Published in final edited form as:
Cancer. 2013 January 15; 119(2): 429–437. doi:10.1002/cncr.27688.

General Population Norms for the Functional Assessment of Cancer Therapy – Kidney Symptom Index (FKSI)

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Abstract

Background—Metastatic renal cell cancer is associated with poor long-term survival and has no cure. Traditional clinical endpoints are best supplemented by patient-reported outcomes designed to assess symptoms and function. We obtained normative data on the NCCN - Functional Assessment of Cancer Therapy – Kidney Symptom Index (NFKSI) to aid in score interpretation and planning of future trials.

Methods—General population data were obtained from 2000 respondents, who completed the NFKSI-19, as well the SF-36 and the PROMIS-29, both general health status measures. Basic demographic and self-reported comorbidity data were also collected.

Results—The sample was 50% female, 85.7% Caucasian, with an equal distribution across age bands 18–75+. Most respondents (62.8%) had more than a high school education and reported an ECOG performance status of normal activity without symptoms (63.4%). Score distributions on the NFKSI-19, its subscales, and individual items are summarized.

Conclusions—The NFKSI-19 and its subscales now have scores for the general US population, allowing comparability to generic questionnaires such as the SF-36 and PROMIS-29. These data can be used to guide treatment expectations and plan future comparative effectiveness research using the scales.

Keywords

quality of life; questionnaire; renal cell cancer; general population

BACKGROUND

Although there are new, effective agents in the treatment of metastatic renal cell cancer, it is still associated with poor long-term survival and has no cure. The disease and its treatment can have significant impact on a patient, making relief of symptoms and maintenance of function key goals of any medical intervention.[1,2] Traditional endpoints in clinical oncology, such as patient survival and tumor response, are important, but must be supplemented by patient-reported outcomes (PROs) designed to assess symptoms and function. One such

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The authors have no additional financial disclosures related to this manuscript.

PRO measure is the Functional Assessment of Cancer Therapy –Kidney Symptom Index (FKSI).[3]

The 15-item Functional Assessment of Cancer Therapy – Kidney Symptom Index (FKSI-15)[3] and its 9-item subset of disease-related symptoms (FKSI-DRS)[4] were originally developed with input from patients with kidney cancer and clinical experts,[5] who prioritized important symptoms and concerns.[6] We recently sought to further verify adequate coverage of items to address regulatory guidance on the development of patient reported outcomes.[7] To do so, we solicited open-ended input from advanced kidney cancer patients. Participants' responses in that study were used to modify the original FKSI instrument to produce the NCCN-FKSI-19 (NFKSI-19), assessing symptoms of importance to patients with advanced kidney cancer.[8] The NFKSI-19 contains all of the items of the original FKSI-15 and the FKSI-DRS. Open-ended patient input as part of the NFKSI-19 development resulted in the addition of items on weakness, nausea, diarrhea, and being content with quality of life to the assessment (see Table 4).

Currently FKSI scores can be used, for example, to compare groups within a cross-sectional study or to compare outcomes between randomized groups in a clinical trial. However, scores obtained in any given study are not easily referenced to a larger population due to a lack of normative data. External reference data on the same instrument in larger samples can place the results of a specific study in context. To that end, the objective of the present project was to obtain general population reference values for the FKSI to aid in the interpretation and understanding of clinical research data.

We present normative data for the FKSI based on data from a sample of the general U.S. adult population. These norms enhance the usefulness and interpretability of the FKSI by allowing scores obtained by patients to be compared to those of a reference group, by offering data on the distribution of scores, and through use of T-scores, allowing comparisons of scores measured on different scales. Furthermore, general population normative data on the FKSI allows for calculation of standardized effect sizes, which facilitate comparisons of effect sizes across studies.

RESEARCH METHODS

Participant recruitment and survey administration

We contracted with an internet panel company, Toluna/Greenfield, for participant recruitment and data collection. Toluna/Greenfield maintains 33 actively managed proprietary panel communities around the world, exclusively for marketing and opinion research. Members are recruited from a broad array of online and offline approaches that best represent the online community as a whole in each country.

