

Original Article

Reliability and Validity of the Functional Assessment of Chronic Illness Therapy-Palliative Care (FACIT-Pal) Scale

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Abstract

The Functional Assessment of Chronic Illness Therapy (FACIT) system provides a general, multidimensional measure of health-related quality of life (FACT-G) that can be augmented with disease or symptom-specific subscales. The 19-item palliative care subscale of the FACIT system has undergone little psychometric evaluation to date. The aim of this paper is to report the internal consistency, factor structure, and construct validity of the instrument using the palliative care subscale (FACIT-Pal). Two hundred fifty-six persons with advanced cancer in a randomized trial testing a palliative care psychoeducational intervention completed the 46-item FACIT-Pal at baseline. Internal consistency was greater than 0.74 for all subscales and the total score. Seventeen of the 19 palliative care subscale items loaded onto the four-factor solution of the established core measure (FACT-G). As hypothesized, total scores were correlated with measures of symptom intensity ($r = -0.73$, $P < 0.001$) and depression ($r = -0.75$, $P < 0.001$). The FACIT-Pal was able to discriminate between participants who died within three months of completing the baseline and participants who lived for at least one year after completing the baseline assessment ($t = -4.05$, $P < 0.001$). The functional well-being subscale discriminated between participants who had a Karnofsky performance score of 70 and below and participants with a Karnofsky performance score of 80 and above ($t = 3.40$, $P < 0.001$). The findings support the internal consistency reliability and validity of the FACIT-Pal as a measure of health-related quality of life for persons with advanced cancer. J Pain Symptom Manage 2009;37:23–32. © 2009 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care, quality of life, psychometrics

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Introduction

Quality-of-life measurement is an important aspect of palliative care outcomes research given that maximizing quality of life is the overarching goal of palliative care.¹ Researchers have long debated appropriate definitions and conceptual models of the ambiguous construct of quality of life.²⁻⁴ Operational definitions of quality of life likewise vary widely. Some researchers advocate for measuring quality of life with a single item⁵ whereas others use multiple items to assess various quality of life domains such as physical, social, emotional,⁶ and spiritual well-being.⁷ Researchers have also designed quality-of-life instruments for specific populations of patients, for example, people with cancer⁸ or those in the last six months of life.⁹

The Functional Assessment of Chronic Illness Therapy (FACIT) system is an established, comprehensive set of health-related quality-of-life measures.^{10,11} In this system, quality of life is defined as “the extent to which one’s usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment.”¹¹(p.S11) The FACIT system includes a 27-item general measure, the Functional Assessment of Cancer Therapy (FACT-G),⁶ which can be combined with disease or treatment-specific subscales. The FACT-G captures four domains of health-related quality of life: physical, social, emotional, and functional well-being. (Note: The FACIT measurement system was formerly termed the Functional Assessment of Cancer Therapy or FACT. The FACT-G acronym was used to refer to the general measure [with the domains of physical, social/family, emotional and functional well-being] and is still in popular use today. The palliative care subscale was developed after the name changed and is referred to as the FACIT-Pal. Therefore, throughout this manuscript, we use FACT-G to refer to the general 27-item measure and FACIT-Pal to refer to the FACT-G plus the palliative care subscale.) The supplemental subscales measure additional concerns of a specific disease (e.g., breast cancer) or treatment (e.g., bone marrow transplantation). For example, the breast cancer subscale includes breast cancer-relevant items regarding lymphedema, body image, and fertility.¹² Researchers can,

therefore, customize the FACIT instrument to yield a general score (FACT-G), a total score (FACT-G plus a disease-specific subscale), or any of the individual subscale scores. The FACIT system has demonstrated adequate reliability and construct validity over a series of psychometric studies.^{6,10-16}

