 0.70$ and $\alpha > 0.70$ 0.90 the thresholds for reliable group and individual level (inter-individual comparisons at a single time point) measurement, respectively. For structural validity, we evaluated unidimensionality of the PROMIS PF short forms using factor analysis methods, with a mean- and variance-adjusted weighted least square (WLSMV) estimator. Goodness of model fit indicators and thresholds included: comparative fit index (CFI), and the Tucker-Lewis Index (TLI). We tested multiple types of construct validity across age and race-ethnicity groups. We examined convergent and discriminant construct validity by calculating Pearson correlations between Physical Function and other administered scales. The PROMIS PF short forms were expected to be positively correlated with social role participation and another measure of physical function (the FACT - Physical Wellbeing subscale) and negatively correlated with symptom severity (e.g., more fatigue or pain) and weakly correlated other non-physical function measures (e.g., FACIT Spirituality, Financial Burden, and Acculturation). We used chi-square tests to evaluate known-group validity of expected a priori differences in physical function (all forms), for the total sample. Specific variables, hypotheses and supporting citations are described in table 5, any minimally important differences between race-ethnicity or age groups (PROMIS physical function T-score 4, a meaningful important score difference [27], are also identified). Factor analysis was conducted using Mplus (version 7.1, Los Angeles, CA); all other analyses were conducted using SAS (v. 9.3, SAS Institute, Cary, NC).

Results

Overall, participants in the MY-Health cohort are demographically and clinically diverse, important for establishing generalizability to other cancer populations (Table 1). Non-White participants comprised 57% percent of the total cohort and 59% of participants were under 65 years of age. Eighteen percent of the cohort reported less than a high school education (Hispanics, 37%; Blacks, 22%; and Asians, 14%), 15% and 50% of the cohort reported household income levels under \$60,000. Thirty percent were not born in the U.S., and 9% of surveys were completed in Spanish or Mandarin Chinese. Cancer incidence by type ranged from cervix (3%) to breast (30%); 12% of patients were diagnosed with stage IV cancer; and about half reported the receipt of chemotherapy (48%).

This cohort reported a mean PROMIS Physical Function score (using the PF 16-item short form score) of 44.9 (Table 2), one half standard deviation lower than the overall U.S. population mean. Mean differences in PROMIS PF short form scores and the 16-item MY-Health form ranged from 0.05 (PF 10a) to 0.80 points (PF 4a), all well-within the mean standard error of measurement (2.2 - 3.9 points). These differences remained consistent

across age and race-ethnicity groups. Reliability of all PROMIS Physical Function short forms was high (α =0.92–0.96, Table 2), and remained >0 .90 when restricted to subgroups based on age and race/ethnic groups (not shown in tables). Floor effects were minimal across all forms, but ceiling effects were evident in PF 4a (34.5%) and PF 6a (25%).

For structural validity, confirmatory factor analysis for a one factor model fit to all 16 items generally showed good fit (CFI and TLI = 0.99). Exploratory factor analysis identified one strong factor (Eigenvalue=12.7) and high factor loadings (>0.6) for all items. A second, highly correlated factor (r=0.83) was identified for items that ask about self-care actions (e.g., wash and dry your body, shampoo your hair) that are only found on the PF 10a (Table 3).

For convergent and discriminant validity, physical function was correlated with other PRO domains as hypothesized (see Table 4), and consistent with previous literature. There were strong correlations (r 0.67) with ability to participate in social roles, fatigue, pain, and functioning on the FACT-G PWB scale. The domain was moderately associated (r=-0.38 to -0.50) with depression, anxiety, and sleep disturbance scores. Physical function showed weak to moderate correlations (r 0.26) with spirituality, financial burden, and acculturation.

Known-groups testing confirmed our a priori hypothesis about differences in physical function (Table 5). Only two sub-group comparisons (cancer site, and performance status) showed age and race-ethnic differences that were 4 or more points higher or lower than the reference groups. Among cancer clinical variables, cancer patients diagnosed with advanced cancer and those who received chemotherapy both reported significantly lower physical function scores (-4.40 and -5.35 points, respectively). Of all cancer types, lung cancer patients had the lowest mean physical function scores (39.1), while men with prostate cancer reported the highest mean scores (49.6).

Self-reported comorbidities were associated with large decreases in physical function by both the number of other conditions reported and whether COPD or asthma was reported. As expected, the largest differences in physical function (13 points, p<0.001) were found if a person indicated they had any trouble walking. These findings also were consistent when physical function was evaluated by ECOG performance status, covering a large range of disability. Overall each decrease in performance status level (normal, some symptoms, <50% bed rest, >50% bed rest), was also a large, statistically significant decrease in physical function, while the scores and standard deviations were consistent across each level (Figure 2).