Toluna/Greenfield employs several procedures to confirm the identity of their panelists, some of which are outlined below. At registration, a user's email must be both valid and unique within the panel. Additionally, the US panel is checked regularly against third party databases for the verification of the existence of the panelist at the address used at enrollment. They also regularly run consistency checks between the basic registration data given and ongoing profiling data, and they include questions in profiling questionnaires to identify inconsistencies in responses.

Toluna/Greenfield sent email invitations to eligible panel members from among its 536,000 US members in order to obtain data from 2000 participants. Panelists were given a link that took them to a secure website where the survey was administered, after they provided

consent. Participants' survey responses cannot be linked in any way to any identifying information.

Measures

Participants completed the NFKSI-19, the SF-36 (version 2), the PROMIS-29, as well as a brief set of demographic questions and items asking about self-reported chronic conditions.

The NFKSI-19 is described above and in a recent publication (see Table 4 for item content).[8] From the NFKSI-19, one can derive scores for the original 15-item FKSI (FKSI-15), the original 9-item Disease-Related Symptoms Scale (FKSI-DRS-9), and the expanded 13-item Disease-Related Symptoms Scale (NFKSI-DRS-13) drawn from the NFKSI-19. (A 12-item DRS focused on physical symptoms can also be derived.) Higher scores are better; lower scores indicate a more symptomatic respondent. The NFKSI-19 and scoring instructions can be found at www.facit.org.

The SF-36 v.2[9] is one of the most widely used general measures of health status. The 36-item instrument provides a profile of eight health subscale scores and two aggregate higher-order scores from these eight subscales – physical component summary (PCS) and mental component summary (MCS) – which explain 80–85% of the reliable variance. Higher scores represent better health-related quality of life.

The Patient Reported Outcomes Measurement Information System (PROMIS) network (www.nihpromis.org) developed several profile measures, such as the PROMIS-29, which assesses: fatigue, depression, anxiety, sleep, physical function, social function, and pain (intensity and interference with function).[10] Norm-based scores are available so that scores of 50 ± 10 represent the Mean ± SD of the general population. Higher scores on the symptom-oriented domains indicated worse symptoms and higher scores on the function-oriented domains indicate better functioning.

Sample

Data collection occurred in fall, 2011. A total of 2000 participants were successfully surveyed from the internet panel of the general population. As seen in Table 1, we established quotas by gender and age, leading to an equal gender split and equal age bands of 18–29, 30–44, 45–59, 60–74, and 75 and above. Our sample was primarily non-Hispanic (94.5%), white (85.7%), and married (46.8%). Many respondents had some college or a technical degree (41.9%) and more than half had an income of less than $40,000. Most respondents reported that they had normal activity without symptoms (63.4%); though, notably, 30.8% indicated experiencing symptoms that did not require bed rest during the waking day.

We polled respondents regarding specific health conditions using an investigator-developed checklist. A summary of those data are provided in Table 2. Many respondents (22.4%) reported no comorbid conditions and just over a third (34.7%) reported 1 or 2 comorbid conditions. The most common conditions endorsed were rheumatism (e.g., arthritis; n=628) and depression (n=503).

Data analysis

Responses on the FKSI were scored using the standard FACT scoring methodology. If greater than 50% of items were completed the FKSI scores were calculated as the sum of the item responses divided by the number of items completed multiplied by the total number of items in the scale (e.g., 19 in the case of the NFKSI-19). If fewer than 50% of the items were completed, the scores were considered missing.

Within each age and gender subgroup, on the FKSI, we calculated mean, standard deviation, percentage scoring the lowest possible score, percentage scoring the highest possible score, the lowest and highest observed scores, the 25th, 50th (median), and 75th percentiles.

We also assessed how well our sample represented the U.S. population by comparing the age, gender, and race to data from the 2000 U.S. Census. We identified a subset of our sample that matched the demographic profile of the general US population using disproportionate sampling ("raking") in the manner applied by Liu et al.[11] Descriptive statistics of the FKSI scores were recalculated for this subset; these data are not presented here but are available from the authors.