The FACIT system includes a 19-item palliative care subscale with items that pertain to persons with life-limiting illness (FACIT-Pal). Similar to the other scales in the FACIT system, the palliative care items were generated through interviews with patients and their family members. Greisinger and colleagues interviewed 194 patients who had various types of cancer and a life expectancy of six months or less.¹⁷ The interviews explored patients’ quality-of-life concerns such as feelings about family, hopefulness, and ability to openly express feelings to others. Consequently, the palliative care subscale has items that pertain to symptoms that can be seen in advanced illness (e.g., shortness of breath, constipation, xerostomia), family and friend relationships (e.g., feeling appreciated by family, being a burden to family, maintaining contact with friends), life closure issues (e.g., having “made peace” with others, feeling hopeful, making “each day count”), and decision making and communication abilities (e.g., ability to make decisions, think clearly, and openly discuss concerns). As with other disease-specific subscales that have been developed to complement the FACT-G, the FACIT-Pal items may not represent one homogeneous domain.¹³ For example, the item “I have been vomiting” likely reflects physical well-being whereas the item “I maintain contact with my friends” likely reflects social well-being. It is common practice to combine the score of the FACT-G with the disease-specific subscale and report one total score (in this case, referred to as the FACIT-Pal score).

The FACIT-Pal is one of a few tools that have been developed to assess quality of life for persons with advanced or life-limiting illness. The FACIT-Pal is similar to the EORTC QLQ-C15-PAL¹⁸ and the McGill Quality of Life Questionnaire¹⁹ in that they all have items that measure one’s physical symptoms, functional status, and emotional status. However, the latter two tools are shorter than the FACIT-Pal and do not contain items that specifically assess one’s

relationships with family and friends (though the McGill Quality of Life Questionnaire does ask about the degree to which one feels supported). The FACIT-Pal has fewer items that pertain to faith and spirituality when compared to the FACIT-Spiritual module²⁰ and fewer items that pertain to life completion and finding meaning in life when compared to the Missoula-VITAS Quality of Life Index.⁹

The FACIT-Pal has face validity in that it contains items that do appear relevant to persons living with advanced illness. However, the psychometrics of the FACIT-Pal have not been reported (Cella, 2005, personal communication). The purpose of this study was to assess the internal consistency reliability and validity of the FACIT-Pal for persons with advanced cancer.

Methods

Study Design

These analyses were conducted in the context of a randomized clinical trial (RCT) designed to test a palliative care intervention for persons with advanced cancer. The study was approved by the Institutional Review Board of Dartmouth College and all participants signed an informed consent document. The RCT tests the hypotheses that patients assigned to the palliative care intervention will experience greater quality of life, lower symptom intensity, lower health care utilization costs, and perceive a better match between care desired and care received as compared to participants randomized to usual care. Details of the RCT are described elsewhere²¹ and recruitment is ongoing. Baseline assessments were used to evaluate the validity and internal consistency reliability of the FACIT-Pal, the primary outcome measure of quality of life. The research question guiding these analyses was "Is the FACIT-Pal a reliable and valid indicator of health-related quality of life for the population of persons with advanced cancer?"

Participants and Procedures

Persons newly diagnosed with advanced cancer were identified through weekly tumor board meetings. Inclusion criteria were a diagnosis of one of the following: unresectable Stage III or IV gastrointestinal cancer; or Stage

IIIB or IV non-small cell lung cancer or extensive small cell lung cancer; or Stage IV breast cancer with poor prognostic indicators (i.e., prognosis of two years or less and may have had the following: visceral crisis, lung or liver metastasis, estrogen receptor negative [ER-], human epidermal growth factor receptor 2 positive [HER 2 neu +], cancer recurrence within two years of first treatment or recurred on treatment); or Stage IV genitourinary cancer (prostate cancer inclusion is limited to persons with hormone refractory prostate cancer). Patients were excluded if they were unable to pass a cognitive screen (i.e., <17 on the Adult Lifestyles and Function Interview [ALFI-MMSE]²²), or were engaged in active substance use (>14 drinks per week), or had a diagnosis of schizophrenia or bipolar disorder.

At the time of this analysis, 256 participants had completed the baseline assessment. Diagnosis, disease stage, and Karnofsky performance status (KPS) were obtained via chart review. KPS is assessed by nursing assistants and verified by the oncology clinician during each office visit. Demographics of the participants are listed in Table 1.