We found that scores near the floor and ceiling of this domain were similar across all short forms examined. Groups anticipated to be very low functioning near the floor of this domain (>50% bed rest) reported similar scores (<0.5 of a point) across all physical function short forms. The highest-functioning group (reported vigorous activity 5 or more times a week) had a two-point mean difference between 4-item and the full 16-item measures, still within the standard error of measurement for both forms (data not shown).

Discussion

This study demonstrated the validity and reliability of PROMIS Physical Function short forms in a socio-demographically diverse, population-based cohort of cancer patients. We found that scores across all short forms performed consistently across race-ethnic and age groups. Reliability and validity criteria were met for race-ethnic and age groups across all tested physical function forms, providing strong evidence that these measures are accurate, precise, and comparable in a diverse cohort of cancer patients.

Previous work validating the PROMIS Physical Function bank suggested that, like virtually all extant measures of self-reported physical function, there may be content gaps at the ceiling of the measure (i.e., items that can measure high levels of physical function and athleticism) [28]. We observed similar findings in this lower physical functioning cohort. Ceiling effects were identified for all physical function short forms in use, and were notably higher in the 4-item form; floor effects were minimal across all short forms. This suggests that when physical function short forms are administered in higher-functioning populations a full standard deviation above U.S. population (60) or higher, custom item selection for higher functioning individuals becomes increasingly important to ensure accurate measurement. Assessment administration method (fixed item short form vs. CAT) should also be considered in selection, as recent studies show that CAT administration of the PROMIS Physical Function item bank in both clinical and general population samples reduces this ceiling effect [29; 30] and new items have been added that directly address ceiling and floor effects [31; 32]. However, when the administration of a fixed short form is necessary, our findings suggest that increasing short form length (i.e., 6b or higher) reduces ceiling effects.

Factor analyses suggest that the 4 items measuring self-care (e.g., washing hair) may form a separate factor; however, the high correlations with the other physical function items support the unidimensionality of the PROMIS Physical Function item bank. This replicates results from the initial validation and calibration of the full physical function item bank recommending a parsimonious one factor solution [15; 30]. Questions focusing on self-care actions may not be as relevant for a general ambulatory cancer population. Because these 4 self-care items are administered on one short form (10a), understanding the clinical needs of the population is important prior to a short-form selection. The PROMIS physical function domain has addressed some of these issues, offering tailored assessment for upper extremity function and use of mobility aids [33], increasing flexibility and relevance of this domain across a broad range of physical function.

PROMIS currently offers a wide range of physical function short forms, geared toward different patient groups and functional ability. This study confirmed the expectation that longer forms reduce the standard error of measurement (i.e., reliability increased with longer short forms). However, the 6b form reported better internal consistency than the 10a form, with a smaller ceiling effect than that identified in the 4a form. While all forms performed well, the results presented here suggest diminishing gains in precision in the 10a and 16 forms (but lower floor and ceiling effects) compared to the 6b form in this population. Recent work has confirmed these findings [12; 15; 28; 30–32], extending the range of items

at the floor and the ceiling When high precision is necessary in research settings, the PROMIS PF-20 (an extension of the PF 10a form tested here) is coming into broad use as a replacement for the traditional HAQ-DI. It has been found to be more sensitive to change and requires smaller sample sizes without increasing questionnaire burden.

This study has a few notable strengths and limitations. This population is limited to participants diagnosed with cancer, measuring average or lower physical function, limiting the generalizability of these findings to very-high functioning individuals. However this population is also a strength of this study as the broad cancer inclusion criteria (7 cancers, all stages) allowed for a wide range of disability levels encountered in many medical conditions. In addition, by using a large, community-based patient cohort with verified diagnoses and clinical characteristics, this study extends previous work that reported only self-report illness status or small clinical samples to a diverse community-based cohort. Furthermore, PROMIS measures are designed to provide cross-condition comparisons using a standard, non-cancer specific scale of measurement. Therefore these findings are relevant and applicable across a full range of physical function from individuals with little to no impairment to those on bed rest.