RESULTS

Table 3 presents normative general population scores across the total sample and by gender for the NFKSI-19 and its subscales. (Normative scores by age band are available upon request.) The NFKSI-19 (range = 0–76) had a median value of 62 and mean of 59.8 (SD=11.2). The FKSI-15 (range = 0–60) had a median value of 48 and a mean of 46.6 (SD=9). The NFKSI-DRS-13 (range = 0–52) had a median value of 43 and a mean of 41.0 (SD=8). Finally, the FKSI-DRS-9 (range = 0–36) had a median value of 31 and a mean of 29.5 (SD = 5.6). Table 4 shows individual item statistics.

Respondents also completed the SF-36 version 2 and the PROMIS-29 instruments. As seen in Table 5, scores on the SF-36 mental and physical summary components as well as the PROMIS physical function, anxiety, depression, fatigue, sleep disturbance, satisfaction with social role, and the pain interference scales were quite comparable to the respective normative data for those scales. Symptom reports on the FKSI scales were significantly correlated with the SF-36 and PROMIS-29 scales (Spearman correlations = 0.49 – 0.72), suggesting that while there is shared variance between the FKSI and the general measures, the FKSI scales also measure unique aspects of symptom experience.

We designed our study to purposefully sample for an equal split by gender and across specified age bands. We also reviewed FKSI scores after defining a subset of 1,247 from the total sample of 2000 that approximated age and gender percentages from the 2000 US Census figures.[11] We found no meaningful differences between the complete sample and the Census-based subsample (n=1247) on FKSI, SF-36, or PROMIS averages. Most score differences were on the order of 1 point or less.

Many of our respondents reported having at least one chronic or comorbid medical conditions. To provide a theoretical upper bound for FKSI scores, Table 6 summarizes total FKSI and FKSI-DRS scores for the sample of 448 respondents who reported no comorbid medical conditions, the 140 respondents who reported having only hypertension, and the combined group (n=588) of individuals we expected would be a relatively healthy US sample without a major medical condition. As expected, these scores were higher (better) than those derived from the entire sample, which included people with one or more diagnosed diseases or disorders.

To facilitate comparisons of patient data to these general population scores, we have included a T-score look up table (Table 7) for the NFKSI subscales using data from our complete normative group (N=2000). The T-score is a linear conversion of the raw scores using the following equation: T-score = [(raw score − raw score mean)/raw score SD] * 10 ± 50.

Differences in FKSI scale scores across categories of patient-reported ECOG performance status and number of comorbid conditions are presented in Table 8. Differences in scores

across the scales were statistically significant ($p < .0001$) between adjacent categories in almost all cases. The only exceptions were between the two worst categories of ECOG performance status, which were rated similarly across the summary measures.

SUMMARY

We have presented normative data for the FKSI and related symptom indexes, which can be useful for planning trials and for interpreting data from clinical trials that use the scale. In this paper, we provide general population normative data for the NCCN-Functional Assessment of Cancer Therapy - Kidney Symptom Index and its derivatives, which will aid in the interpretation of future clinical and research data that use these scales. We also provide validity data to show that in the general population, symptom severity increases with worsening ECOG performance status and with increased medical comorbidity. FKSI scores also measure aspects of health-related quality of life not assessed using the SF-36 or PROMIS-29, such as nausea, diarrhea, bone pain, and being bothered by fevers.

We provide raw score distributions for our general populations FKSI data and also provide a convenient look-up table to convert raw score values to the T-score metric. T-scores have the advantage of being easy to use and interpret (M=50, SD=10) and can facilitate comparisons with other scales when placed on the same metric. A difference in T-scores of one half standard deviation, or 5 points on the T-score template can be interpreted as likely to reflect a meaningful difference, with the understanding that the minimally important difference is likely less than 5 points.[12] For example, if the mean raw score for a patient sample corresponds to a T-score less than 45 or greater than 55, one might conclude that the patient sample symptoms are meaningfully different from those in the general US population. Our sample was drawn from an online panel similar to the US general population on several demographic characteristics, but future testing should address the generalizability of such data to individuals who do not have internet access.