Measures

FACIT-Pal. The FACIT-Pal is a 46-item measure of self-reported health-related quality of life. The FACIT-Pal contains the 27-item FACT-G that measures four domains of quality of life: physical well-being (seven items), social/family well-being (seven items), emotional well-being (six items), and functional well-being (seven items). The FACT-G has a one-week test-retest reliability of $r = 0.92$.⁶ Internal consistency reliability of the subscales ranges from $\alpha = 0.69$ (social well-being) to $\alpha = 0.82$ (physical well-being), with an overall internal consistency of $\alpha = 0.89$ for the entire 27 items. Construct validity of the FACT-G is supported by relationships with mood (as measured by the brief Profile of Mood States²³), activity level (as measured by the Eastern Cooperative Oncology Group performance status rating²⁴), and another quality-of-life measure (i.e., the Functional Living Index-Cancer⁸). As expected, the FACT-G does not correlate with social desirability (as measured by the Marlowe-Crowne Social Desirability Scale²⁵). Construct validity was demonstrated

Table 1
Participant Characteristics (n = 256)

	n (%)
Age in years; mean (SD)	65.4 (10.9)
Gender	
Male	156 (61)
Primary disease site	
GI	106 (42)
Lung	84 (33)
GU	37 (14)
Breast	29 (11)
Marital status	
Never married	19 (7)
Married or living with partner	176 (69)
Divorced or separated	33 (13)
Widowed	25 (10)
Unknown	3 (1)
Education	
Less than high school graduate	34 (13)
High school graduate or GED	149 (58)
College graduate	69 (27)
Unknown	4 (2)
Ethnicity	
Not Hispanic	252 (98)
Unknown	4 (2)
Race	
White	252 (98)
American Indian/Alaska Native	2 (1)
Other	2 (1)

by distinguishing between groups known to differ on stage of disease, performance status, and need for emotional support.

In addition to the 27-item FACT-G, the FACIT-Pal adds 19 items that were generated according to concerns reported via interviews with persons with advanced cancer.¹⁷ These 19 items form the palliative care subscale. It has become common practice to use the physical well-being and functional well-being subscales in combination with a disease-specific subscale as a “trial outcome index” (TOI), as they have been found to be most sensitive to disease symptomatology and the impact of symptoms on ability to function.¹⁰ Scores range from 0 to 184 for the FACIT-Pal, 0 to 76 for the palliative scale alone, and 0 to 132 for the TOI. Higher scores indicate better quality of life.

Edmonton Symptom Assessment Scale (ESAS). The ESAS is a self-report measure of symptom intensity.²⁶ The ESAS assesses nine symptoms rated by severity on visual analogue scales for each symptom (10 cm line). These include pain, activity, nausea, depression, anxiety, drowsiness, appetite, sense of well-being, and shortness of

breath. The sum of responses to these nine symptoms, in millimeters, is the ESAS total score. Because the current study used an optical scanning method for data collection, the scales were redesigned as Likert scales with discrete check boxes (0–10). The ESAS was developed for a palliative care population²⁶ and validated in a general cancer population.²⁷ In this latter validation study, internal consistency reliability was found to be 0.79 for the ESAS and two-day test-retest reliability was likewise adequate, showing significant Spearman correlations between ratings of each item. Construct validity was supported by significant correlations between ESAS items and similar items on the Memorial Symptom Assessment Scale²⁸ and the FACT-G. Higher scores indicate greater symptom intensity.

Center for Epidemiological Studies-Depression (CES-D). The CES-D is a 20-item self-report measure of depressive symptoms that has been widely used in epidemiological studies of depression.²⁹ Participants are asked to rate how frequently they have experienced each symptom on a four-point scale ranging from “Rarely or none of the time” to “Most or all of the time.” Internal consistency reliability was consistently greater than $\alpha = 0.84$ during reliability studies in both general population and psychiatric patient samples and the tool was found to discriminate between those two samples. Construct validity is supported by correlations with other measures of depression and psychopathology. Higher scores indicate more severe depressive symptoms.

KPS Scale. The KPS is a 10-point scale designed to measure a person’s ability to perform daily tasks.³⁰ Higher scores indicate higher performance ability. In this study, the score was documented as part of the standard procedure in the oncology or palliative care service by the treating clinician and obtained by medical record review by the research assistant. The KPS has strong interrater reliability ($r = 0.89$).³¹ Construct validity has been demonstrated by close associations with other standard measures of daily function.^{31,32} The KPS has also been shown to accurately predict survival time.³²

Analyses

Internal Consistency Reliability. Internal consistency is a measure of reliability that assesses the degree to which the items are related to

each other and are measuring a unified construct.³³ Internal consistency reliability was evaluated with Cronbach's alpha for each subscale, for the FACT-G, for the FACIT-Pal, and the TOI. Based on the published studies of the FACIT system, we hypothesized that internal consistency reliability of all of the scales would be greater than $\alpha = 0.70$.