An additional limitation regarding the sample is the relatively low participation rate of eligible patients. The overall response rate (this includes those unable to be contacted, died or later deemed ineligible) for this study was approximately 31%, higher among those able to be reached by study staff (53%). While low these rates are consistent with large, SEER-based surveys of recently diagnosed cancer patients [34–36]. Additionally, this study specifically targeted and oversampled patients from under-represented populations and patients with metastatic disease. As a result, these groups reported lower response rates (5–7% lower), than younger, white, or non-metastatic study participants.

A third limitation is that this paper focused on reliability and validity of common short forms across age and race-ethnic groups using classical test theory methods. Further work evaluating this domain with psychometric criteria such as differential item function (DIF) that identifies systematic differences in how groups respond to specific items is an important and complementary effort, currently underway. For example, past evaluations have determined that DIF by age group may be especially important for physical function [37].

Finally, it is important to note that while clinical characteristics about cancer type and stage were reported from the registry, treatment and comorbidity information was self-reported by patients. These two variables may be less accurate than other methods of data collection, such as medical record abstraction, and can be associated with an information bias. However, these are standard questions used in other national cancer surveys [34]. Therefore we feel confident this information is sufficient to evaluate known group validity.

The final study limitation is the inability to evaluate the PF 8b, an 8-item PROMIS PF short form, because we did not administer all 8 items in this survey. Therefore, these findings cannot be extended to this short form. However, the 6b short form entirely overlaps the 8b, suggesting it will perform as well, if not better than the 6b.

Conclusions

This study confirms the validity and reliability of the PROMIS Physical Function item back and short forms across a wide range of age and race-ethnic groups reflecting the extensive diversity of the U.S. population. It shows that these short forms can precisely measure meaningful group differences in cancer patient populations, accurately reflecting both disease burden and comorbidities across all versions. While some isolated measurement issues were identified, and should be considered when selecting a short form, their impact on the normalized scoring is minimal.

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Fig. 1. MY-Health Cohort Flow Chart

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Fig. 2.

PROMIS Physical Function Short Form Mean and Standard Deviation by ECOG Performance Status

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Demographics and Clinical Characteristics by Race-ethnicity

	Ove	rall	Non-Hispanic White	Black	Hispanic	Asian
	u	% *	%	%	%	%
			Demographics			
Age at Diagnosis (years)						
21–49	1057	22	19	19	29	25
50-64	1812	37	33	46	35	39
65–84	2011	42	49	35	36	36
Sex						
Male	1988	41	43	44	39	33
Female	2892	59	57	56	61	67
Comorbidities (Number)						
0	1714	35	33	33	33	46
I	1246	26	25	25	25	28
2+	1920	39	42	42	42	26
Married	2868	59	65	42	53	70
Education Level						
< High School Degree	865	18	8	22	37	14
High School Degree	606	19	22	21	18	10
Some College	1558	32	36	37	28	21
College Degree	887	18	20	11	6	33
Graduate Degree	577	12	14	7	9	20
Income Level						
< \$10,000	497	10	5	17	16	6
\$10,000 to \$59,999	1924	40	36	47	47	32
\$60,000 to \$99,999	812	17	22	12	12	15
\$100,000 to \$199,999	611	13	17	9	9	18

	Ove	rall	Non-Hispanic White	Black	Hispanic	Asian
	n	*%	%	%	%	%
> \$200,000	172	4	5	1	2	5
Current Employment						
Working	2121	43	45	37	44	100
Retired	1886	39	43	38	32	36
Unemployed/Disabled	813	17	12	23	22	16
Born in U.S.	3420	70	94	93	41	16
Survey Language						
English	4450	91	100	100	68	85
Spanish	302	9	0	0	31	0
Chinese	128	33	0	0	-	15
TOTAL	488 (100	%) 80	2079 (43%)	1019 (21%)	960 (19%)	822 (17%)
			Clinical Variables			
Cancer Type						
Breast	1450	30	25	27	30	44
Prostate	1065	22	20	29	22	17
Colorectal	824	17	16	18	18	18
Lung	641	13	20	11	9	9
NHL	413	8	11	9	6	9
Uterus	358	٢	9	7	10	7
Cervix	129	3	2	2	S	2
Cancer Stage						
Ι	1851	38	39	33	38	39
П	1583	32	29	37	32	35
III	866	18	18	18	18	17
M	580	12	13	12	11	6
Initial Treatment						

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	Ovei	all [Non-Hispanic White	Black	Hispanic	Asian
	u	%°*	%	%	%	%
Surgery	3354	69	69	64	99	76
Chemotherapy	2335	48	46	48	51	50
Radiation	2003	41	42	40	39	43
Performance Status						
No Symptoms	2213	46	48	43	37	54
Some Symptoms	1782	37	37	38	40	32
50% Bed Rest	581	12	12	12	16	8
>50% Bed Rest	214	4	33	5	7	4
Walking Support						
No Help	3731	TT	62	70	73	84
Cane or Some Support	531	11	6	17	13	7
Walker	123	ю	2	4	3	1
Wheelchair	270	6	6	5	7	4

* due to missing values numbers may not equal 100%

Qual Life Res. Author manuscript; available in PMC 2016 October 25.