Review of recent findings may be useful for illustration purposes. For example, Cella et al[2] investigated the health-related quality of life from a phase III trial of 750 patients with metastatic renal cell carcinoma, randomized to either first-line oral sunitinib or subcutaneous interferon-α. The model mean of post-baseline assessments on the primary symptom endpoint, the FKSI-DRS, indicated that patients on sunitinib fared better than those on interferon- α (29.9 vs 27.53, raw scale). Referencing Table 7, one can also appreciate that while there were mean differences between gtreatment arms, they are also within a half standard deviation of the general population mean (i.e. they were not extremely symptomatic). In another study, Cella and colleagues,[13] evaluated the effect of second-line axinitib versus sorafenib on kidney-cancer-specific symptoms and functioning as part of an open-label, randomized Phase III trial of 723 patients with metastatic renal cell carcinoma. The mean overall post-baseline scores were not significantly different between the axitinib versus the sorafenib arms on the FKSI-15 (42.2 vs 41.9; least squares mean) or the FKSI-DRS (28.6 vs. 28.4; least squares mean). The FKSI-15 scores of patients in this trial were meaningfully different than the general population norms, at just over half of a standard deviation of the population mean, and the patients' FKSI Disease Related Symptom subscale scores were within 1/3 standard deviation of the general population mean (i.e. comparable to the general population).

This is the first available general population data for the NFKSI-19 and its subscales. While the symptoms assessed on the FKSI scales are common in patients with renal cell carcinoma, this study illustrates that the questions asked in the FKSI are potentially applicable to all people, with or without a medical condition. They are symptoms experienced to some degree in the general population. These data can be used to guide

treatment expectations; in some cases, maintaining patient NFKSI scores at a stable level may be more realistic than expecting improvement, especially in areas where patients are similar to the general population at trial onset. In this report, we summarized general population normative data for the FKSI that should be useful in guiding future comparative effectiveness research using the scales.

Acknowledgments

This study was sponsored by Pfizer Inc. Pfizer paid Northwestern University for the scientific and consultative expertise of Zeeshan Butt, John Peipert, Kimberly Webster, and David Cella in connection with the development of this manuscript. John Peipert is now affiliated with the Division of General Medical Sciences, Washington University School of Medicine. Zeeshan Butt was also supported in part by grant KL2RR025740 from the National Center for Research Resources (National Institutes of Health). Connie Chen is an employee and stockholder of Pfizer, Inc.

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Table 1

General U.S. Population Sample (*N*=2000)

	n	%
Gender		
Female	1000	50.0
Male	1000	50.0
Age		
18–29	400	20.0
30–44	400	20.0
45–59	400	20.0
60–74	400	20.0
75+	400	20.0
Ethnicity		
Hispanic	110	5.5
Non-Hispanic	1890	94.5
Race*		
White	1713	85.7
Black or African American	160	8.0
American Indian/Alaska Native	34	1.7
Asian	74	3.7
Native Hawaiian or Other Pacific Islander	5	0.3
Other	55	2.8
Marital Status		
Never Married	401	20.1
Married	935	46.8
In committed relationship	189	9.5
Separated	44	2.2
Divorced	231	11.6
Widowed	200	10.0
Education		
< High School Grad/GED	68	3.6
High School Grad/GED	501	25.1
Some college/Technical degree/AA	837	41.9
College degree (BA/BS)	418	20.9
Advanced degree (MA, MS, MBA, Ph.D., MD, JD)	176	8.8
Patient ECOG Performance Status		
I have normal activity without symptoms	1268	63.4
I have some symptoms but do not require bed rest during the waking day	615	30.8
I require bed rest for less than 50% of the waking day	87	4.4
I require bed rest for more than 50% of the waking day	25	1.3
I am unable to get out of bed	5	0.3

Notes: Participants could endorse more than one race; ECOG = Eastern Cooperative Oncology Group

Table 2

Prevalence of Comorbid Conditions

	N	%
Total Number of Comorbid Conditions		
0	448	22.4
1–2	694	34.7
3	257	12.9
4+	601	30.1
Frequency of Specific Conditions		
Hypertension	895	44.8
Rheumatism	628	31.4
Depression	503	25.2
Anxiety	400	20.0
Diabetes	342	17.1
Migraines	327	16.4
Asthma	296	14.8
Osteoarthritis	280	14.0
Sleep Disorder	275	13.8
COPD	208	10.4
Angina	193	9.7
Cancer	171	8.6
Heart Attack (Myocardial Infarction)	121	6.1
Alcohol or Drug Problem	121	6.1
Coronary Artery Disease	115	5.8
Heart failure/Congestive Heart Failure	109	5.5
Liver Disease, Hepatitis, or Cirrhosis	95	4.8
Stroke or Transient Ischemic Attack (TIA)	92	4.6
Kidney Disease	70	3.5
Multiple Sclerosis (MS)	18	0.9
HIV or AIDS	15	0.8