Factor Structure. Factor analyses were conducted to assess the degree to which the 19-item palliative care subscale provided any unique information when added to the FACT-G. Although the vast majority of items were answered by most participants, three items had more than 10 missing observations (FACT-G Partner support: 16 missing; FACT-G Sex life: 114 missing; PAL Reconcile with others: 20 missing). For all factor analyses, missing data were handled by substitution of the item mean. We explored the factor structure of the 46-item FACIT-Pal in two stages. First, we sought to confirm the four-factor structure of the 27-item FACT-G in our sample by using a principal component analysis with oblimin rotation. Despite the potential for a slight reduction in the replicability of the solution as a consequence of estimating factor intercorrelations as opposed to artificially restricting their values to zero, oblique rotation was chosen on the basis of theorized and empirically observed associations among the FACIT subscales. Following analysis of the FACT-G, we conducted a principal components analysis of the full 46-item FACIT-Pal. Because the scree plot suggested five factors, the final analysis was restricted to a five-factor solution. All five factors had an eigenvalue >1 .

Validity. To explore the construct validity of the FACIT-Pal, we first correlated the subscales, FACT-G, FACIT-Pal, and TOI with the ESAS and CES-D (Pearson's correlations). We hypothesized that overall quality of life and physical, functional, and palliative subscales would be related to symptom intensity and depression (convergent validity displayed by negative correlations between the measures). We assessed the sensitivity of the measure by testing its ability to discriminate between known groups. We identified participants who died within three months of completing the baseline assessment ($n = 34$) and participants who lived for at least one year after completing the baseline assessment ($n = 33$) and

conducted a *t*-test to determine if their scores were significantly different on the subscales, the FACT-G, the FACIT-Pal, and TOI. Given that people with advanced cancer generally experience multiple symptoms and physical decline before death,^{34–36} we hypothesized that the groups would differ on the physical, functional, and palliative subscales and the FACT-G, FACIT-Pal, and TOI. Additionally, we tested to see if persons with higher performance status had higher quality of life. We hypothesized that participants with a KPS score of ≥ 80 would have higher quality of life than participants with a KPS score of ≤ 70 . A conservative *P*-value of 0.001 was adopted as a cutoff for statistical significance, as we conducted 40 comparisons for the validity analyses (0.05 divided by 40 = 0.00125).

Results

Reliability

Internal consistency reliability of the subscales and composite scores are presented in Table 2. Cronbach's alpha was lowest for the social well-being subscale ($\alpha = 0.75$) and highest for the FACIT-Pal ($\alpha = 0.93$). The palliative care subscale demonstrated adequate internal consistency reliability at $\alpha = 0.82$.

Factor Structure

The principal components analysis of the FACT-G generally replicated the original authors' conceptualization of the four domains. The factor analysis of the 46-item FACIT-Pal is presented in Table 3. The Kaiser-Meyer-Olkin

Table 2
Internal Consistency of Total Score, Trial Outcome Index, and Subscales ($n = 256$)

Scale	Number of Items	Range of Scores	Mean (SD)	Alpha
Physical well-being	7	2–28	19.4 (5.7)	0.85
Social/family well-being	7	3–28	22.5 (4.6)	0.75
Emotional well-being	6	3–24	17.6 (4.7)	0.80
Functional well-being	7	0–28	15.7 (6.1)	0.84
Palliative subscale	19	27–76	56.6 (10.2)	0.82
FACT-G	27	34–106	75.3 (15.6)	0.89
FACIT-Pal	46	61–179	132.0 (24.7)	0.93
TOI ^a	33	43–129	91.8 (19.2)	0.91

^aTOI = Trial Outcome Index and comprises Physical, Functional, and Palliative subscales.