Jensen et al.

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Table 2

Item-Level and Short-Form Properties

PROMIS Item Identifier		Short	Form		Floor (%)	Ceiling (%)	Mean*	SD		Item	Text	
	PF 4a	PF 6b	PF 10a	PF 16								
PFA1	I	I	X	x	25.1	16.2	2.7	1.4	Does your health ne lifting heavy object	w limit you in doing s, participating in stre	vigorous activities, nuous sports?	such as running,
PFC36	I	I	X	X	18.7	36.8	3.3	1.5	Does your health ne	ow limit you in walkin	ng more than a mile	
PFC37	I	I	X	X	6.6	47.5	3.8	1.3	Does your health ne	ow limit you in climbi	ing one flight of stai	cs?
PFA5	I	I	X	X	6.7	43.1	3.8	1.3	Does your health ne	w limit you in lifting	or carrying grocerie	s?
PFA3	I	I	X	X	6.6	37.6	3.6	1.3	Does your health ne	ow limit you in bendin	ıg, kneeling, or stoo	ping?
PFA7	I	I	I	X	4.7	34.7	3.6	1.3	How much do phys (such as walking or	ical health problems n climbing stairs)?	10w limit your usual	physical activities
PFB1	I	X	I	x	5.5	44.5	3.8	1.3	Does your health ne vacuuming, sweepi	w limit you in doing ng floors or carrying i	moderate work arou in groceries?	nd the house like
PFC12	I	X	I	Х	16.5	30.8	3.3	1.5	Does your health ne	w limit you in doing	two hours of physic	al labor?
PFA11	X	X	X	X	11.1	39.4	3.7	1.4	Are you able to do	chores such as vacuun	ning or yard work?	
PFA16	Ι	I	Х	Х	1.1	76.9	4.6	0.8	Are you able to dre	ss yourself, including	tying shoelaces and	doing buttons?
PFB26	I	I	Х	Х	1.7	85.6	4.7	0.8	Are you able to sha	mpoo your hair?		
PFA55	I	I	X	Х	0.8	84.2	4.7	0.7	Are you able to wa	sh and dry your body?		
PFC45	I	I	X	X	0.5	84.1	4.8	0.7	Are you able to get	on and off the toilet?		
PFA 21	X	X	I	Х	6.5	54.2	4.1	1.2	Are you able to go	up and down stairs at	a normal pace?	
PFA23	X	X	I	X	7.1	6.09	4.2	1.2	Are you able to go	for a walk of at least 1	15 minutes?	
PFA53	X	X	I	X	6.3	59.9	4.2	1.2	Are you able to run	errands and shop?		
		By Sho	rt Form			By Race (PF	16)			By Age (PF 16)		
	PF 4a	PF 6b	PF 10a	PF 16	White	Black	Hisp.	Asian	21–49	50-64	65–84	
Total Floor (%)	2.2	1.7	0.2	0.2	0.1	0.3	0.3	0.1	0.2	0.1	0.3	
Total Ceiling (%)	34.5	25.0	13.1	12.2	13.7	12.0	9.3	12.3	14.2	14.4	9.2	
Mean	45.8	45.3	44.9	44.9	45.7	43.6	43.5	46.4	46.3	45.5	43.7	
SEM mean	3.9	3.1	2.7	2.2	2.2	2.1	2.0	2.2	2.3	2.3	2.0	
SD	9.7	9.9	9.9	10.0	9.9	10.3	10.0	9.3	9.6	10.1	9.9	
Cronbach's a	0.92	0.94	0.92	0.96	0.96	0.96	0.96	0.96	0.96	0.96	0.96	

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Note: X indicates item included on short form.

* Item scores ranged from 1–5. All items use the following response scale: 5=Without any difficulty, 4=With a little difficulty, 3=With some difficulty, 2=With much difficulty, 1=Unable to do.