Note: COPD = chronic obstructive pulmonary disease

Table 3

Normative Data of General U.S. Adult Population

	NFKSI-19 *Range 0–76*	FKSI-15 *Range 0–60*	NFKSI-DRS-13 *Range 0–52*	FKSI-DRS-9 *Range 0–36*
TOTAL SAMPLE (*N* = 2000)				
Mean	59.8	46.6	41.0	29.5
Standard Deviation	11.2	9.0	8.0	5.6
Percent at Floor	0.0	0.0	0.0	0.1
Percent at Ceiling	2.5	2.9	3.45	10.3
Minimum Observed Score	13.0	10.0	5.0	0
25th Percentile	54.0	41.0	37.0	27.0
50th Percentile (Median)	62.0	48.0	43.0	31.0
75th Percentile	68.0	53.0	47.0	34.0
Maximum Observed Score	76.0	60.0	52.0	36.0
Males (*N* = 1000)				
Mean	59.7	46.6	41.1	29.7
Standard Deviation	11.2	9.0	8.0	5.8
Percent at Floor	0.0	0.0	0.0	0.0
Percent at Ceiling	2.6	3.3	3.9	13.3
Minimum Observed Score	13.0	10.0	5.0	1.0
25th Percentile	54.0	41.0	37.0	27.0
50th Percentile (Median)	62.0	48.0	43.0	31.0
75th Percentile	68.0	53.0	47.0	34.0
Maximum Observed Score	76.0	60.0	52.0	36.0
Females (*N* = 1000)				
Mean	59.8	46.5	40.8	29.3
Standard Deviation	11.2	9.0	8.0	5.5
Percent at Floor	0.0	0.0	0.0	0.2
Percent at Ceiling	2.4	2.5	3.0	7.2
Minimum Observed Score	16.0	12.0	8.0	0
25th Percentile	53.5	41.0	36.0	26.0
50th Percentile (Median)	62.0	48.0	43.0	31.0
75th Percentile	68.0	54.0	47.0	33.0
Maximum Observed Score	76.0	60.0	52.0	36.0

Table 4

FKSI Item Content and Descriptive Statistics (N=2000)

Item Content	FKSI-15?	NFKSI-DRS-13?	FKSI-DRS-9?	Mean*	SD
I have a lack of energy	Yes	Yes	Yes	2.64	1.18
I have pain	Yes	Yes	Yes	2.71	1.24
I am losing weight	Yes	Yes	Yes	3.47	0.89
I feel fatigued	Yes	Yes	Yes	2.74	1.20
I have been short of breath	Yes	Yes	Yes	3.32	1.00
I am bothered by fevers	Yes	Yes	Yes	3.85	0.55
I have bone pain	Yes	Yes	Yes	3.45	1.03
I have been coughing	Yes	Yes	Yes	3.95	0.98
I feel weak all over		Yes		3.46	0.97
I have had blood in my urine	Yes	Yes	Yes	3.91	0.45
I worry that my condition will get worse	Yes	Yes		3.27	1.14
I have a good appetite	Yes	Yes		2.68	1.22
I am sleeping well	Yes	Yes		2.08	1.27
I have nausea				3.74	0.68
I have diarrhea				3.69	0.55
I am bothered by side effects of treatment	Yes			3.68	0.83
I am able to work (include work at home)	Yes			2.62	1.49
I am able to enjoy life	Yes			2.74	1.52
I am content with the quality of my life right now				2.30	1.31

*Notes: (1) These are not raw data values; some items have been reverse-scored per FACIT convention so that higher scores indicate better outcomes.

(2) Items in table comprise the NFKSI-19. Specific items administered as part of other FKSI scales are indicated.