Table 3
Principal Components Analysis of FACIT-Pal Restricted to Five Factors—Rotated Pattern Matrix ($n = 256$)

	Component				
	Physical Well-Being	Functional Well-Being	Emotional Well-Being	Social Well-Being	Clarity of Thought and Decisions
Energy	0.50	0.44	0.04	-0.15	-0.07
Nausea	0.77	0.01	0.04	-0.04	-0.14
Trouble meeting family needs	0.50	0.33	-0.05	-0.11	0.10
Pain	0.46	0.00	-0.17	0.11	0.37
Side effects	0.73	-0.14	-0.07	0.07	-0.03
Feel ill	0.76	0.01	-0.12	0.00	0.10
Spend time in bed	0.61	0.14	-0.07	0.06	-0.03
Close to friends	-0.20	0.31	-0.01	0.56	0.38
Family emotional support	0.07	-0.06	0.07	0.73	0.02
Friend support	-0.21	0.36	0.07	0.60	0.38
Family accepted illness	-0.06	-0.03	-0.16	0.61	-0.13
Family communication	0.07	-0.16	-0.11	0.72	-0.11
Partner support	0.03	0.07	0.24	0.48	-0.09
Sex life	0.08	0.08	-0.15	0.03	0.07
Sad	0.15	0.08	-0.58	0.08	-0.10
Coping	0.07	0.19	-0.20	0.11	-0.37
Losing hope	0.10	0.10	-0.56	0.05	-0.06
Nervous	-0.04	0.02	-0.79	0.00	0.01
Worry about dying	-0.07	-0.08	-0.85	-0.03	-0.05
Worry about getting worse	0.06	-0.04	-0.84	-0.07	0.07
Able to work	0.11	0.73	0.09	-0.12	0.04
Work is fulfilling	-0.10	0.76	0.03	0.01	0.13
Enjoy life	0.06	0.70	-0.10	0.10	-0.08
Accept illness	-0.06	0.16	-0.22	0.31	-0.46
Sleep well	0.21	0.24	-0.08	0.22	-0.10
Enjoy things for fun	0.19	0.66	-0.00	0.06	0.00
Quality of life	0.19	0.64	-0.18	0.02	-0.12
PAL—maintain contact with friends	-0.02	0.45	0.12	0.45	0.26
PAL—family members will take on my responsibilities	0.02	-0.15	-0.08	0.67	0.10
PAL—family appreciates me	0.05	-0.17	-0.11	0.71	0.04
PAL—feel like burden to family	0.15	0.37	-0.26	-0.17	0.13
PAL—have been short of breath	0.15	0.20	0.01	0.18	0.39
PAL—am constipated	0.40	-0.06	-0.12	0.03	0.22
PAL—am losing weight	0.50	0.10	0.02	-0.05	-0.01
PAL—have been vomiting	0.66	-0.06	0.19	0.04	-0.09
PAL—have swelling in parts of body	0.28	0.09	-0.10	0.06	0.36
PAL—mouth and throat are dry	0.38	0.03	-0.13	0.03	0.04
PAL—feel independent	-0.02	0.72	-0.14	-0.09	-0.10
PAL—feel useful	0.03	0.79	-0.10	-0.05	-0.10
PAL—make each day count	-0.02	0.60	-0.13	0.16	-0.10
PAL—have peace of mind	-0.11	0.40	-0.50	0.15	-0.10
PAL—feel hopeful	-0.04	0.42	-0.36	0.22	-0.03
PAL—able to make decisions	0.13	0.26	-0.12	0.25	-0.57
PAL—thinking is clear	0.18	0.29	0.01	0.22	-0.53
PAL—have been able to reconcile with others	0.03	0.17	0.03	0.48	-0.04
PAL—openly discuss concerns	0.02	0.08	-0.06	0.56	-0.23

Extraction: Principal Component Analysis; Rotation method: Oblimin with Kaiser; Normalization (rotation converged in nine iterations). Values ≥ 0.50 in bold.

measure of sampling adequacy was 0.86 and Bartlett's test of sphericity was significant, with Chi-squared of 2,733.66. The five-factor solution suggested by the scree plot explained 48% of the variance. Four of the factors were essentially the same as those observed in the analysis of the FACT-G. Two palliative care subscale items ("I am able to make decisions" and "My thinking is clear") formed a fifth factor. The majority of the remaining PAL items loaded at or

above 0.50 on the established four domains of the FACT-G.