Abbreviations: PF, Physical Function; SD, standard deviation; SEM, = standard error of measurement

Table 3

Physical Function Factor Loadings (Oblique Rotation) and Correlations

_	Fac	tor
Item	1	2
PFA1	0.85	0.59
PFC36	0.89	0.65
PFC37	0.89	0.74
PFA5	0.91	0.77
PFA3	0.86	0.73
PFA7	0.92	0.75
PFB1	0.94	0.79
PFC12	0.90	0.67
PFA11	0.93	0.79
PFA16	0.79	0.92
PFB26	0.79	0.95
PFA55	0.81	0.99
PFC45	0.78	0.91
PFA21	0.89	0.82
PFA23	0.90	0.78
PFA53	0.91	0.83
Eigenvalue	12.57	1.08
Factor C	orrelatio	ns
	1	2
1	1	
2	0.83	1

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Score Correlations	PF [16]	PF [4a]	PF [6b]	PF [10a]	Hypothesized Association
PROMIS Domains					
Ability to Participate in Social Roles	0.76	0.74	0.76	0.75	+
Fatigue	-0.72	-0.67	-0.70	-0.70	+
Pain Interference	-0.67	-0.64	065	-0.67	+
Depression	-0.50	-0.47	-0.49	-0.50	*
Anxiety	-0.48	-0.45	-0.47	-0.48	*
Sleep Disturbance	-0.41	-0.38	-0.40	-0.41	*
Validated Measures					
FACT - Physical Well-Being Subscale	0.71	0.70	0.71	0.70	+
Spirituality	0.26	0.25	0.26	0.25	I
Faith	0.03	0.03	0.04	0.03	I
Meaning/Peace	0.37	0.35	0.36	0.36	I
Financial Burden	0.20	0.19	0.19	0.20	I
Acculturation (n=1280) **	-0.14	-0.13	-0.14	-0.15	I

Convergent and Discriminant Validity by Physical Function Short Forn

+ Strong (r 0.70);

Qual Life Res. Author manuscript; available in PMC 2016 October 25.

* Moderate (0.30< r <0.70);

– Weak (r 0.30);

** Non U.S. Born Only

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Table 5

Known Groups Validity, Score Differences in Physical Function (PF 16 short form)

Known Groups Comparisons	Hypothesized Lower Physical Function	Group 1: Mean (SD)	Group 2: Mean (SD)	Mean Group Difference [*]	Large sub-group differences ^{**} (±4 or more points vs. ref. group)	Citations
Demographic						
Sex: Women vs. Men	Women	43.8 (9.7)	46.6 (10.1)	-2.88		[35]
Age: Old (65–84) vs. Young (21–49)	Older	43.7 (9.9)	46.4 (9.6)	-2.70		[36]
Education: Low (<hs) (college)<="" high="" td="" vs.=""><td>Lower Education</td><td>41.0 (10.0)</td><td>48.6 (8.9)</td><td>-7.60</td><td></td><td>[37]</td></hs)>	Lower Education	41.0 (10.0)	48.6 (8.9)	-7.60		[37]
Clinical						
Site: Lung vs. Prostate	Lung Cancer	39.1 (8.5)	49.6 (9.5)	-10.6	21–50 years (–6.7) Asian (+4.3)	[38,39]
Stage: Advanced vs. Localized	Advanced Stage	41.1 (9.8)	45.5 (9.9)	-4.40		[38,40]
Treatment: Chemotherapy (Yes vs. No)	Chemotherapy	42.2 (9.0)	47.5 (10.1)	-5.35		[41,42]
Asthma (Yes vs. No)	History of Asthma	41.5 (10.1)	45.5 (9.8)	-4.00		[43]
COPD (Yes vs. No)	History of COPD	37.9 (9.0)	46.0 (9.7)	-8.10		[44]
Arthritis (Yes vs. No)	History of Arthritis	41.0 (9.2)	47.0 (9.8)	-6.00		[45]
Functional						
Difficulty Walking (Yes vs. No)	Any Dif. Walking	34.5 (6.3)	48.4 (8.4)	-13.9		[46]
Number of Conditions (2+ vs. 0)	Multi-morbidity	40.3 (9.2)	49.1 (9.1)	-8.82		[47]
Performance Status : >50% Bed Rest vs. Normal	Bed Rest	40.4 (7.2)	51.4 (8.2)	-11.0	Black (+4.2); Asian (+4.5)	[46]
Vigorous exercise: None vs. >4 Times a week	No Exercise	42.1 (9.1)	54.3 (8.4)	-12.2		[48]
* All known group differences p<0.001;						

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** Reference Groups: White (race/ethnicity), 65–84 (age)