Table 5

General Health-Related Quality of Life (N=2000)

	M (SD)	Median
SF-36 v.2 Scores (Standardized)		
Mental Component Summary	47.7 (12.3)	50.8
Physical Component Summary	46.1 (11.2)	48.6
PROMIS-29 Scores (Standardized)		
Physical Function	50.5 (10.0)	49.0
Anxiety	50.1 (10.3)	48.9
Depression	47.3 (9.7)	46.4
Fatigue	47.9 (9.2)	48.1
Sleep Disturbance	52.0 (10.0)	52.4
Satisfaction with Social Role	49.3 (10.1)	49.9
Pain Disturbance	49.2 (9.2)	49.6
Pain Intensity	3.0 (2.6)	2.0

Note: Except for Pain Intensity, all scores standardized to M (SD) = 50 (10), based on respective normative samples. Pain intensity score, based on a single 0–10 rating, was not transformed.

Table 6

Normative Data for Respondents with No Co-morbidities or Hypertension Only

	NFKSI-19 *Range 0–76*	FKSI-15 *Range 0–60*	NFKSI-DRS-13 *Range 0–52*	FKSI-DRS-9 *Range 0–36*
No medical comorbidities or chronic conditions (n=448)				
Mean	65.6	51.3	45.2	32.6
Standard Deviation	7.8	6.4	5.3	3.8
Minimum Observed Score	35.0	28.0	20.0	14.0
25th Percentile	61.0	48.0	43.0	31.0
50th Percentile (Median)	67.5	53.0	46.0	34.0
75th Percentile	71.0	56.0	49.0	35.0
Maximum Observed Score	76.0	60.0	52.0	36.0
Hypertension only (n=140)				
Mean	66.0	51.5	45.3	32.5
Standard Deviation	6.9	5.9	4.8	3.2
Minimum Observed Score	44.0	34.0	28.0	21.0
25th Percentile	63.0	49.0	43.0	31.0
50th Percentile (Median)	66.5	52.0	46.0	33.0
75th Percentile	71.0	56.0	49.0	35.0
Maximum Observed Score	76.0	60.0	52.0	36.0
No medical comorbidities or chronic conditions *or* hypertension (n=588)				
Mean	65.7	51.4	45.2	32.6
Standard Deviation	7.6	6.3	5.2	3.6
Minimum Observed Score	35.0	28.0	20.0	14.0
25th Percentile	62.0	48.0	43.0	31.0
50th Percentile (Median)	67.0	52.0	46.0	34.0
75th Percentile	71.0	56.0	49.0	35.0
Maximum Observed Score	76.0	60.0	52.0	36.0

Table 7

T-score Conversion Table for the General U.S. Adult Population (*N*=2000)

NFKSI-19		FKSI-15		NFKSI-DRS-13		FKSI-DRS-9	
Raw Score	***T-score***	***Raw Score***	***T-score***	***Raw Score***	***T-score***	***Raw Score***	***T-score***
0	−3.4	0	−1.8	0	−1.3	0	−2.5
1	−2.5	1	−0.7	1	0.0	1	−0.7
2	−1.6	2	0.4	2	1.3	2	1.1
3	−0.7	3	1.5	3	2.5	3	2.9
4	0.2	4	2.6	4	3.8	4	4.7
5	1.1	5	3.7	5	5.0	5	6.4
6	2.0	6	4.8	6	6.3	6	8.2
7	2.9	7	6.0	7	7.5	7	10.0
8	3.8	8	7.1	8	8.8	8	11.8
9	4.6	9	8.2	9	10.0	9	13.6
10	5.5	10	9.3	10	11.3	10	15.3
11	6.4	11	10.4	11	12.5	11	17.1
12	7.3	12	11.5	12	13.8	12	18.9
13	8.2	13	12.6	13	15.0	13	20.7
14	9.1	14	13.8	14	16.3	14	22.5
15	10.0	15	14.9	15	17.5	15	24.2
16	10.9	16	16.0	16	18.8	16	26.0
17	11.8	17	17.1	17	20.0	17	27.8
18	12.7	18	18.2	18	21.3	18	29.6
19	13.6	19	19.3	19	22.5	19	31.4
20	14.5	20	20.4	20	23.8	20	33.1
21	15.4	21	21.5	21	25.0	21	34.9
22	16.3	22	22.7	22	26.3	22	36.7
23	17.2	23	23.8	23	27.5	23	38.5
24	18.1	24	24.9	24	28.8	24	40.2
25	18.9	25	26.0	25	30.0	25	42.0
26	19.8	26	27.1	26	31.3	26	43.8