Construct Validity

Correlations between the FACIT scales and the ESAS and CES-D are presented in Table 4. Both symptom intensity (per ESAS) and depressive symptoms (per CES-D) were significantly related to all subscales and composite scales of the FACIT-Pal. As hypothesized, the

Table 4
Convergent Validity of FACIT-Pal ($n = 256$)

Scale	ESAS ($P < 0.001$)	CES-D ($P < 0.001$)
Physical well-being	-0.72	-0.56
Social/family well-being	-0.24	-0.32
Emotional well-being	-0.47	-0.66
Functional well-being	-0.57	-0.60
Palliative subscale	-0.68	-0.69
FACT-G	-0.71	-0.74
FACIT-Pal	-0.73	-0.75
TOI ^a	-0.76	-0.72

Pearson correlation coefficients.

^aTOI = Trial Outcome Index and comprises Physical, Functional, and Palliative subscales.

group of participants who died within three months of completing the baseline assessment had significantly lower scores than the participants who were alive at one year after completing the baseline assessment for all scales except the emotional and social well-being subscales (these latter scales had small effect sizes that were nonsignificant in this subsample of participants). Statistics are presented in Table 5. Table 6 demonstrates that participants with a higher performance status (as measured by KPS) had higher functional well-being when compared to participants with lower performance status ($t = 3.40$, $P < 0.001$).

Discussion

Overall, these analyses provide evidence to support the internal consistency reliability and validity of the palliative care subscale for use in this population. The alpha coefficient for the palliative care subscale ($\alpha = 0.82$) is similar to the alphas reported for other FACIT disease-specific subscales (e.g., the esophageal¹⁶ or taxane³⁷ subscales) and are above

the 0.70 recommendation advocated by some instrument developers.³⁸ When combined with the FACT-G, the alpha increases to 0.93 for the FACIT-Pal. This internal consistency is somewhat high for an overall instrument score, in light of the fact that the tool has multiple domains (i.e., the presence of subscales suggests that items will be assessing different domains and may not all be highly related). However, the alpha of 0.93 is not surprising, as alpha coefficients tend to increase as the number of items increases, as long as the items are positively correlated with each other.³³ This suggests that the various items and domains are tapping into a unifying construct of quality of life.

The factor analysis revealed that most of the palliative care subscale items do indeed reflect the established domains of FACT-G. This is consistent with the purpose of the FACIT system, that is, to have a core measure that is augmented by subscales reflecting issues that may be pertinent to a particular disease or symptom. The factor analysis suggests that two items of the palliative care subscale are tapping into a domain not fully covered by the current FACT-G. The items about clarity of thinking and ability to make decisions may, therefore, play a unique and interesting role in well-being for this sample of people with advanced cancer.

Regarding construct validity, the FACIT-Pal is operating in a coherent and conceptually appropriate manner in this sample. Quality of life, as measured by both the complete FACIT-Pal and the 19-item palliative subscale, was lower for participants with higher symptom intensity and with more depressive symptoms. Both the FACIT-Pal and the FACT-G

Table 5
Construct Validity of FACIT-Pal: Ability to Distinguish Between Groups Known to Differ Regarding Prognosis

Scale	Died Within Three Months of Baseline ($n = 34$)	Lived At Least One Year After Baseline ($n = 33$)	df	t Statistic	P -Value	Effect Size d
	(Mean \pm SD)	(Mean \pm SD)				
Physical	16.5 (6)	21.3 (4.2)	65	-3.78	<0.001	-0.94
Social	22.0 (5.2)	23.4 (3.6)	65	-1.34	0.18	-0.33
Emotional	15.8 (4.8)	17.6 (4.3)	65	-1.62	0.11	-0.40
Functional	12.4 (6)	17.5 (5.7)	65	-3.51	<0.001	-0.87
Palliative	51.2 (11)	60.6 (7.9)	65	-3.96	<0.001	-0.98
FACT-G	66.7 (15)	80.0 (13)	65	-3.76	<0.001	-0.93
FACIT-Pal	117.9 (25)	140.6 (20)	65	-4.05	<0.001	-1.00
TOI ^a	80.2 (19)	99.5 (14)	65	-4.56	<0.001	-1.13

^aTOI = Trial Outcome Index and comprises Physical, Functional, and Palliative subscales.

Table 6
**Construct Validity of FACIT-Pal: Ability to Distinguish between Groups Known to Differ
 Regarding Performance Status**

Scale	Karnofsky Performance Scale Score 70 or Below; (<i>n</i> = 56) (Mean +/- SD)	Karnofsky Performance Scale Score 80 or Above; (<i>n</i> = 127) (Mean +/- SD)	df	<i>t</i> Statistic	<i>P</i> value	Effect size <i>d</i>
Physical	18.1 (5.7)	19.5 (5.9)	181	1.44	0.15	0.23
Social	22.8 (4.5)	22.8 (4.5)	181	0.02	0.98	0.00
Emotional	17.2 (5.2)	17.4 (4.5)	181	0.23	0.82	0.04
Functional	13.7 (5.7)	16.9 (5.9)	181	3.40	<0.001	0.55
Palliative	53.5 (10.3)	57.7 (9.6)	181	2.65	0.009	0.43
FACT-G	71.8 (16.1)	76.6 (15.4)	181	1.87	0.062	0.30
FACIT-Pal	125.3 (25.2)	134.3 (24)	181	2.29	0.023	0.37
TOI ^a	85.3 (19.2)	94 (18.4)	181	2.89	0.004	0.47

^aTOI = Trial Outcome Index comprises Physical, Functional, and Palliative subscales.

were able to distinguish between known groups that differed on prognosis. Additionally, the palliative care subscale itself was able to detect this difference. Neither the FACIT-Pal nor the palliative care subscale was able to distinguish between groups that differed on performance status; however, trends were seen in both measures (small effect sizes with *P*-values <0.05 that did not reach statistical significance given the Bonferroni correction made to account for multiple comparisons). As one would expect given that the KPS score reflects performance status, the functional well-being subscale was able to distinguish between the participants with higher KPS scores and those with lower KPS scores.

It is important to note that the data for these analyses were collected within the context of an RCT. The RCT was designed to testing the efficacy of an intervention as opposed to test the psychometrics of the FACIT-Pal. Therefore, we are unable to report on test–retest reliability (the degree to which the tool consistently provides the same score for individuals who have not experienced actual change in the variable being measured) and do not have measures to explore divergent validity of the tool. Additionally, this culturally homogeneous sample reflects people who agreed to participate in an RCT and were able to complete an assessment packet that took approximately 20 minutes to finish. Although the FACIT-Pal is operating in a coherent way for this sample, the analyses do suggest directions for future analyses and instrument development. First, it is uncertain as to how generalizable the findings are to a more racially and ethnically diverse

population. As there is evidence to suggest that health-related quality of life varies among different cultures,³⁹ it would be helpful to replicate these validation analyses with ethnically diverse samples. Second, although there is a debate regarding the criteria to use to judge the adequacy of sample size when conducting factor analyses,⁴⁰ we recognize that some might judge our sample minimally adequate. Once again, replication in other diverse and larger samples would help us to understand the psychometric properties of the FACIT-Pal.

Finally, it would be interesting to explore the parsimony of the measure, given the value of using brief measures in a study of people with advanced cancer. Although high internal consistency is important, it suggests that items are intercorrelated and it is possible that some items may be redundant and could be dropped without reducing the validity of the tool. The FACT-G, the FACIT-Pal, and the TOI generally tell the same story in the validity analyses and one could argue that the TOI alone does an adequate job of capturing quality of life in this population. However, using the TOI alone negates two important advantages of the FACIT-Pal. First, the TOI has some items related to social well-being, but does not include the social well-being domain. The focus on social well-being is a factor that distinguishes the FACIT-Pal from shorter measures such as the McGill or the EORTC. Second, when one uses the full FACIT-Pal as opposed to the TOI, one can then also calculate a FACT-G score that can be used to compare a sample to other studies that used the core FACT-G.

In summary, the FACIT-Pal is longer than other quality-of-life measures for this population,

yet the full scale offers the advantages of focusing on social well-being and allowing comparison to other studies using the FACT-G. If participant burden is not a significant concern, the FACIT-Pal appears to be a reliable and valid measure to use with persons with advanced cancer. Further research should be done to replicate the findings in culturally diverse and larger samples from the palliative care population.

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