NFKSI-19		FKSI-15		NFKSI-DRS-13		FKSI-DRS-9	
Raw Score	*T-score*	*Raw Score*	*T-score*	*Raw Score*	*T-score*	*Raw Score*	*T-score*
27	20.7	27	28.2	27	32.5	27	45.6
28	21.6	28	29.3	28	33.8	28	47.4
29	22.5	29	30.5	29	35.0	29	49.1
30	23.4	30	31.6	30	36.3	30	50.9
31	24.3	31	32.7	31	37.5	31	52.7
32	25.2	32	33.8	32	38.8	32	54.5
33	26.1	33	34.9	33	40.0	33	56.3
34	27.0	34	36.0	34	41.3	34	58.0
35	27.9	35	37.1	35	42.5	35	59.8
36	28.8	36	38.3	36	43.8	36	61.6
37	29.7	37	39.4	37	45.0		
38	30.6	38	40.5	38	46.3		
39	31.5	39	41.6	39	47.5		
40	32.4	40	42.7	40	48.8		
41	33.2	41	43.8	41	50.0		
42	34.1	42	44.9	42	51.3		
43	35.0	43	46.0	43	52.5		
44	35.9	44	47.2	44	53.8		
45	36.8	45	48.3	45	55.0		
46	37.7	46	49.4	46	56.3		
47	38.6	47	50.5	47	57.5		
48	39.5	48	51.6	48	58.8		
49	40.4	49	52.7	49	60.0		
50	41.3	50	53.8	50	61.3		
51	42.2	51	55.0	51	62.5		
52	43.1	52	56.1	52	63.8		
53	44.0	53	57.2				
54	44.9	54	58.3				
55	45.8	55	59.4				
56	46.6	56	60.5				

NFKSI-19		FKSI-15		NFKSI-DRS-13		FKSI-DRS-9	
Raw Score	***T-score***	***Raw Score***	***T-score***	***Raw Score***	***T-score***	***Raw Score***	***T-score***
57	47.5	57	61.6				
58	48.4	58	62.8				
59	49.3	59	63.9				
60	50.2	60	65.0				
61	51.1						
62	52.0						
63	52.9						
64	53.8						
65	54.7						
66	55.6						
67	56.5						
68	57.4						
69	58.3						
70	59.2						
71	60.1						
72	60.9						
73	61.8						
74	62.7						
75	63.6						
76	64.5						

Table 8

FKSI comparisons by ECOG Performance Status and Number of Comorbid Conditions

		NFKSI-19			FKSI-15			NFKSI-DRS-13			FKSI- DRS-9		
	n	**M**	**SD**	**p- value***	**M**	**SD**	**p- value***	**M**	**SD**	**p- value***	**M**	**SD**	**p- value***
ECOG													
I have normal activity without symptoms	1268	63.7	9.0	<.0001	49.8	7.2	<.0001	43.7	6.3	<.0001	31.4	4.6	<.0001
I have some symptoms but do not require bed rest during the waking day	615	54.4	10.6	<.0001	42.0	8.5	<.0001	37.1	7.8	<.001	26.8	5.5	<.0001
I require bed rest for less than 50% of the waking day	87	45.4	11.7	.66	35.2	9.3	.77	31.3	8.6	.85	23.2	6.1	.76
I require bed rest for more than 50% of the waking day	25	44.4	12.3		34.7	9.4		31.6	8.8		23.5	6.3	
Comorbid Conditions													
0	448	65.6	7.8	.0002	51.3	6.4	.0001	45.2	5.3	<.0001	32.6	3.8	<.0001
1–2	694	63.4	8.6	<.0001	49.5	6.9	<.0001	43.6	6.0	<.0001	31.2	4.2	<.0001
3	257	58.9	8.9	<.0001	45.8	7.2	<.0001	40.6	6.4	<.0001	29.2	4.4	<.0001
4+	601	51.6	12.0		39.9	9.5		35.0	8.6		25.3	6.2	

*Note: p-values are tests for differences between adjacent categories.